MEDICARE'S DURABLE MEDICAL EQUIPMENT COM-PETITIVE BIDDING PROGRAM: HOW ARE SMALL SUPPLIERS FARING?

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CONTENTS

OPENING STATEMENTS

Hon. Renee Ellmers	Page 1
Hon. Cearle Richmond	2
WITNESSES	
Laurence D. Wilson, Director, Chronic Care Policy Group, Centers for Medicare and Medicaid Services, Baltimore, MD	3
Peter Cramton, Ph.D., Professor of Economics, University of Maryland, College Park, MD	15
Tammy Zelenko, President/CEO, Advacare Home Services, Bridgeville, PA	17
Randy Mire, Owner, Gem Drugs, Reserve, LA	19
APPENDIX	
Prepared Statements:	
Laurence D. Wilson, Director, Chronic Care Policy Group, Centers for Medicare and Medicaid Services, Baltimore, MD	31
Peter Cramton, Ph.D., Professor of Economics, University of Maryland, College Park, MD	43
Tammy Zelenko, President/CEO, Advacare Home Services, Bridgeville, PA	62
Randy Mire, Owner, Gem Drugs, Reserve, LA	76
Questions for the Record:	
Chairman Graves Questions for Laurence Wilson	83
Chairwoman Ellmers Questions for Laurence Wilson	85
Answers for the Record:	
Wilson Answers for the Record	86
Additional Materials for the Record:	
Statement of the Health Industry Distributors Association	91
"Competitive Bidding for Durable Medical Equipment: An Estimate of the Economic Impact on Iowa," by Ken Brown, Ph.D	95
National Association for the Support of Long Term Care Statement for the Record	101
The VGM Group Statement for the Record	106
Statement of Charles R. Plott for the Record	114
Hogan Hansen Statement for the Record	120
A Market Pricing Program to Fix Medicare's Bidding System for Home Medical Equipment and Services Statement for the Record	131
Response to the Congressional Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program by Peter Cramton	136

MEDICARE'S DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM: HOW ARE SMALL SUPPLIERS FARING?

TUESDAY, SEPTEMBER 11, 2012

House of Representatives,
Subcommittee on Healthcare and Technology,
Committee on Small Business,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:10 a.m., in room 2360, Rayburn House Office Building, Hon. Renee Ellmers (chairwoman of the Subcommittee) presiding.

Present: Representatives Ellmers, King, and Richmond. Also Present: Representatives Shilling and Thompson.

Chairwoman ELLMERS. Good morning, this hearing will come to order. I want to thank the witnesses on both panels for testifying. We appreciate your participation.

I would like to at this time welcome Representative Thompson. Mr. Thompson is from Pennsylvania, a former committee member who has requested and received permission to sit on the panel for today's hearing. We welcome Mr. Thompson today.

We also have with us Mr. King from Iowa, who also will have some questions to submit or some statements from constituents, is

that? Yes. Thank you again for being part of this.

We are here today to assess the Medicare durable medical equipment competitive bidding program and its impact on patients, small business suppliers, and the implications for program expansion. Congress mandated the use of competitive bidding to establish payment rates for high cost and high volume DME in the Medicare Modernization Act of 2003. Congress took this action in response to evidence that Medicare fee schedule payment rates often far exceed retail prices. In fact in some cases Medicare beneficiary copays exceeded the cost of the device on the open market. These generous payment rates also made the DME benefit especially vulnerable to waste, fraud and abuse. A successful small scale test required through the Balance Budget Act of 1997 showed that the competitive bidding for DME was feasible.

The Centers for Medicare and Medicaid Services implemented a competitive bidding process for nine DME product categories in nine geographic areas on January 1, 2011. This first phase of implementation is known as Round One. The competitive bidding program will soon undergo significant expansion beyond the initial nine metropolitan statistical areas, or MSAs. The Affordable Care Act, which we will be referring to as ACA, expanded the program

so that Round Two includes an additional 91 MSAs. CMS is now assessing supplier bids for Round Two with the intent that competitively bid prices in these 91 MSAs take effect in mid-2013. The ASA directed the Secretary of the Department of Health and Human Services to use competitively bid prices nationwide begin-

ning in 2016.

The DME supplier industry as well as the many small businesses that operate in this industry have long had concerns about the use of competitive bidding. Before we expand the program more than tenfold it is important to understand these concerns, not only because numerous patients rely on medical equipment to keep them in their homes and out of the hospital, but also because many of the suppliers are small businesses that make up the fabric of our economy.

Most of us can agree that it is important for Medicare to pay a responsible price for durable medical equipment so that beneficiaries and taxpayer dollars are used wisely. CMS has reported that the competitive bidding program resulted in \$202 million in savings in 2011. These first year program savings are derived largely from competitive based payment amounts that are on average 32 percent lower than DME fee scheduled prices, and these lower prices mean the beneficiaries are paying less in the form of their 20 percent coinsurance.

Lower prices for patients as well as for taxpayers are something all of us can celebrate, but how those prices are obtained and the methods by which the small business suppliers are allowed to participate and compete fairly are crucial to this program. We must seek to ensure that this program protects patient access to vital products needed while giving small business suppliers the environment to grow and thrive. While I strongly believe in the competitive forces of the private market, the process by which the competition is conducted must be fair and truly competitive.

To help the Subcommittee understand the success and challenges associated with Round One before the program's scheduled expansion next year we will hear from witnesses, industry experts, as well as small business owners who collectively provide a balanced range of perspective on the competitive bidding program.

Again, I want to thank all of our witnesses today for being here.

And now I would like to yield to Ranking Member Richmond for

his remarks.

Mr. RICHMOND. Thank you, Madam Chairwoman, for this very productive and timely hearing. It is no secret that our Nation's population is beginning to age and many of our Baby Boomers are now turning 65 years old. A projected 72 million, roughly one-fifth of the U.S. population, will be that age or older by 2030.

As more Baby Boomers age into Medicare, the program is becoming increasingly vital to our health care system. Medicare serves 50 million seniors and people with disabilities. That is nearly 1 in 6 Americans.

It is also a program served predominantly by small businesses. Small firms are an essential part of the health care market and fill many of the gaps larger businesses either cannot or will not. In fact small suppliers constitute over 90 percent of the Nation's medical equipment providers. Today's hearing will shed some light on

their importance to Medicare.

The Centers for Medicare and Medicaid Services Competitive Bidding Program for Durable Medical Equipment, or DME, was implemented in nine metropolitan areas in 2011. The initiative allows Medicare to award contracts for durable medical equipment to suppliers with the lowest bids. This bidding system was supposed to ensure beneficiary access to quality medical supplies and services while reducing out-of-pocket expenses and improving the effective-

ness of DME payments.
While CMS estimates the savings from the first year to be 202 million, it is not clear that the new COMPETITIVE BIDDING PROGRAM is achieving this goal without driving small firms out of business. Instead there is evidence that many DME small business providers have already gone out of business or soon will go under. This issue is of particular concern to me, because New Orleans is one of the areas selected to implement competitive bidding in Round Two. Like a number of my colleagues, I have some concerns about the impact on small firms in my district. We should all be doing what we can to mitigate the impact that these changes will have on these firms.

It is also important to me that CMS work with Congress and stakeholders to ensure that Medicare beneficiaries have access to care and service from their local supplier. It is perfectly appropriate for Congress to take a hard look at competitive bidding and its impact on small suppliers.

With that I would like to take this opportunity to thank all the

witnesses for being here. I look forward to hearing your perspectives on this vital matter. Thank you and I yield back.

Chairwoman Ellmers. Okay, at this time we will proceed and I would just like to ask that if any of the Subcommittee members have an opening statement prepared, I just ask that they submit it for the record.

Just to briefly go over the light system that we have, you will have 5 minutes to deliver your testimony. The light will be green. When you have 1 minute left it will turn yellow and then it will turn red. I ask that everyone try to adhere to the limited time. I know we have a number of questions, so that will just help this move along.

So with that I would like to introduce Mr. Laurence Wilson, Director of the Chronic Care Group with the Centers for Medicare and Medicaid Services in Baltimore, Maryland. He has responsibility for a broad range of health care benefits, including post acute care, home health dialysis, and durable medical equipment. Welcome, Mr. Wilson, good to see you again. You have 5 minutes for your testimony.

STATEMENT OF LAURENCE D. WILSON, DIRECTOR, CHRONIC CARE POLICY GROUP, CENTERS FOR MEDICARE AND MED-ICAID SERVICES, BALTIMORE, MD

Mr. WILSON. Good morning and good morning, Ranking Member Richmond and distinguished members of the Subcommittee. I am very pleased to be here today to discuss the durable medical equipment prosthetics, orthotics and supplies competitive bidding program. This important initiative required under the Medicare Modernization Act of 2003 and recently expanded under the Affordable Care Act has been effective in reducing beneficiary out-of-pocket costs, improving the accuracy of Medicare's payments, reducing over utilization and ensuring beneficiary access to high quality items and services.

CMS successfully implemented the program on January 1, 2011, in nine metropolitan areas after making a number of important improvements based on new requirements from Congress and after listening to feedback from our stakeholders. We are pleased to report that the program has saved \$202 million in its first year of operation, a reduction of over 42 percent compared to 2010, with no reduction in access or negative health consequences for our beneficiaries. We are now continuing with the expansion of the program to 91 additional areas of the country as the law requires.

CMS worked closely with stakeholders to design and implement the program in a way that is fair for suppliers and sensitive to the needs of beneficiaries. In particular, the program includes specific provisions to promote small supplier participation. First, CMS worked in collaboration with the Small Business Administration to develop a new more representative definition of a small supplier. CMS then designed policies linked to this new definition to help small suppliers. For example, the final regulation allows small suppliers to band together in networks in order to meet program requirements. The regulation also employs a formula to ensure that multiple contract suppliers are selected for each of the product categories in an area, so lots of suppliers are awarded a contract.

Most importantly, the regulation established a special 30 percent target for small supplier participation in the program. CMS was very pleased that we exceeded this 30 percent target in the nine Round One areas, with 51 percent of contracts going to small sup-

pliers.

The program also includes numerous protections for beneficiaries. It results in a large number of winners so that beneficiaries are assured access and choice and there will continue to be competition among contract suppliers on the basis of customer service and equality. In addition, the program thoroughly screens bids and bidders, includes quality standards and accreditation, and employs financial standards and other safeguards to weed out bad actors while ensuring accurate and sustainable payment amounts and providing a level playing field for legitimate suppliers.

CMS has carried forward the many improvements to the program made by Congress and CMS to successive rounds. These changes provide for a fair process that is less complex for suppliers to navigate and result in more effective scrutiny of suppliers' qualifications in the integrity of their bids. We continue to be open to

further improvements as the program expands.

Our experience with the Round One Rebid has shown that competitive bidding brings value to Medicare beneficiaries and tax-payers compared to the old fee schedule system. In fact, average price discounts across the nine metropolitan areas are about 35 percent. The CMS actuary projects that the program will save \$25.7 billion for Medicare over 10 years, and an additional \$17.1 billion for beneficiaries through lower coinsurance and premiums.

An example of the price savings, in Charlotte, North Carolina the purchase amount of a standard power wheelchair dropped \$1,089. That equates to an \$871 savings for Medicare and the taxpayers and a further \$218 savings for the beneficiary in terms of reduced coinsurance.

More importantly, our state-of-art monitoring system reveals no trends related to patient health status or access to care that cause us concern. This system tracks over 3,400 data points, including things like mortality, utilization, hospitalization, hospital length of stay, emergency room visits and many others to provide us with information about the health of Medicare beneficiaries and the services they receive.

As the program expands in 2013, we will continue to rely on our extensive network built around our national ombudsman, local ombudsman, regional offices, CMS case workers, contractors and Medicare call center to address questions and concerns and be prepared to act swiftly on behalf of beneficiaries and suppliers. And in summary, we will continue to be thoughtful and diligent in our implementation of this important program as it expands to more areas of the country and opens to further improvements.

Again, I appreciate the invitation to testify before you today and

would be very happy to take any questions you may have.

Chairwoman ELLMERS. Thank you, Mr. Wilson. I will begin my questioning. My first question has to do with the nonbinding nature of the bids. Given the significant opposition to the lack of binding bids as a part of the competitive bidding program as well as numerous testimony by both economists and auction experts, why has CMS chosen to make bids submitted by suppliers non-

binding?

Mr. Wilson. Chairwoman, that is an important issue that we looked at very closely. We took notice of the letter sent to the administration by a number of economists and by Dr. Cramton, who is here today. We met with him, we looked at that issue very closely. I think there are two issues that prevented us from moving in that direction. One, we are talking about a health care program where we are providing health care services to patients in their homes. So forcing a supplier to provide services to a patient in their home may not result in the best outcome for a patient. I think that is one concern.

The other concern is Medicare is a voluntary program for suppliers, for beneficiaries. Our ability to force them under current law to do something they don't want to do does not currently exist. That is, we don't have the authority to do that under current law. But again, I think one of the main concerns is what does that mean for beneficiaries.

The other point that I would mention on this as well is that I am not aware of any particular proposal even in the industry's legislation that would get us to the point where we could bind suppliers. The industry's legislation merely applies a stiff financial penalty to small and other suppliers, and I am not sure that is fair either for a supplier that just can't do it.

Chairwoman Ellmers. One of the main concerns in that area is for those providers that end up turning down the contractors after the bid process that CMS continues to include that calculation of the bid amount. If they backed out, if they put the bid in play and they maybe realize that they can't actually provide that and then they back out, why then does the bid not leave with them and then have a chance for another bidding or the next subsequent bid be considered?

Mr. WILSON. Sure. Very good question. Another issue that we looked at very closely in rulemaking. I guess at the outset I would say that wasn't a particular problem that we had. I think suppliers accepted 92 percent of the time, they accepted their contract so we were very pleased to see that. When you looked at the bids that were not accepted about half the prices were above, half were below. But more importantly, whether they accept the contract or not, the bids that they submit are scrutinized very carefully under a bona fide bid process. If they are on the low end, we would ask for price lists from manufacturers, invoices, or other information to validate that they could provide the item and any associated services for that price. So we are comfortable that the information we are putting into the price is appropriate. And, at the end of the day, if we were to go back and have to reset the prices if someone turned down a contract, then others may deny their contract and there would be multiple iterative rounds until we finally got all of the contracts in place, because even if you were to do this approach, some prices could go down for items, some could go up. Everybody provides a different mix of items and so there is no assurance that everybody would be satisfied with the ultimate product. So we really just have to go with the best information that we have up front.

Chairwoman Ellmers. Along that line is there a concern that 50 percent of the winning bidders are offered contracts at prices that are less than their bids? Does that fall in line with that informa-

tion that you have just given us?

Mr. WILSON. I think that is another important issue that we looked at very closely in rulemaking. We considered whether to set the price at the pivotal bid or the high price point for the winners, whether to set it at the low point or whether to set it at the median the way we do for a number of different Medicare payment systems. This is not a procurement, a government procurement, it is not an auction, this is a Medicare payment system that utilizes competition under the Medicare statute. So it is different than some of the things that you may hear with respect to auctions for commodities and things like that. So I think what we were trying to do was recognize that we wanted a good price point that suppliers would accept and would result in good products, good items being provided to our patients, which is the most important thing for us.

Chairwoman Ellmers. Mr. Wilson, one of the issues that has been raised by many of the small business owners and the suppliers and constituents is that 80 percent, 80 to 90 percent of American businesses are being excluded in this program. At the May 9th Ways and Means hearing you used Pittsburgh as an example of success. In 2010 there were approximately 815 suppliers in Pittsburgh; however, there were only 60 winning suppliers in the program. The other 700 plus no doubt are small businesses like neighborhood pharmacies which offer DME as a sideline for service

and customer satisfaction when a physician prescribes it. You eliminated close to 750 suppliers, or at least 93 percent of the Pittsburgh small businesses, thereby selectively excluding 95 percent of the industry. With such a drastic reduction in the number of small business suppliers in the marketplace, do you believe that excluding more than 95 percent of small businesses previously providing quality DME products is having a positive or a negative impact on patient access to these vital products and services?

Mr. WILSON. I think one of the most important things for us, there are two goals in this program, one is to provide savings on behalf of our taxpayers, on behalf of beneficiaries and on behalf of the Medicare program. The second part is really to ensure that patients continue to get what they need. We have monitored very closely in all nine areas access, health status, and we don't have concerns that patients aren't getting what they need. So at the outset I would just like to be clear that we are very, very sensitive to that issue and are doing quite a bit to monitor that on a biweekly basis.

With respect to the number of suppliers, I think it is important to remember, and I do recall the Pittsburgh example, I used a North Carolina example today, so I will provide that for you. If you look at a place like Charlotte, there are 951 suppliers, but only 207 have Medicare revenues higher than \$10,000. So for most of the suppliers, Medicare is a very small part of their business. I don't want to minimize \$10,000 that could be important to a small business. But, at the same time, that is not the main part of their business, it is probably a very, very small part. So, you know, a lot of suppliers are providing things like retail diabetic test strips. These are, as you said, community pharmacies, that is not even included in the Medicare program. Others are providing off-the-shelf orthotics, we have not bid those. They may be orthotists. So we are not excluding all of the providers. I think that is sort of an inaccurate picture of what the program is doing.

I provide another number as well. I think when you look at the total number of suppliers in the nine areas in 2010, it was just over 23,000. In 2011 that went down by about 1.5 percent. If you look in competitor areas that we track as part of our monitoring there were about 2,000, but that went down a little bit too by about negative 1.2 percent. So to the extent that we see suppliers going out of the program, it is very small and it is not just an occurrence in the nine competitive bidding areas, but it is a more general trend.

Chairwoman Ellmers. Would you say that looking at it from that perspective of the products that they offer, was this an effort by CMS to better control the small business suppliers so that you have a better idea of who you are dealing with or—

Mr. WILSON. I think there are benefits in terms of oversight to the program because it employs financial standards and erects other checks to allow suppliers to participate, so I think it has benefits for program integrity. But, our point in pursuing the program wasn't to somehow eliminate suppliers. The statute requires that there be winners and there be losers. It also requires that suppliers bid. So, if you look at Charlotte again, you know, there were 207 suppliers that had Medicare revenues over \$10,000; only 115 of them bid, and about half of those got contracts.

Chairwoman Ellmers. Okay, great. I do have a couple more-Mr. Wilson. I

Chairwoman Ellmers. Oh, I am sorry, I thought you were finished.

Mr. Wilson. I am.

Chairwoman Ellmers. I was going say I do have a couple more questions but at this point I would love for the rest of the Subcommittee to chime in with theirs, so I will now turn to Ranking Member Richmond for his questions.

Mr. RICHMOND. Thank you and thank you, Director Wilson, for

From the comments and the calls that we received and the input that we sought out, what we got back about Round One was that people faced several problems initially in the bidding process from taking excessive time to input data and that data was lost or there was incorrect disqualification of suppliers, which I think caused you all to extend the time at some point on those bids. Now you are moving into Round Two. What have you all done or what are you all going to do to make sure that we don't have those types of problems for Round Two?

Mr. WILSON. Thank you. I think the problems that you are describing are ones that we experienced in our 2008 round, after which Congress delayed the program and I think the picture you provided does accurately describe some of the problems that we had. We went through a process, talking with our stakeholders and, of course, implementing provisions of the MIPPA law in 2008 to make some improvements to the program. These improvements were things like redevelopment of the online bidding system so we don't have problems with people losing information, streamlining the financial documentation requirements, putting in a process that Congress required where, to the extent a supplier was missing a financial document and may otherwise be disqualified, they would get a second bite at the apple. We would get to contact them and say, hey, you are missing your balance sheet, could you send that, and they would send it. So we put in those kinds of improve-

Education was very important. In the 2008 round we didn't get to educate early enough and we didn't focus in on some of the issues that we ultimately learned to be of concern for small suppliers so we educated earlier, and it was targeted on specific issues that were problematic, in particular, the financial documentation requirements. We really, really focused in on auditing and verifying the information in the bids, and checking licensing of suppliers to make sure only licensed suppliers were coming into the program. So a lot of different things that we did both on process and on sort of ease of use for suppliers were put in place before we went to this current round which was effective in 2011. And I think the reaction that we got was positive from those that we heard from with respect to the system. I think there are other improvements that could be made, there were still a few little glitches in the electronic system but we were able to work through those, there were no delays and no big issues with people losing information.

Mr. RICHMOND. Thank you and actually you answered probably

a couple of my questions all in that one.

Earlier you mentioned in an attempt to help small businesses that they could band together and form networks to bid. How many actually did that?

Mr. WILSON. In the Round One Rebid in 2011 we have three network bids and one that was awarded a contract. So, we didn't see a lot of bids but we still could in this next round.

Mr. RICHMOND. Are you all doing anything to encourage it or to educate the small suppliers on the ability to do that or the advan-

tages to doing that?

Mr. WILSON. Absolutely. I think we ought to be and we are educating suppliers, small suppliers about the availability of that option. So it is part of our online educational toolkit. The online bidders conferences and the other materials that we have. We do discuss this option and present the details of it. We don't encourage people to bid in a certain way, they have to make that business decision on their own, but we want to provide all the information so that they can.

Mr. RICHMOND. The other thing you mentioned was the 8 percent that were awarded a contract and ultimately declined not to sign. What was the predominant reason or give me a little demographic about that 8 percent? And I know we look at it as 8 percent, but I went to one of those funny little high schools where an A was 93 to 100, so you are right around a B-plus range. So what does that

8 percent look like?

Mr. WILSON. The only information I have about the 8 percent—I don't know why they didn't accept, we didn't ask them. I think the information that I have is what I shared with Chairwoman Ellmers, which is that when you looked at their bids they didn't not accept because their bid was higher than the price or lower than the price, it sort of cut both ways. So it was obviously for some other business associated reason.

And we can—I can check if there is more information available

on that. I will go back to the staff and ask.

Mr. RICHMOND. One other one. There appears to be two different criteria in the mail order diabetes suppliers, that they have to bid based on their complete list of diabetic supplies while small suppliers bid and win by using a smaller list of low cost products. Is that by design, is that accurate?

Mr. WILSON. That is not accurate, that is not a requirement. What I would say is that Congress put in place a requirement, we call it the 50 percent rule, where under the national mail order program for diabetic supplies their bid must reflect 50 percent of the products on the market. So it is really geared towards ensuring that all the most popular brands are included in their bids, and that is what we are implementing as part of the national mail order program.

Mr. RICHMOND. Do you all currently have bids out right now?

Mr. WILSON. Yes, yes, sir. Under the Round Two and national mail order program we received bids and are currently evaluating them. We would expect to, sometime later in the fall, announce the prices from that program; early next year announce the bid winners, and then we would put those prices and contracts into effect on July 2013.

Mr. RICHMOND. Okay. Madam Chairwoman, thank you and I yield back.

Chairwoman Ellmers. Okay, at this time I would like to intro-

duce my colleague from Iowa, Mr. King, for his questions.

Mr. KING. Thank you, Madam Chair. Director Wilson, I appreciate your testimony. First, I would like to introduce into the record three reports, one of them from the VGM Group, the durable medical equipment competitive bidding report, and competitive bidding report also from Dr. Ken Brown, University of Northern Iowa, that is dated July 18, 2012, and a Hogan-Hansen study on Medicare's ability to accept beneficiary calls, that is August 13, 2013.

Chairwoman Ellmers. Without objection, so ordered.

Mr. KING. Thank you, Madam Chair. Director Wilson, I do appreciate your testimony and I know that taking the directive of Congress and turning it into actual effect is a difficult task. And a series of things I think about as I listen to your testimony and I expect there will be three witnesses behind you that would like to have testified first so that the questions that they might pose could be directed to you, and I am going to try to anticipate some of that.

What happens under this proposal to patient choice? If there is a patient that has a provider that they have a tradition with and they appreciate the service and quality of that service, what hap-

pens to patient choice?

Mr. WILSON. I think there are a few features of this program which support patient choice. One, we have a formula here for selecting the contractors that really goes towards ensuring that there are multiple contractors, contract suppliers selected for each region or each competitive bidding area. So lots of suppliers means choice for beneficiaries. It also means that those suppliers, they compete amongst each other on the basis of customer service and quality in order to get patients.

Mr. KING. Can-

Mr. WILSON. I think it's important to get that consistency, if I may, you are talking about, sir, that there is a grandfathering provision, a feature that allows suppliers to maintain their relationship for the equipment with patients and the majority of suppliers, even though they didn't within a contract, and so the majority of suppliers did maintain relationships with their beneficiaries.

Mr. KING. I know what the grandfather clause does, it takes away some of the resistance in the short term but eventually ends up with the same result in the long term and that would be the result of who are awarded the contracts. And this so it does—in at least one of these reports that I have introduced into the record will be I think an effective rebuttal to that position, whatever the intent is, then that result I think is perhaps different. But the suicide bid issue, and I will—just as I don't know how many government contracts I have bid, I spent my life in the contracting business. We bid on low bid, we put a bond out on the table, a 10 percent bid bond, for example. So if we are going to bid a million dollar project we put \$100,000 cash equivalent in the middle of the table, and that might be a certified check or it might be a bid bond, but it puts my capital out on the line. And what it says is I am serious about this bid. And if I am the successful bidder and offered the contract, and I don't complete the contract, I don't sign

the contract provide performance and payment bonds to replace the bid bond I forfeit my bid bond. So it is ante up \$100,000 to bid a million dollar project that says my word is good, not to finish the contract, just to enter into it. And then in order to enter into it I have to provide a performance and payments bond.

Does the statute allow you to write rules that set standards of bid bonds so that you don't have suicide bids and you don't have

people backing out of those contracts.

Mr. Wilson. It does not provide us the authority to do what you described, sir.

Mr. KING. What prohibits you then from enforcing such an authority at the discretion of the executive branch?

Mr. WILSON. If that authority were put in place?

Mr. KING. If it doesn't specify that authority, what is out there

in statute that would prohibit you from asserting that authority? Mr. WILSON. Well, this is a program with a prescription and a statute on how it is designed. We have talked about this issue with our general counsel. We don't see that we have authority to do it. Mr. King. Did you want to do that? Was it something you looked

at from the beginning though and you wanted to put more stand-

Mr. Wilson. I have some concerns about an approach that forces suppliers, small suppliers, to pay a large penalty. I also have a concern about forcing suppliers to provide health care services to a beneficiary in their home when they don't want to.

Mr. King. Now-

Mr. WILSON. But I think it is worth considering.

Mr. KING [continuing]. You do write the specifications for the bid, correct, and you have the statutory authority to do that?

Mr. WILSON. Yes, sir, to write specifications.

Mr. KING. And you spoke—sometimes they bid things in not exactly the same way so it is hard to match up apples to apples in your earlier testimony. Can't you write those specifications so that they are direct and specific and then in order to get a product here that is going to be apples to apples and going to be legitimate bidders, can't you come to Congress and ask us to fix this so that you do have the authority to have a legitimate competitive bidding process rather than one that opens the door up for suicide bids?

Mr. Wilson. Well, I am not aware of any suicide bids. We put in a process to address that issue, it is called a bona fide bid proc-

Mr. KING. Well, you can audit but don't enter into it, so those would be the ones defined as suicide bids. If the chairwoman would

Chairwoman Ellmers. Without objection, please continue.

Mr. KING. I am concerned about a bidding process that leaves the door open to that. But the other specific question that I am very interested in is how you selected—how you selected the median bid as the standard on what to basis your award. Is a median bid out of three bidders, is that a legitimate measure, at what level do you have enough bids that a median bid tells you anything? And why wouldn't you come back to us and say we want these people bonded and we want to award it to the lowest bidder?

Mr. WILSON. Well, I think the way this program was set up we had a very high demand target, a cushion because what we are trying to guarantee is patient access, that is the most important thing, so lots and lots of suppliers, so we have a very high demand target. That makes it comfortable using a median measure when you have lots and lots of bidders and lots and lots of contract awards. So we are very comfortable that we get—and that also has an upward effect on price by the way. So we are very, very comfortable in terms of patient access with the approach that we use. And we think the prices are also quite reasonable, particularly in the context of many of the reports that we see from the OIG and the GAO on acquisition costs for oxygen, wheelchairs and other products.

Mr. KING. I will just say this, large companies will like this,

small companies will not. Thank you, and I yield back.

Chairwoman Ellmers. Thank you. At this time I would like to introduce my colleagues from Pennsylvania, Mr. Thompson, for his questions.

Mr. THOMPSON. Thank you, Chairwoman, and the ranking member for your courtesy in allowing a former member of the small business committee to rejoin today on a very important topic.

Director Wilson, Laurence, it is good to see you, I want to thank you for your longtime service in the chronic care division at CMS. This obviously, to me this is a very important topic for me when I not too many years ago, BC, before Congress, I was working with individuals facing life changing disease and disabilities. That is how I ran my paycheck to support my family, and my off hours I ran as an EMT. So I was out in homes in the middle of the night seeing folks who were relying on this durable medical equipment and the service that comes with that equipment to really be able to have improved quality of life and to be as independent as possible. And I have tremendous concerns obviously with the competitive bidding process. And I support competition, but this is a system that I am concerned with the competition as it is defined in this program. I think it is flawed.

I was pleased to hear your willingness to make changes. You indicated that, and frankly we are right on track with the two principles, having a responsibility to the Medicare beneficiary and responsibility to the taxpayers. When you look at Pittsburgh market which is closest to obviously my home, 93 percent loss of providers, I have to hope, I would hope, but I wonder whether CMS is really taking a look at long-term impact of that. What we do today is for today, but the seeds that are planted for tomorrow I think could be devastating. You can't have competition when you begin to lose businesses, when you shrink that competitive pole. And then there is the whole question of people that are bidding in this process, they may not be in the communities to provide the access. I can tell you oxygen is great as long as you have somebody that is a phone call away, and frankly minutes away in the middle of the night when you run into problems with it. You need that, in all durable medical equipment you need that access, that technical assistance. And frankly that is not something—we think about this pricing this thing on the equipment but it really is a full package.

So I really appreciate what you said about opening to change, so I am going to propose some change for you and run it by you. I think you are familiar with the proposal for the market pricing system with durable medical equipment. What are your thoughts on market pricing program as a proposal in terms of saving the same amount of money, fairness to providers and frankly assuring the

beneficiaries access?

Mr. Wilson. And good to see you, sir. Very interesting proposal. We have not talked with representatives of industry about it. I did have the opportunity to read the statutory language. I guess at the outset I would have a few concerns. One—we have a successful program that is working, this program would seem to require about 8 years to implement. We have iterative, multiple rounds of rule-making, Paperwork Reduction Act, IT development, multiple rounds of contracting. So I don't see this program being implemented before about 8 years. It took about 5 years to implement the current program and this has again multiple processes built in that would require additional time.

So I think that is a concern, because again we have a program that is providing beneficiaries what they need and is saving dollars

for taxpayers and beneficiaries in Medicare.

I think there are some other things there. We talked about choice a little bit today. This assigns patients essentially to certain small suppliers, it has a small supplier target that says they get 30 percent of the business. The only way to implement that is to assign a patient to a supplier and take away their choice. That is a concern for me. So I think there are some issues and concern there that need to be addressed, but I don't see replacing a system that is working for one that has some problems.

Mr. THOMPSON. And I think that at least from my perspective, I question whether it is working, I question whether we really have a handle on what the long-term effects of this are as we put small businesses out of business and as we lose jobs, as we decrease that pole for competition. Competition is really a good thing, it generally results in lower costs and higher quality. But if you create monopolies then it is an issue. So just say that my worst nightmares over the next period of time become a reality, does CMS have the statutory authority to implement changes that would be consistent with

a market pricing program?

Mr. WILSON. There are many features of the market pricing program that we would not have statutory authority to do. Some of them we may have statutory authority to do, I have not reviewed it with general counsel to I think answer all those questions. I think with respect to applying a bond, performance bond, that is something, to lock in the bidders, that is something we cannot do to look under the statutory language. But there are other things as well that I think we would have problems, but we would need to review that from a legal perspective I think to answer that question adequately for you. But I think some of the fundamental features would require statutory change.
Mr. Thompson. Thank you. Thank you, Chairwoman.

Chairwoman Ellmers. Thank you, and I do have one additional question for you, Mr. Wilson. You mentioned the GAO and a recent report by the Government Accountability Office concluded that although the first year of the competitive bidding program, Round One bidding process was completed, it is too soon to determine its

full affect on Medicare beneficiaries and DME suppliers.

GAO also found also that the first—within the first 6 months of 2011 patient utilization of some competitively bid products declined in some areas. Do you agree that it is too early to call this program a success? You are saying the program works, but isn't it a little early, especially based on what the GAO is saying, and does the decline in patient utilization mean seniors didn't have access to the

care they needed?

Mr. Wilson. Very good question. The GAO looked at about 6 months of data, we are working on close to a year and a half through our monitoring program. They don't have that type of monitoring program. We did share that information with them. So I think we are very pleased with the success of the program and very confident at this point. I think we have to remain vigilant though and we have to be open to change. So I am not just comfortable sitting back on my laurels and telling the staff not to think about where we are making improvements and not to look and see that beneficiaries—to be sure that beneficiaries are getting what they need. We need to do that. So that is sort of the perspective that we come to on this and lots of our programs, it is the reason why we invested in some of the monitoring systems. We have the same type of monitoring system for the new ESRD system that I work on because we want to make sure that end stage renal disease patients are getting the services that they need in light of the fact that we have put in a new payment system.

So I think that is the perspective that we bring to this and I apologize, Chairwoman Ellmers. I think you had another part of

your question and I missed that.

Chairwoman Ellmers. No, no, you basically answered for me. Again you feel at this point that it is successful. I guess the question was do you feel that patients' access to the durable medical

equipment in any way is being jeopardized?

Mr. WILSON. No, no, I do not. We put in place a system to help beneficiaries and to help suppliers. So we have a national ombudsman, local ombudsman, we have case workers, we have a contractor call center, we have lots of different resources to help suppliers and help patients when they need something. So that is what

we have invested in heavily.

As we move to Round Two in 91 additional areas it is vitally important that we carry forward all those resources an expand them to meet the needs of patients. And as far as utilization goes, utilization is not a measure of whether patients have access or are receiving good quality care, it is no secret that there has been overutilization in the Medicare program, particularly in places like Miami and a few other places around the country. So when we look at utilization data and look at utilization going down, that is an expected result. When we see a significant swing, the reason why we monitor that allows us to go in and check. And I will give you just a very quick example being respectful of your time. We saw mail order diabetic supplies, the volume going way, way down. So we went out and we surveyed 200 beneficiaries to see why they were no longer ordering. They had ordered before in 2010, they were not

ordering supplies in 2011. All of them had many, many months supply. I think over 60 percent had over 10 months supply. So we saw that there was rampant overutilization under the prior system,

and that is something that we need to try to correct.

Chairwoman Ellmers. Well, thank you, Mr. Wilson. I really appreciate your participation today. We will continue to closely monitor this program to ensure that small suppliers are treated fairly. You are excused now at this time, thank you. However, I would like to ask that you identify the person—is there someone here from CMS that will be staying? Great. That will be helpful to sit in for the second panel. And if you could just make sure that we submit name and title, that would be helpful. So thank you very much, Mr. Wilson, for your time. I truly appreciate it.

Mr. WILSON. Thank you.

Chairwoman Ellmers. I now call the second panel to come forward and be seated at the witness table.

Thank you to our second panel. We appreciate your testimony.

I just want to say, just to reiterate the button system. You will see the little talk button there. When you are going to give your testimony or answer questions you want to just push that button, it will shine red. You will have 5 minutes to submit your initial testimony after I introduce you. And we will just try hard to keep to that amount of time so we can be respectful to everyone's time today. This is a very, very important Subcommittee hearing and I know that you have a lot of information that you would like to share with us. Again as far as the system goes you will have 5 minutes. It will be green, when have you 1 minute left it will be yellow and then it will turn red.

I will start off by introducing Dr. Cramton, Ph.D., a professor of economics at the University of Maryland. Dr. Cramton has conducted research on auction theory and practice with his main focus with design on auctions. He received his bachelor of science and engineering from Cornell University and his Ph.D. in business from Stanford University. Welcome, Dr. Cramton, you have 5 minutes

for your testimony.

STATEMENTS OF PETER CRAMTON, PH.D., PROFESSOR OF EC-ONOMICS, UNIVERSITY OF MARYLAND, COLLEGE PARK, MD; TAMMY ZELENKO, PRESIDENT/CEO, ADVACARE HOME SERV-ICES, BRIDGEVILLE, PA, ON BEHALF OF THE AMERICAN AS-SOCIATION OF HEALTH CARE; AND RANDY MIRE, OWNER, GEM DRUGS, RESERVE, LA, ON BEHALF OF NATIONAL COM-MUNITY PHARMACISTS ASSOCIATION

STATEMENT OF PETER CRAMTON, PH.D.

Mr. CRAMTON. Thank you very much.

Today I speak on a matter of great significance to our future, Medicare auction reform. Without the effective use of market methods to control costs, Medicare is unsustainable.

This is why it is essential for Congress to step in and insist that CMS replace its fatally flawed action program with an efficient auction.

My testimony is that of an independent auction expert. I have spent in excess of 1,000 hours studying the CMS program. My work has involved five main steps: Identify the problems in the CMS design, develop an efficient Medicare auction based on best practice and science, educate the stakeholders about the problem with the CMS design, educate the stakeholders about how the problems with the CMS design can be addressed, and convince stakeholders that a reformed Medicare auction does indeed work.

Let me start with a point of consensus. Small businesses are the engine of innovation to allow the U.S. economy to grow and prosper. We only need to think of Apple, Google and Microsoft. These former small businesses are the true job creators. Indeed, consensus will be a theme in my remarks. There is no disagreement among experts about what I will say and the issue is nonpartisan.

The fatal flaws the CMS auction design were first identified by auction experts in September 2010. One hundred sixty-seven distinguished experts sent a letter to congressional committees pointing out the flaws. Congress responded with numerous letters to CMS and HHS demanding action but CMS failed to act. As a result of this inaction in June 2011, an expanded group of 244 experts, including four Nobel laureates, wrote to the White House again urging action. I summarize from the letter. The flaws in the action administered by CMS are numerous. The use of nonbinding bids together with setting the price equal to the median of the winning bid provides a strong incentive for low ball bids. This leads to complete market failure in theory and partial market failure in the lab.

Another problem is the lack of transparency. Quantities are chosen arbitrarily by CMS, enabling a large range of prices to emerge that have no relation to competitive market prices. The CMS competitive bidding program violates basic principles of regulation, especially the principles of transparency and of basing regulations on the best available science. Indeed, the current program is the antithesis of science and contradicts all we know about proper market design

Since the writing of our letter in September, several of us have done further detailed scientific study to explore the properties of the CMS design and contrast it to modern efficient auctions.

The findings are dramatic and illustrate the power of science to

inform auction design.

Specifically, auction theory was used to demonstrate the poor incentive properties of the CMS design and how these lead to poor outcomes. Laboratory experiments were conducted at Cal tech and the University of Maryland that demonstrate that these poor theoretical properties are observed in the lab.

Finally, some of us have studied extensively the Medicare settings, speaking with hundreds of DME providers and beneficiaries, and developed a modern auction design for the setting that is consistent with the best practice and market design methodology.

This design step was far from a theoretical exercise. In April 2011 a Medicare auction conference was conducted at the University of Maryland to show how the modern auction methods work and how to conduct a nearly full scale demonstration of an efficient auction. Over 100 leaders in government and the DME industry attended the event. The mock auction achieved an efficiency of 97 percent. In sharp contrast the CMS auction exhibited efficiencies well below 50 percent in the laboratory.

The complete lack of transparency is inappropriate for a government auction. We know now that CMS also had complete discretion with respect to setting prices in a nontransparent way. It is now clear that the CMS design is not an auction at all but an arbitrary pricing process.

Sincerely, 244 auction experts.

In contrast, the proposed market pricing program is a reformed Medicare auction based on best practice and science. MPP addresses each of the flaws identified in the CMS design. Nonbinding bids and the median pricing rule are easily fixed. MPP makes bids binding commitments, the median pricing rule replaces the clearing price, the price at which supply and demand balance. MPP uses a simple and effective auction mechanism, the simultaneous descending clock auction. The auction format has been used for over 10 years in many industries with great success. Through theory, experiment and practice, MPP has been shown to achieve least cost sustainable prices.

One point on CMS's assertion that the CMS auction saves money: I am reminded of the saying my dad taught me, "figures don't lie, but liars do figure." The CMS cost savings of \$42.8 billion is a gross overestimate. The number has no basis in fact. It simply scales up an erroneous \$202 million number to the entire country

for each of the next 10 years.

Chairwoman Ellmers. Dr. Cramton, I am going to stop you there just because we have gone over a little bit, but what we will have you do is submit the remainder of your testimony for the record, okay? And then we will move on. And I know we have many questions for you. So thank you.

Mr. CRAMTON. Thank you.

Chairwoman Ellmers. At this time I do-our next panelist is Ms. Zelenko, and actually Mr. Thompson from Pennsylvania is

going to introduce her.

Mr. THOMPSON. Thank you, Chairwoman. It really is an honor to introduce our next witness, Tammy Zelenko. Tammy, Ms. Zelenko, is the president and CEO of Advacare Home Services in Bridgeville, Pennsylvania. She purchased Advacare in 1999 when it had 10 employees and 1 location, and today it has 47 employees and 4 locations. And she is testifying on behalf of the American Association for Homecare.

Welcome, Ms. Zelenko, and thank you, Chairwoman.

STATEMENT OF TAMMY ZELENKO

Ms. ZELENKO. Thank you. Thank you so much.

Good morning, Chairwoman Ellmers, Ranking Member Richmond and members of the Subcommittee. My name is Tammy Zelenko, and I am president and CEO of Advacare Home Services, and we serve about 2,000 patients with 4 locations.

Advacare specializes in respiratory care, which means we serve patients with COPD and other lung diseases, along with frail seniors who need help in order to live safely in their homes.

You may also know us as durable medical equipment providers, or DME. DME is an essential and extremely cost-effective component of our Nation's continuum of care. For a few dollars per day, home-care providers like me enable patients to be discharged from hospitals to home. We help control the Nation's healthcare costs by providing the equipment and services. We allow Medicare to reap savings by preventing hospital and ER visits and reducing exceptionally high, expensive institutional care.

DME represents about 1.4 percent of the annual Medicare budget; however, falling payment rates and sharply rising regulatory burdens make it extremely difficult to continue to provide quality

services without compromising care.

As a member of the American Association for Homecare and the Pennsylvania Association of Medical Suppliers, I am very, very grateful that you held this meeting. The poor designed bidding program has needlessly harmed hundreds of small providers like me and has eliminated 85 percent of providers from participating in the program in the nine areas included in round one. How can we truly have a competitive program if the program is designed to eliminate competitors?

As the bidding program now expands to another 91 areas throughout the United States, small providers face severe cuts and arbitrary exclusion from the Medicare participation. There is no doubt thousands of good providers will be driven out of business as

a result of this expansion.

As you alluded to, 10,000 baby-boomers turning 65 every day, need for cost-effective home care is growing. Unfortunately this bidding program is destroying the infrastructure to help supply that demand. In spite of the rhetoric from Medicare about the set-asides for small businesses, let us be clear: This bidding program is anti-

small business. It is a business and job killer.

We do not oppose market-based pricing or a well-thought-out auction system. In fact, we endorse an alternative system developed by auction experts who design bidding systems for a living. We are often the eyes and ears of the elderly living in their homes. We create a customized care plan based on physician orders and patient-specific goals, and we communicate critical information to the physician. This is what enables patients with acute care or chronic needs to remain in their homes, safe and independent. However, there are costs to providing this level of care.

These are not simple commodities we are providing. As a business owner, I have always been able to compete against the local, regional and national providers within my market. Each year I gain market share, grow my business and receive recognition due to the outstanding service that my company provided. But all of

that changed overnight when I lost the Medicare bid.

The bidding program for me and thousands of providers like me has created the biggest barrier to my company's survival. The government should not ration benefits or otherwise bar qualified pro-

viders from serving Medicare beneficiaries.

As I prepared for the bidding program, I made my business as lean and as efficient as possible. I invested in electronic medical records, purchased GPS tracking devices, and invested in a new billing system. And I really believed that that would save me and that that would prepare us for the bidding program. I was wrong. This is the first year that I did not grow my company, the first time that I had to pass on all of the healthcare premium increases

to my employees, and the first time that I had to limit reimbursement for continuing education, and the first time I had to give

away my Medicare patients.

Before the bidding program began, my company competed based on the level of service we provided through education, clinical assessment and follow-up. But now, because of the severe design faults, this bidding system has eliminated my opportunity to compete in my communities where I have invested in physical loca-

tions, inventory, vehicles, and highly-trained staff.

In closing, more than 200 economists and auction experts have warned CMS that the current bidding program will fail if significant modifications aren't made. These experts designed an alternative program called the Market Pricing Program. It achieves sustainability, market-based pricing; it preserves access to quality care; and it gives small providers like me a fighting chance for survival. Please give us this chance by enacting the market pricing.

Thank you.

Chairwoman Ellmers. Thank you for your testimony, Ms. Zelenko.

Chairwoman Ellmers. At this time we will be introducing our last panelist Mr. Mire, and my colleague Mr. Richmond will do

Mr. RICHMOND. Madam Chairwoman, it is my pleasure to introduce our next witness, Randy Mire, the owner of Gem Drugs located in my district, actually two locations. Gem Drugs has been in business for over 35 years and offers a wide range of medical

services to the community.

Just this year Mr. Mire was awarded the Small Business of the Year Award from the River Region Chamber of Commerce. He is testifying today on behalf of the National Community Pharmacists Association, which represents pharmacists, owners, managers, and employees of more than 23,000 independent community pharmacies across the country, and he has just survived Hurricane Isaac, so I am glad to have you here today.

Welcome, Mr. Mire, Ms. Zelenko, and Dr. Cramton. Thank you.

STATEMENT OF RANDY MIRE

Mr. MIRE. Chairwoman Ellmers, Ranking Member Richmond, and distinguished members of the Subcommittee, I want to thank you for holding this hearing on Medicare's competitive bidding program for durable medical equipment. I would also like to take this opportunity to thank Chairwoman Ellmers for her cosponsorship of

H.R. 1936, the Medicare Access to Diabetes Supply Act.

I am honored to be here to discuss my experience as a small business community pharmacy owner and what impact competitive bidding would have on my business as well as access to care for the patients that I serve. My name is Randy Mire, and I own Gem Drugs in Reserve and Gramercy, Louisiana. I attended Tulane University, where I was a commissioned officer in the Army; also Loyola University, where I received a bachelor's of science degree and a doctor of pharmacy degree from Xavier University College of Pharmacv.

With over 25 million people, or 8.3 percent of the population of the United States, suffering from diabetes, this is a national issue.

In my State of Louisiana, over 10.3 percent of the population have been diagnosed with diabetes, which is far above the national average. The patients I serve are mostly minority populations that are indigent, with limited mobility. On a daily basis I witness patients who do not receive their DME supplies through the mail on time and need a short supply from me to get through. And I have seen firsthand this problem with the recent flooding in Louisiana.

My patients turn to me and my pharmacies to provide them with the DME supplies that they desperately need when they have nowhere else to turn with their mail-order supplies. With countless hoops that the community pharmacies must already undergo to provide DME, I do not provide these supplies solely for profit. Obtaining DME accreditation, possessing a surety bond, complying with the burdensome documentation requirements, and receiving much slower-than-normal payments are all in order for me to provide a spectrum of care to all of my patients.

I am honored to spend time with my patients in face-to-face counseling, monitoring their adherence, decreasing overutilization, and making certain that they know how to use the products prop-

erly.

My pharmacies, like all community pharmacies, play an essential role in providing and improving healthcare outcomes, while decreasing long-term healthcare costs. If community pharmacists are not exempt from the competitive bidding program—and I repeat, if community pharmacies are not exempt from the competitive bidding program—and are forced to undergo drastic cuts in reimbursement for DME, many of these pharmacies like myself will have no choice but to stop providing these services to patients. Whether these drastic cuts are seen from subjecting all retail pharmacies to competitive bidding or competitive bidding pricing for diabetic testing supplies by 2016 by CMS' inherent reasonableness authority, community pharmacies cannot continue to provide access to these essential supplies while undergoing such drastic cuts.

If I were to cease providing these services in the areas that my pharmacies serve, it is bad enough that the patients would have to go 5 to 10 miles to obtain their diabetic testing strips from a large chain pharmacy, but it could be—and this is so very important for everyone to realize—it could be over 50 miles to obtain other DME supplies such as wheelchairs. And as I stated earlier, mail order

is not a viable option for beneficiaries in these areas.

This is not just an issue of convenience. This is about providing reasonable access to beneficiaries. If beneficiaries do not access their Part B supplies, this decreases adherence, decreases the quality of care beneficiaries receive, and drives up the overall healthcare costs.

In order to preserve this access to care I would strongly urge all members of the subcommittee to follow the lead of Chairwoman Ellmers and cosponsor H.R. 1936, the Medicare Access to Diabetes Supply Act. H.R. 1936 has bipartisan support and was introduced by Representatives Schock and Welch. The bill would exempt small pharmacies from competitive bidding and preserve patient access to diabetes supplies. This legislation will protect patients, keep the importance of face-to-face interactions with their independent pharmacist for effective diabetes monitoring, and ensure that all bene-

ficiaries have immediate access to the specific diabetic testing supplies that they need.

My pharmacy is one of very few pharmacies still in the area that provides essential DME supplies to patients. To me, this is more than just a prescription. I provide DME supplies in order to make certain that beneficiaries have access to the supplies that they need. If I were to decide not to offer these DME supplies because the burden of offering such supplies has become too high and costs too much, then these beneficiaries would have nowhere else to turn to receive the face-to-face consultations and quality supplies that I provide to them and that they deserve.

Thank you again for inviting me here today to speak, and I look forward to any questions that members of the subcommittee may have.

Chairwoman Ellmers. Thank you.

Chairwoman Ellmers. At this time we will start our questioning. Dr. Cramton, I will start with you. And, Mr. Mire, I think I mispronounced your name initially, so I apologize, and I will try not to do that again.

Dr. Cramton, in your expert opinion, what are the fundamental issues you see with the competitive bidding program as it pertains to the—and I am going to just say it, and you can correct me if I am wrong—the DMEPOS. Is that correct?

Mr. CRAMTON. Correct.

Chairwoman Ellmers. Okay—as established by CMS, and do

other experts agree with you?

Mr. CRAMTON. Well, let us look at the basic principles of an auction. The basic principles of a government auction like this are efficiency, transparency, simplicity, and fairness. The CMS auction gets a letter grade of F on each dimension. This is not good. And, in fact, all experts agree with me, and, in fact, that was the point of the letters from originally 167 and then 244, including 4 Nobel laureates.

So there is unanimous consent on this, and, in fact, I have been working on this for 2 years. I have talked to people around the world, and, indeed, I have never heard anybody disagree with the remarks that I presented today and that are presented in my written testimony before you.

So the two biggest problems are the nonbinding bids and the median pricing rule. Those combine to create a perfect storm effectively. When thinking about how to bid in the auction, I often advise bidders in high-stake auctions in various industries, and so I often will think like a bidder. And I am asked to figure out what

a good strategy would be in this auction.

Well, in this auction the first thing to note is you don't have to think about your costs at all when submitting bids. The bid is simply you are able to get an option to say yea or nay to the price that is offered subsequent to the bid. There is very little chance that your bid is going to impact the price, and so your incentive is to bid the smallest number that you can get away with. So this is why the first go-round in November 2008, the original round one, Congress had to step in days after the auction and cancel the auction because the bids were crazy.

So, the response to that was to introduce this concept of the bona fide bid, which is effectively a floor on how low you can bid. It is quite clear to any expert and, I suspect, anybody here that when you are doing a procurement auction, and the idea is to get the lowest competitive price, if the auction needs to have a floor, that is sort of strange. In fact, it is very common for procurement auctions to have ceilings in order to protect in the event of insufficient competition. But floors are exceptionally unusual, and it is an artifact of this extremely poor design.

In the words of Mr. Wilson, he said, quote, "This is not an auction." This is one thing I completely agree with Mr. Wilson about, it is not an auction, and that is a very damning critique for the following reason: In 2003, Congress passed legislation that required that CMS conduct a competitive bidding program for durable medical equipment. Competitive bids and auction are the exact same thing. So he is saying that CMS is not abiding by the law, and I

would agree with him on that point.

Chairwoman Ellmers. Thank you, Dr. Cramton.

Ms. Zelenko, what do you consider to be—and you were very detailed in your testimony as well, so I am basically going to be asking you to reiterate—but what would you consider to be the most troubling problems with the current competitive bidding program?

Ms. ZELENKO. It is the nonbinding bids. It is absolutely to allow providers to come in and bid the lowest that they can bid without being responsible for that bid or that care is probably the most

damaging of the program.

The lack of transparency of the winning bids is another area. We have asked for transparency to find out how they determined the bid, and the median price is—and not allowing that price to increase when providers chose not to take the contracts. I was a provider that chose not to take a walker contract, so I was in that 8 percent, and I can tell you the reason why is because the price was too low. I could not provide that service at that price.

Chairwoman Ellmers. And just briefly, it sounded to me from your testimony that you are in favor of the market pricing plan. Is

that——

Ms. ZELENKO. It eliminates the problems that we have discussed with the current bidding program.

Chairwoman Ellmers. And so something, a solution like that would be something you would support?

Ms. Zelenko. Yes, it is.

Chairwoman Ellmers. Okay. Mr. Mire, what impact has the DME competitive bidding been on your pharmacy as a business owner?

Mr. MIRE. Yes, ma'am. We service many patients, and I have patients that come in that are not just your diabetic patients, but if we were just to talk about a diabetic patient, sometimes they experience amputees, and they need wheelchairs, walkers, so forth, rollators to help with that situation. For us to have to tell them that they have to go 50 miles because someone won a bid 50 miles away, it is just not practical for them, and they are not going to be compliant. They do not get the training on the equipment if they were to find a family member or someone that could bring them there. Transportation is a major issue.

So there are a lot of problems that the patients are experiencing. Accessibility would be a major one; adherence, and being compliant to know how to use the equipment, because they are not going to be able to go 50 miles away coming from a rural area to get the proper training and everything as discussed, and a lot of times they just give up on it. They may decide to just stay bedridden and so forth, and they begin to get more issues, bedsores, etc. And they miss that one-on-one counseling that a healthcare professional can give them, as opposed to just a delivery driver or someone showing up 50 miles away, if they do have delivery services, to bring them this equipment.

Chairwoman ELLMERS. You bring up an excellent point. As a nurse, I know. These are patients who have multiple problems, and when we are being so shortsighted on how they are able to obtain the equipment that they need, you know, we are not considering

that, and I think that is one of the big flaws. So thank you.

At this time I would like to yield to Mr. Richmond for any of his

questions.

Mr. RICHMOND. I will start with Mr. Mire. You basically answered the first one, which is the award to companies with no connection or location in close proximity to the community, and the effect it has especially on our large diabetic population in New Orleans. Let me ask you this one: According to Mr. Wilson, in response to complaints from suppliers having difficulty navigating the process, CMS launched a new bidder education program. Since you are going through it now, have you had any interaction with that program? Is it helpful?

Mr. MIRE. Actually, sir, there was no one to even point out the program. Nobody from CMS ever contacted us. I speak for many pharmacies that participate in this. There was no knowledge or education of the program that was even out there for people to maybe come together and bid as a group, or even an educational program that would help you just as an individual pharmacy. There was no knowledge that any of us were privy to until I found

that out today.

Mr. RICHMOND. And, Ms. Zelenko, your first round did not go as you would want it and as we would want it. If you had that program or access to that education program, do you think it would have helped?

Ms. ZELENKO. Well, actually, I won the oxygen bid in the round one, and it was at a price that I felt that was sustainable. Unfortu-

nately, when we had to go through round 1.2, I did not win.

The education comes from our national and State associations, and not through the government. So we had many opportunities to learn, but it was not through the government, and when we did have the government, they weren't able to answer our questions and asked us to submit them, and they would get back to us. So all of the education that we had was through our own industry.

Mr. RICHMOND. Professor—Dr. Cramton, not about the market approach, this is something that just strikes me kind of out there, and I would be interested in your economic assessment of it. The competitive bidding program does not allow for adjustment of bids for economic factors. And I believe that you are locked in for 3 years, and considering the volatility of energy costs, gas prices, you

name it, how could you create an adjustment structure without completely reopening bids, or can you do that?

Mr. CRAMTON. Well, the way to do it is to have a proper auction, and, in fact, the reason that we are having an auction is because CMS doesn't know what the right price is. They want to identify the least cost-competitive, sustainable price, and an efficient auction does exactly that. And so the MPP actually occurs every year and uses simple econometric models to establish the price in those—on those products or regions that are not competitively bid that year. But all products and regions are competitively bid over time, so it is much more fluid pricing that is consistent with the dynamics that we see in our economy.

Mr. RICHMOND. And I guess this question could be either for Ms. Zelenko or Dr. Cramton. When price becomes the primary factor for determining a Medicare contract, suppliers must feel tremendous pressure to eliminate high-quality products. Is that pressure real, or do you see it in terms of the quality of care, the quality of the

products that are out there?

Mr. CRAMTON. If I may, this is a very common problem in the procurement setting, and this is a procurement setting. The government is procuring on the behalf of beneficiaries durable medical equipment. The problem is called "the race to the bottom." And if the auction is not well designed, that is, if there is not proper qualification, proper deposits, proper bid bonds, proper performance bonds, there will certainly be a race to the bottom. This is observed again and again in government procurements throughout the world.

The way it is avoided is with a properly designed auction that elicits the competitive price. That is done by eliciting the true costs from the providers. The current system does not elicit the true costs from the providers. Mr. Wilson stated that in his response, and I quote, "The winners rejected or accepted not based on their bid."

That is, the consideration was just what Ms. Zelenko said. The consideration in accepting or rejecting was whether she thought she could provide the goods and services at the price. Okay? So it has nothing to do with her bid. And in a competitive, efficient auction, the trick of making an efficient auction is to elicit the bidder's true costs, and then, in fact, the acceptance or rejection would be based upon the bid. And that is exactly what an efficient auction does when it identifies the clearing price. Those that bid below the clearing price are accepted; those that bid above are rejected.

Ms. Zelenko. And I think it is important that we understand when we talk about true costs, it is not the cost of the equipment. The cost of the equipment is a fraction of what our costs are. Our costs are in the service sector of what the services we provide. It is the education for our staff. It is the respiratory therapist, and hundreds and hundreds and hundreds of hours of teaching and training to go out to that beneficiary's home. We have all of the regulatory agencies that we need to adhere to, joint commission accreditation.

These are all costs, and every day we are faced with those costs. And not to mention, we cannot pass on any of those costs. We absorb every single one of those costs. When we look at the fuel—I mean, I still have to give raises to my staff or I can't keep my staff. I have to be able to compete in my own marketplace.

So the misconception that our costs—that we are paid too much because of what the equipment costs is a misconception. It is not about our equipment. We are a service industry.

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

Chairwoman Ellmers. Thank you for those responses.

And now I will turn to my colleague Mr. King for his questions. Mr. KING. Thank you, Madam Chair, and I thank the witnesses.

First, Ms. Zelenko, I would ask you if you could take us through the walker bid, I think you referred to it as. And a series of questions come to mind for me and the narrative I think could be helpful. How many bidders were there? Where did you fit in that rank order? How did it turn out that you were the successful bidder, but on 2.1, I think you said, you were—you had to turn it down because they offered you something below your costs. Could you explain how that went; just go through that process so that I can fit in my mind's eye.

Ms. ZELENKO. Well, initially we went into round one, and obviously I put in an enormous amount of time, my staff put in an enormous amount of time to really look at what our true costs are. We based it off of activity-based costing, which is—you know, pulls in all of your costs from intake to delivery, to assessment, and determined the price that I felt that I could continue to provide quality services. And I am a for-profit. The risk is there. It is all here on my shoulders to make sure that I can take care of payroll and everything else that comes along with that. So it was a very informed and realistic price.

When round two came out, or-

Mr. KING. Where did you fit in the rank order? How many bidders and generally how big of dollars are we talking about?

Ms. ZELENKO. I will need to get back to you on that, and I can put it in writing.

Mr. KING. The number of bidders, don't you have a kind of range so we have got a concept to work with today?

Mr. Cramton. No data. The data is not available.

Ms. Zelenko. That is part of it.

Mr. KING. That is part of the problem? You don't know who you are bidding against, but you were successful because they selected you as the median bidder, but you don't know the median of what the range were?

Ms. Zelenko. Correct.

Mr. KING. You don't know how many suicide bids were out there. He says that there aren't suicide bids, but the data shows there are at least 8 percent that are, and it could be a lot more than that. And I don't know that I would qualify you, under this scenario, as a suicide bidder under this scenario that we are talking about. That is people at the bottom that puts you in the median.

Ms. Zelenko. Correct.

Mr. KING. And so for me it is a bizarre bidding process to have

no transparency.

What about qualified bidders? Do they only accept bids from qualified bidders? You said your accreditation is a piece of this. Is that a component as well? Ms. Zelenko. Yes, it is.

Mr. KING. You have to be qualified.

Ms. Zelenko. You do have to be qualified.

Mr. KING. This is, to me, and I am trying—I can't get into this world, but I would like to go to Dr. Cramton in the time that clock that is now moving against me. Do you believe that CMS has the statutory authority to require a bonding process for bid bonds and

performance bonds?

Mr. Cramton. Absolutely. The government and pretty much across the board in all of the proper auctions that I am aware of in government, not just the United States, you know, the individual States, around the world, all have protections with respect to bid bonds or deposits. In the case—in the case of an auction actually rather than a bid bond, a preferable instrument is a deposit. And that is because a deposit can be used because performance with respect to a bid is easy. You either sign the contract at the end of the auction or not. That is the performance. Then there is performance after you sign the contract, and that might be a little bit gray. But performance with respect to an auction is black and white, and so—

Mr. KING. Were you astonished to hear Director Wilson testify that they didn't have the statutory authority to require bonding?

Mr. CRAMTON. I was astonished, absolutely astonished. When I talked with him, he did say that I did talk to them, and when I marched in and talked to CMS the first time, they told me the reason that they can't have binding bids is because they can't have contracts. And that is nonsensical to me. After all, they sign a supply contract. You are a contract supplier. They even use the word, and, in fact, you do sign something.

Ms. ZELENKO. You do.

Mr. CRAMTON. So they said, well, it can't be—it has to be voluntary. An auction by its nature is voluntary. Nobody is forced to bid, and, in fact, you get to bid what you like. And especially in a proper auction you are not constrained by a floor and a ceiling.

Mr. KING. What about the grandfather clause? I would ask Ms. Zelenko. What happens with companies that are grandfathered in? Do you see that being in effect 10 years from now, these companies that are grandfathered in, or how does that affect the way you do

your business?

Ms. ZELENKO. Well, I chose to grandfather in, and one was because I was hoping that we would be able to eliminate the current program or repeal and replace it. So I kept my patients that I have had. It is hard to say what is going to happen, because the players are changing probably as we speak. And, you know, the small providers that were part of that initial round one are no longer going to be here.

Mr. KING. Well, thank you.

Here is my concluding observation, and that is having started up a business from scratch, dealing with large institutionalized companies, I know that they have an ability to sit down with the people who write the specifications for the bidding process, and if you are a little old company trying to get a toehold, and there are big companies in there that are at the table negotiating how this bidding

process goes, that gives a tremendous advantage to the people that

write the specs.

And I don't know who Director Wilson is meeting with from the independent companies out there, but the pattern of this is a pattern that I have seen for my entire business life, which spans about 38 years now. And that pattern is big companies are at the table writing the specifications for the bidding process—as bizarre as this is, I would suspect that they had a voice in this—and small companies are on the outside trying to figure out how to compete while they are playing in a set of rules that are written to keep their competition out.

And so I appreciate your testimony. I am completely convinced there is a lot more in all of this document that we didn't get to hear today, and I hope the other panelists are able to review this and our staff is, and we can come with a real solution to this.

Thank you, Madam Chair and the witnesses, and I yield back.

Chairwoman Ellmers. Thank you.

And now, Mr. Thompson, did you have any questions?

Mr. THOMPSON. Sure. Thanks, Madam Chair.

Ms. Zelenko, you talk about true costs. I was curious. Is there—among those true costs is there a cost for you in terms of the cost of compliance with—specifically with Medicare regulations? Is that a part of your cost of doing business?

Ms. ZELENKO. Oh, absolutely. It is an enormous amount.

Mr. THOMPSON. Well, any idea of a percentage?

Ms. ZELENKO. Well, offhand I can't give that to you, but I

Mr. Thompson. It is significant.

Ms. Zelenko. It is significant. The price of the equipment is probably 12 percent of what we do. So that is a very small component of our costs. The costs really come down into the intake, getting prescriptions to and from the physician, and then managing that patient. We are managing their care.

Mr. THOMPSON. Right. These gas prices probably don't help your

business at all either.

Ms. ZELENKO. And we cannot pass on any of this.

Mr. THOMPSON. Yeah.

Dr. Cramton, I don't know if you are familiar with H.R. 1041. It is a bill I have been proud to be a sponsor of, Fairness in Medicare Billing Act. There is 172 cosponsors, so there is a strong recognition in Congress that competitive bidding is flawed.

Now, it is a start to repeal competitive bidding. I think working with the industry, there has kind of been a middle ground that has been identified that is the Market Pricing Program. Can you explain how the Market Pricing Program would improve the bidding process and, frankly, the allocation of DME to Medicare beneficiaries?

Mr. Cramton. Certainly. Well, let me just go back to the four principles that I mentioned earlier: efficiency, transparency, simplicity and fairness. With respect to efficiency, what the Market Pricing Program is doing is using a very well-established auction procedure that has performed extremely well in theory, in the lab, and in the field for many decades, and some elements of it for actu-

ally thousands of years. It is really the fundamental market clear-

ing price where supply and demand balance.

With respect to transparency, the Market Pricing Program is extremely highly transparent. It is quite responsive, so that rather than taking the bids and then waiting 1 year before announcing what the prices are and who the winners are, in fact, the prices and winners can be identified in less than 1 second. So a dramatic improvement.

Also with respect to transparency, the data would be available, and this is very important, and the data would not just be available to the public, but it would be available to the Independent Market Monitor. This is an extremely important innovation that began actually after the California electricity crisis in 2000-2001. Now every electricity market in the United States has an Independent Market Monitor. The market monitor has access to all of the data. They are watching the market. They write a detailed annual report about how the market is doing, what can be improved, proposals. When they see a problem, they immediately jump on the problem and address the problem. So this is an important element of transparency and also in fine-tuning the process.

If one takes a look at the 1-year report that CMS did, which I think was released on April 17th of 2012—it is on my Website, it is on their Website—you will see a 16-page report that does not address any of the issues that all of the experts agree are extremely serious problems with their program. Not one word about any of the issues. So it is not a critique, it doesn't give data, it just makes

and assertion.

In contrast, in my written testimony I give a link for the independent market monitoring report of PJM, which is our electricity market here, and you will see that there is just a—this is a small business. The Independent Market Monitor, it is a company of 25 full-time employees, an incredibly sophisticated and detailed analysis of the market, the process, everything. It just is night and day.

Mr. THOMPSON. Director Wilson had talked about that it would take 8 years to implement this. Now, I understand from your testimony you implemented a-and I recognize it was a pilot, a mock auction through the University of Maryland, so I have to wonder if the 8 years, is that the speed of CMS, or-

Mr. CRAMTON. Yes.

Mr. Thompson. Is it denial with all of the—you know, in public policy we—frequently in debate we get wrapped into emotion, you know, a lot of emotion. But, you know, I love the fact that there is a lot of science that you have brought to this issue, and a lot over 260 colleagues who have weighed in on this.

How long do you think, in your opinion, would it take to really

implement an MPP?

Mr. CRAMTON. Well, the longest lead time is with respect to the regulatory process, but it could be streamlined and accomplished by congressional instruction in 8 to 12 months. And I say that with a great deal of experience. So not 8 years; 8 months. That is what we are talking about if it is done properly, if the experts are engaged.

With respect to, for example, the system that performs the auction, this can be procured through competitive bid by government, as the Federal Government does. So, for example, the FCC routinely involves experts in their design, which has been incredibly successful, so successful that this is their design for spectrum auctions. It has been implemented throughout the world.

So I think that there is no question that if it is mandated by Congress, and Congress does give CMS detailed instructions on what to do and the timetable for doing it, that, in fact, this can be done in—8 to 12 months would be—that would be the fastest, I

would say. But certainly the—yeah, 8 years is just crazy.

I would like to say one other thing that was raised, and that is who this harms or helps. It has been suggested that this harms small businesses. That is absolutely true. This existing program obliterates, will obliterate thousands of small businesses. It already obliterated about 4,000 in the round one rebid. But it is also the case that this is very bad for big businesses and medium-size businesses. This is bad for all businesses. It is not the case that there is some special interest of providers that has been lobbying and rigging the rules in a particular way. In fact, I don't know of any providers, any providers, small, medium, large, who like the existing rules. They are just crazy.

Mr. THOMPSON. Thank you.

Chairwoman ELLMERS. Thank you, and thank you so much for our panel and your testimony and your answers to our questions. It is helping us to get a better grasp of the situation and what we need to do to rectify it.

So at the beginning of this hearing, I said that we were here to assess the impact of the Medicare Durable Medical Equipment Competitive Bidding Program. Our intent was to understand the program's impact on patients, small business suppliers, and the implications for the program expansion. At this point I would say we have gotten great insight into how the program operates and some of the struggles it is going through, some of which are very troubling.

Certainly all of us can agree that lower prices means the patients are paying less for the DME products and services they must have. These lower prices are something all of us can celebrate; however, how those prices are obtained and the methods by which the small business suppliers are allowed to participate and compete fairly are critical to this program. This hearing began the process, but, going forward, we must seek to ensure that this program protects patient access to the vital products and care that they need. While I strongly believe in the competitive forces of the private market, the process by which the competition is conducted must be fair and truly competitive.

I want to thank each of you for your testimony today and helping the Subcommittee understand the successes and challenges associated with the round one system, and hope that we have shed light on a number of things that should be changed before the program's

scheduled expansion next year.

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

[The information follows:]
Chairwoman Ellmers. This hearing is now adjourned.

[Whereupon, at 11:54 a.m., the Subcommittee was adjourned.]

STATEMENT OF

LAURENCE D. WILSON

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

ON

MEDICARE'S DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM: HOW ARE SMALL SUPPLIERS FARING?

BEFORE THE

U.S. HOUSE COMMITTEE ON SMALL BUSINESS SUBCOMMITTEE ON HEALTHCARE AND TECHNOLOGY

SEPTEMBER 11, 2012

Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How Are Small Suppliers Faring?

U.S. House Committee on Small Business, Subcommittee on Healthcare and Technology September 11, 2012

Chairwoman Ellmers, Ranking Member Richmond, 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). This important initiative is reducing beneficiary out-of-pocket costs and program outlays, while ensuring continued access to high quality DMEPOS items and services, establishing Medicare's DMEPOS payments based on competitive market pricing, and helping combat supplier fraud. On January 1, 2011, CMS launched the first phase of the program in nine major metropolitan areas for nine product categories. I am pleased to report that in its first year of operation, the DMEPOS competitive bidding program saved the Medicare fee-for-service program approximately \$202.1 million, and according to CMS's Independent Office of the Actuary, the program is projected to save the Medicare Part B Trust Fund \$25.7 billion between 2013 and 2022, with an additional \$17.1 billion in savings for beneficiaries during that period. 1 CMS has worked to ensure that small suppliers remain an important part of the DMEPOS program, and I am pleased to report that small suppliers (defined as those with annual gross revenues of \$3.5 million or less), made up 51 percent of the winning suppliers.

Overview and Program History

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. Each year, DMEPOS suppliers provide items and services, including power wheelchairs, oxygen equipment, walkers and hospital beds, to millions of Medicare beneficiaries. In 2010, before competitive bidding took effect, combined expenditures (including beneficiary cost-sharing) were approximately \$14.3 billion for DMEPOS. About 15.5 million Medicare beneficiaries used DMEPOS in 2010.

¹ Competitive Bidding Update—One Year Implementation Update, April 17, 2012: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf

The current Medicare DMEPOS benefit is plagued by an obsolete pricing methodology, grossly inflated prices, and a well-documented proliferation of fraudulent practices fueled by these inflated prices. With the exception of the 9 areas where competitive bidding is now in effect, Medicare Part B currently pays for DMEPOS items and services using fee schedule rates for covered items. In general, fee schedule rates are calculated per the statute using historical supplier charge data from more than 20 years ago that are often much higher than market prices. 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 Department of Health and Human Services' Office of Inspector General (OIG)³, the Government Accountability Office (GAO), and other independent analysts have repeatedly warned that the 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 customers who purchase these items on their own. These inflated prices in turn increase the amount beneficiaries must pay out-of-pocket for these items.

To provide greater value to the Medicare program, beneficiaries and taxpayers, Congress established the Medicare DMEPOS Competitive Bidding Program in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173). The program was modeled after the successful demonstration projects in Polk County, Florida and San Antonio, Texas between 1999 and 2002, which resulted in 20 percent savings for Medicare and beneficiaries without any negative impact on access to equipment or quality of care for beneficiaries. Under the MMA, the DMEPOS Competitive Bidding Program was to be phased into Medicare so that competition under the program would initially begin 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

²See Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011 for examples of DME related fraud: http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf

³ See, for example, Comparison of Prices for Negative Pressure Wound Therapy Pumps, OEI-02-07-00660, March 2009; Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services, OEI-04-07-00400, August 2009; Medicare Home Oxygen Equipment: Cost and Servicing, OEI-09-04-00420, September 2006.

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, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) delayed the start of the program. MIPPA terminated the Round 1 contracts that were in effect and reinstated fee schedule payment rates, required rebidding of the first round at a later date, and imposed a nationwide 9.5 percent payment reduction for all Round 1 items 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 changes but maintained the competitive bidding program. The Affordable Care Act (P.L. 111-148 and P.L. 111-152) subsequently expanded the number of Round 2 MSAs from 70 to 91 and mandates that all areas of the country be subject either to DMEPOS competitive bidding or payment rate adjustments to the fee schedule using competitively bid rates by 2016.

CMS implemented a variety of operational improvements to the program prior to rebidding the first round as required by MIPPA. CMS incorporated all of the program improvements required by MIPPA, including the "covered document" review process. This process gives bidders who submit their proposal by the covered document review date the opportunity to be notified of missing financial bid documents and submit the missing documents. In addition, CMS implemented a number of other important improvements based on lessons learned from the 2008 bidding process, feedback from stakeholders, and advice from the Program Advisory and Oversight Committee (PAOC). 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; and enhanced bid evaluation processes such as a comprehensive upfront licensing verification process, a more rigorous bona fide bid evaluation process to verify the sustainability of very low bids, and increased scrutiny of expansion plans for suppliers new to an area or product category.

Considerations for Small Suppliers

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

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

- CMS worked in close collaboration with the Small Business Administration to develop a
 new, more appropriate definition of "small supplier" for this program. Under this
 definition, a small supplier is a supplier that generates gross revenues of \$3.5 million or
 less in annual receipts including Medicare and non-Medicare revenue rather than the
 previous standard of \$5 million. We believe that this \$3.5 million standard is
 representative of small suppliers that provide DMEPOS to Medicare beneficiaries.
- Further, recognizing that it may be difficult for small suppliers to furnish all the product
 categories under the program, suppliers are not required to submit bids for all product
 categories. The final regulation implementing the program allows small suppliers to join
 together in "networks" in order to meet the requirement to serve the entire competitive
 bidding area.
- In addition, to help ensure that there are multiple suppliers for all items in each competitive bidding area (CBA), each bidder's estimated capacity, for purposes of bid evaluation only, was limited to 20 percent of the expected beneficiary demand for a product category in a CBA. This policy ensures that multiple contract suppliers for each product category were selected and that more than enough contract suppliers are selected to meet demand for items and services in area. For most areas and product categories, the result of this policy will be an increase of the number of contracts awarded by CMS beyond the statutory threshold of two contracts per product category per CBA.

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

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

Round 1 Rebid

With improvements and protections in place, CMS implemented the Round 1 Rebid of the competitive bidding program in nine MSAs on January 1, 2011, covering nine DMEPOS product categories. ^{4,5} CMS awarded 1,217 DMEPOS competitive bidding program contracts to 356 suppliers. All contract suppliers were thoroughly vetted during bid evaluation to ensure that they were in good standing with Medicare and met Medicare enrollment rules, quality and financial standards, and accreditation and state licensure requirements. CMS also screened and evaluated all bids to ensure that they were bona fide and based on real supplier costs. Only qualified bidders with bona fide bids were offered contracts. The bid evaluation process ensured that there would be more than enough suppliers, including small suppliers, to meet the needs of the beneficiaries living in the competitive bidding areas (CBAs). Approximately 51 percent of the winning suppliers from the Round 1 Rebid are small suppliers, well exceeding the 30 percent goal established by CMS. Ninety-two percent of suppliers that were offered a contract accepted the contract terms.

In addition to the larger programmatic changes described above, MIPPA excluded the Puerto Rico MSA and negative pressure wound therapy (NPWT) devices from the Round 1 Rebid.
 Round 1 Rebid product categories are: Oxygen Supplies and Equipment; Standard Power Wheelchairs, Scooters,

Second 1 Rebid product categories are: 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 Nutrients, 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; and Support Surfaces (Group 2 mattresses and overlays) in Miami only.

While only nine MSAs currently participate in competitive bidding, the program is already generating significant savings for the Federal government and the approximately 2.3 million Medicare fee-for-service beneficiaries residing in the areas where competitive bidding is in effect. According to CMS's analysis of claims from 2010 and 2011, 6 the competitive bidding program has reduced DMEPOS spending by approximately \$202.1 million—or 42 percent overall—in the nine Round 1 Rebid areas. The program has significantly reduced payment amounts, with an average price reduction of 35 percent from the fee schedule. For example, if Medicare suppliers in the nine CBAs had instead been paid the 2011 Medicare fee-schedule amounts, Medicare suppliers would have been paid \$173.31 per month for stationary oxygen equipment (e.g., oxygen concentrators), of which the beneficiary would have paid 20 percent in cost-sharing. The supplier would have received \$2,079.72 over the course of the year, of which the beneficiary would have paid \$415.94 in cost-sharing. Under the competitive bidding program, the average Medicare allowed monthly payment amount for stationary oxygen equipment in the nine competitive bidding areas has been reduced by 33 percent from \$173.31 to \$116.16. Further, a beneficiary's cost-sharing responsibility for stationary oxygen equipment rental for a year has been reduced by an average of \$137 in the nine areas.

The Round 1 Rebid contract period for all product categories except mail-order diabetic supplies expires on Dec 31, 2013. CMS is required by law to recompete contracts under the DMEPOS Competitive Bidding Program at least once every three years. Earlier this year, CMS announced plans to recompete the supplier contracts awarded in the Round 1 Rebid and conducted a prebidding awareness program to encourage suppliers to prepare for bidding. On August 16, 2012, CMS announced the bidding schedule for the Round 1 Recompete and started a comprehensive bidder education program. Bidder registration began on August 20, 2012, and the 60-day bid window is scheduled to open on October 15, 2012.

 $^{^6}$ Medicare fee-for-service claims. Savings derived by comparing 2010 to 2011 Part B-allowed charges, which include program expenditures and beneficiary cost-sharing. Claims for 2011 are estimated to be 98 percent complete.

Monitoring of Beneficiary Health Status and Access

CMS has closely monitored the results of the competitive bidding program since implementation to ensure that savings goals of the program have been achieved and - more importantly - to ensure that beneficiary access to appropriate supplies and equipment has not been compromised. To ensure effective monitoring, CMS implemented a real-time claims monitoring system which analyzes the utilization of the nine product categories. CMS' claims monitoring system was designed to pay particular attention to potential changes in key secondary indicators such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities before and after the implementation of the new payment model. To conduct this monitoring, the system looks at three comparison groups of beneficiaries over time: 1) all Medicare beneficiaries living in one of the nine areas compared to beneficiaries living in a similar geographic area not yet subject to competitive bidding (e.g., Orlando vs. Tampa); 2) beneficiaries most likely to use a particular item living in one of the nine areas compared to beneficiaries most likely to use the item in a similar geographic area; and 3) beneficiaries actually using an item living in one of the nine areas compared to beneficiaries actually using an item living in a similar geographic area. Beneficiaries are considered likely to use a competitively bid item based on the presence of particular health conditions (for instance, patients with pulmonary disease are monitored for use of oxygen therapy).

For the first year of the program, CMS' real-time claims monitoring and subsequent follow-up has indicated that beneficiary access to all necessary and appropriate items and supplies has been preserved in the nine CBAs. Moreover, utilization of hospital services, emergency room visits, physician visits, and skilled nursing facility care has remained consistent with the patterns and trends seen throughout the rest of the country. The results of our claims monitoring are regularly posted on the CMS website.⁷

Using the information generated by the real time monitoring, CMS has conducted follow up as necessary. For example, CMS' monitoring revealed declines in the use of mail-order diabetes test strips and Continuous Positive Airway Pressure (CPAP) supplies in the CBAs. In response

 $^{^7}$ Health status monitoring summaries are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html.

to these utilization declines, CMS initiated three rounds of outbound phone calls to users of these supplies in the nine CBAs, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, which would suggest that beneficiaries had historically received excessive replacement supplies before they were medically necessary. As a result of this monitoring, CMS concludes that the competitive bidding program may have curbed previous inappropriate distribution of these supplies.

In addition to careful monitoring of beneficiary health status, CMS is tracking the number of inquiries and complaints made to our regional offices, 1-800-MEDICARE, and the Medicare Competitive Acquisition Ombudsman's Office. During pre-implementation education, CMS aggressively marketed the 1-800-MEDICARE call center as a primary information tool for beneficiaries. In 2011, CMS received 127,466 beneficiary inquiries regarding the competitive bidding program, which represented less than 1 percent of total call volume at the 1-800-MEDICARE call center. The vast majority of inquiries were about routine matters such as questions about the program or finding a contract supplier. The number of overall beneficiary complaints, defined as inquiries that express dissatisfaction with the program and cannot be resolved by a call center operator, continues to be minimal. All complaints were assigned to program experts for prompt resolution. In the fourth quarter of 2011, CMS received complaints from only six beneficiaries. This is a minute fraction of the 2.3 million fee-for-service beneficiaries residing in the nine CBAs.

Table 1: Beneficiary Complaints by Quarter, 2011

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total
Beneficiary Complaints	43	73	29	6	151

The small number of beneficiary inquiries and complaints further corroborate the positive results shown in the real-time claims monitoring data.

Round 2 Expansion and National Mail Order Competition

Building on the success of the Round 1 Rebid, CMS is expanding the competitive bidding program to 91 additional areas as required by MIPPA and the Affordable Care Act. The bidding process is very similar to the process used successfully in the Round 1 Rebid, with minor adjustments. In addition to the items included in the Round 1 Rebid, CMS has expanded the list of items bid by combining standard manual wheelchairs, standard power wheelchairs, and scooters to form a new expanded standard mobility device product category; expanding bidding for support surfaces throughout all Round 2 areas; and adding negative pressure wound therapy pumps and related supplies and accessories as an additional product category. CMS is also conducting a national mail-order competition for diabetic testing supplies at the same time as Round 2. The national mail-order competition includes all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. The bidding window was open from January 30 to March 30, 2012. CMS is currently evaluating the bids received and expects to announce the payment amounts and begin the contracting process in Fall 2012, with an announcement of contract suppliers in Spring 2013. We anticipate that the Round 2 and national mail-order program contracts and prices will be implemented in July 2013.

CMS is continuing to make additional improvements in the bidding process for Round 2, focusing on increasing the scrutiny of bids and enhancing the successful bidder education program. CMS already used a rigorous bona fide bid review process in Round 1 to protect against unrealistic low bids. During the Round 1 Rebid bid evaluation, we found that about 8 percent of bids were extremely low in comparison to other bids, so we asked these bidders to send us invoices and rationales explaining how they could furnish items at the bid price. Bidders were able to prove that 67 percent of these comparatively low bids were feasible. We rejected all of the bids that were not proven feasible, and we did not offer contracts to these suppliers or include the rejected bids in the calculation of single payment amounts. CMS is strengthening this rigorous process for Round 2 by focusing more on the highest costs, highest volume items and subjecting more bids to additional review beyond the initial screening and evaluation process. CMS also improved bidder education materials to emphasize more strongly the need to submit bids that include the cost for the supplier to buy the item, overhead, and profit.

To help the large number of suppliers in these MSAs understand the process, CMS launched a bidder education program in November 2011. This program was designed to ensure that all DMEPOS suppliers, including small suppliers, interested in bidding received the information and assistance they needed to submit complete bids in a timely manner. Comprehensive information on an array of topics, including bidding rules, user guides, policy fact sheets, checklists and bidding information charts, was made available at http://www.dmecompetitivebid.com. The educational materials explained the small supplier protections provided by the program. Bidders could also call a toll free help desk with expanded hours with any questions about the bidding process. The bidder education program featured numerous enhancements such as improved Request for Bids instructions, updated fact sheets, and a series of educational webcasts. The webcasts were posted online and could be accessed 24 hours a day to ensure maximum opportunities for suppliers to review them.

CMS recognizes that the success of Round 2 will require significant efforts to educate beneficiaries, beneficiary partners, providers, stakeholders and contract suppliers about the program and, accordingly, is preparing to scale up the successful education and outreach efforts used in Round 1. 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 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 deploy our central and regional office staff, along with local ombudsmen to 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. CMS plans to begin Round 2 outreach activities in the coming months, working first to make beneficiaries and stakeholders aware of the program and its benefits, while allaying potential concerns or confusion.

Conclusion

The DMEPOS competitive bidding program is saving money for Medicare and beneficiaries, while continuing to provide access to high quality supplies to those who need them. Over a year into the program, CMS has demonstrated that the program has had no negative impacts to the health of our beneficiaries and has curbed inappropriate use of certain items. As we seek ways to strengthen and preserve Medicare, DMEPOS competitive bidding serves as part of the solution, generating significant long-term savings to the Medicare Part B Trust Fund.

CMS looks forward to building on this success with the implementation of Round 2 of the program and will strive for continual improvement as it expands to serve more beneficiaries. Throughout the implementation process, CMS has appreciated the interest and feedback of Members of this Subcommittee and your constituents as we strive to make the program as effective as possible for the suppliers and beneficiaries in your districts. We look forward to continuing to work with you on this important initiative.

Medicare Auction Reform

Prepared Testimony of Peter Cramton¹ Professor of Economics, University of Maryland Chairman, Market Design Inc.

Before the Subcommittee on Healthcare and Technology United States House Committee on Small Business 11 September 2012

Chairwoman Ellmers, Ranking Member Richmond, and members of the House Committee on Small Business, I am honored to appear before you today and have this opportunity to speak to such a critical committee on a matter of great significance to our future: Medicare auction reform. Without the effective use of market methods to control costs and encourage efficient supply and demand, Medicare is unsustainable. This is why it is essential for Congress to step in and insist that the Centers for Medicare and Medicaid Services (CMS)² replace its fatally-flawed competitive bidding program for Durable Medical Equipment with a modern auction based on best-practice and science (see Market Pricing Program Summary 2012). CMS has had ten years to adopt a sensible auction, but has refused to do so. Congress must give CMS more specific instructions.

My testimony is that of an independent auction expert who has spent well in excess of 1,000 hours studying the CMS DME competitive bidding program. All of this work—with the exception of my first few hours of study—was unpaid. Further, although I often provide auction services to governments, I am not seeking nor do I desire to provide such services to CMS.

My work has involved five main steps:

- Identify the problems in the CMS design. This was the easiest step, since the main flaws are obvious. (See Ayres and Cramton 2010, Cramton and Katzman 2010, 2011c, and Letter from 167 Experts, Cramton 2011e, Cramton 2012)
- Develop an efficient Medicare auction based on best-practice and science. This step drew on my
 considerable experience and skills designing and implementing complex auctions markets for
 many related products. The step included hundreds of hours of working with providers,

¹ My specialty is the design of complex auction markets. Since 1993, I have contributed extensively to the development of innovative auctions in many countries and industries. I have advised nineteen governments on major auctions, including the United States. I am currently advising the governments of the United Kingdom, Canada, and Australia on the design and implementation of major auctions in telecommunications, electricity, and timber. I frequently advise bidders in major auctions around the world. I have written over fifty practical papers on auctions and market design published in peer-reviewed journals. This research is available at www.cramton.umd.edu and citations of my work are available here. I thank the Honorable Nancy Johnson, the twenty-four-year Congresswoman from the great state of Connecticut. She first introduced me to the Medicare auction problem and has been unfailing in her wisdom and encouragement throughout this difficult ordeal.

² Throughout I will refer to those responsible for the CMS competitive bidding program simply as CMS. I do so with apologies to the many staff at CMS who are worthy of praise and not critique. I am well aware that CMS has many outstanding public servants like any large government organization.

beneficiaries, and government leaders to understand well the market for durable medical equipment. (See Cramton 2011a)

- Educate the stakeholders about the problems with the CMS design. The participants and government leaders quickly understood the problems of the CMS design. CMS has thus far failed to respond. (See Cramton 2010a,b,c, Cramton 2011b,c,e,f, Cramton 2012, Cramton, Ellermeyer, and Katzman 2012)
- Educate the stakeholders about how the problems with the CMS design can be addressed. The
 result is a market that identifies the least-cost sustainable prices and the efficient suppliers who
 can provide quality goods and services at those prices. Again the participants quickly understood
 the benefits of the proposed design, but CMS has thus far failed to respond. (See Cramton
 2011b and Cramton 2011f)
- Convince stakeholders that a reformed Medicare auction does indeed work. This step required a great deal of work, especially to convince providers that fixing the flawed CMS design is preferable to a repeal of the legislation that mandates auctions for DME.³ A key event in this step was the April 2011 Medicare Auction Conference held at the University of Maryland. The event brought over 100 stakeholders from government leaders to providers to beneficiaries to experts together to discuss the flaws in the current program and develop an alternative based on best-practice. The event included a nearly full-scale mock auction in which fifty bidding teams competed to supply 56 products. The mock auction was conducted using a state-of-art auction platform customized for the Medicare setting. The auction realized 97% of the potential gains from trade. In sharp contrast, the CMS auction realized less than 50% of the potential gains from trade in experimental laboratories at the Caltech and the University of Maryland despite a much simpler economic environment (Merlob, Plott, and Zhang 2012 and Plott 2012). (See Cramton 2011b, Cramton 2011f, Cramton, Gall, and Sujarittanonta 2011, Letter from 244 Experts, and Medicare Auction Conference 2011)

There is consensus on this issue

Let me start with a point of consensus: Small businesses are the engines of innovation that allow the US economy to grow and prosper. We only need to think of Apple, Google, and Microsoft. All started as small businesses—one or two youths in a garage or a university cubical. These tiny businesses without capital, but with vision, are the true job creators.

Indeed consensus will be a theme of my remarks. There is no disagreement among experts about what I will say and the issue is non-partisan. I have spent two years working hard on this issue—talking and sharing with experts, government leaders, Congressional staff, providers, beneficiaries, Democrats, and Republicans—I have yet to hear a serious logical criticism to the arguments made here. CMS stands alone in arguing that their competitive bidding program should not be changed—yet CMS has to date failed to present any rational argument for the status quo.

³ Indeed strong evidence that I was not and am not a "hired gun" for the provider special interest is that I advocated for many months a position that the providers did not endorse: Medicare auction reform, rather than the repeal of the DME competitive bidding legislation. Providers only recently (I believe about December 2011) began to support auction reform.

The fatal flaws in the CMS design

The fatal flaws in the CMS auction design were first identified by auction experts in September 2010. The auction community—167 distinguished economists, computer scientists, and engineers engaged in auction and market design—sent a letter to many Congressional committees pointing out the flaws and urging action. Congressional offices responded with numerous letters to CMS and HHS demanding action, but CMS failed to act. As a result of this inaction in June 2011, and expanded group of 244 auction experts including four Nobel laureates wrote to the White House again urging auction. Since the letter articulates well the CMS design flaws and a path forward I quote it directly:

We are economists, computer scientists and engineers with expertise in the theory and practice of auctions. ⁴ In September 2010, many of us signed a letter to Congressional leaders pointing out the numerous fatal flaws in the current Medicare competitive bidding program for durable medical equipment (DME). We also emphasized that the flaws could easily be fixed by adopting modern auction methods that have been developed over the last fifteen years and are now well-understood.

The flaws in the auctions administered by the Centers for Medicare and Medicaid Services (CMS) are numerous. The use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids—submitting bids dramatically below actual cost. This leads to complete market failure in theory and partial market failure in the lab. Another problem is the lack of transparency. For example, bidder quantities are chosen arbitrarily by CMS, enabling a wide range of prices to emerge that have no relation to competitive market prices.

We write today, nine months later, to report that—much to our dismay—there are to date no signs that CMS has responded to the professional opinions of auction experts or taken any serious steps to fix the obvious flaws to the competitive bidding program. Rather CMS continues to recite the mantra that all is well and that CMS does not plan to make any changes to the program as it expands from nine pilots to the entire United States.⁵

We find this especially distressing and unreasonable given your Executive Order of 18 January 2011 on regulation. In that order, you lay out numerous sensible principles of regulation that administrative agencies must follow. The CMS competitive bidding program violates all of the principles, especially the principles of transparency and of basing regulations on the best available science. Indeed, the current program is the antithesis of science and contradicts all that is known about proper market design.

⁴ The views expressed here are our own and do not represent the views of any organization. None of us are paid to provide our views; we provide our independent views as experts who understand the advantages and challenges of market methods. For additional information please contact Peter Cramton, University of Maryland, <a href="perestriptions-representations-repres

⁵ For example, "Laurence Wilson, a Medicare official overseeing the bidding process, said his agency is 'very pleased' with how the nine-city rollout has gone and has no major changes scheduled before the new system starts in large cities." (<u>CaliforniaWatch.org</u>, 26 May 2011, Christina Jewett)

Since the writing of our letter in September, several of us have done further detailed scientific study to explore the properties of the CMS design and contrast it to modern efficient auctions. The findings are dramatic and illustrate the power of science to inform auction design. Specifically, auction theory was used to demonstrate the poor incentive properties of the CMS design and how these lead to poor outcomes. Laboratory experiments were conducted at Caltech and the University of Maryland that demonstrate that these poor theoretical properties are observed in the lab. Moreover, simple efficient auctions perform extremely well in both theory and in the economic laboratory. Finally, some of us have studied extensively the Medicare setting, speaking with hundreds of DME providers and beneficiaries, and have developed a modern auction design for the setting that is consistent with the best practice and market design methodologies.

This design step was far from a theoretical exercise. On 1 April 2011, a Medicare auction conference was conducted at the University of Maryland to show how the modern auction methods work and to conduct a nearly full-scale demonstration of an efficient auction. Over 100 leaders in government and the DME industry attended the event. The results are documented at www.cramton.umd.edu/health-care, including a complete video and transcript of the event. The mock auction achieved an auction efficiency of 97%. In sharp contrast, the CMS auction exhibited efficiencies well below 50% in the laboratory, even in simplified environments. Despite these sharp results, CMS continues to assert that all is well and that no significant changes are required.

The problems with the CMS auction grow worse upon closer inspection. The complete lack of transparency is inappropriate for a government auction. For example, we now know that CMS has almost complete discretion with respect to setting prices in a nontransparent way. CMS can and did manipulate the quantities reported by bidders during qualification. These quantities are essential to forming the supply curve, which ultimately sets the price in each product-region. To this date we know little about what quantities were used in the price

⁶ Cramton, Peter, Sean Ellermeyer, and Brett E. Katzman, "Designed to Fail: The Medicare Auction for Durable Medical Equipment," Working Paper, University of Maryland, March 2011. [pdf]

Merlob, Brian, Charles R. Plott, and Yuanjun Zhang, "The CMS Auction: Experimental Studies of a Median-Bid Procurement Auction with Non-Binding Bids," Working Paper, California Institute of Technology, April 2011. [pdf]

⁸ Cramton, Peter, "Auction Design for Medicare Durable Medical Equipment," Working Paper, University of Maryland, June 2011. [pdf]

⁹ Cramton, Peter, Ulrich Gall, and Pacharasut Sujarittanonta, "An Auction for Medicare Durable Medical Equipment: Evidence from an Industry Mock Auction," Working Paper, University of Maryland, April 2011, [pdf]

¹⁰ Tom Bradley, Chief of the Medicare Cost Estimates Unit at the Congressional Budget Office, describes this manipulation in his remarks at the Medicare Auction Conference at minute 49:13, "What they did was they selected bidders up to the quantity well over the amount needed to clear—to serve the given market, and then from that vastly expanded pool, they selected the median. Fundamentally, that's an arbitrary number. It's a number that bears no relationship to the market clearing price." [pdf]

determination. As a result of this lack of transparency, it is now clear that the CMS design is not an auction at all but an arbitrary pricing process.

Given that nine months have passed and given the disregard by CMS of the market design recommendations received from recognized experts, we call upon the executive branch to direct CMS to proceed otherwise. We also ask that you consider supporting new legislation that requires the Secretary of Health and Human Services to conduct efficient Medicare auctions, consistent with the best practice and the best science.

There is much at stake. Unfunded Medicare expenses are estimated to be in the tens of trillions of dollars going forward. Medicare is unsustainable without the introduction of innovative market methods and other fundamental reforms. The DME auction program represents an important first step, especially since failures in homecare will inevitably lead to much more expensive care at the hospital.

We believe that proper design and implementation of market methods can bring gains to all interested parties: Medicare beneficiaries benefit from receiving the quality goods and services they need, Medicare providers benefit from being paid sustainable competitive prices for the quality goods and services they deliver, taxpayers benefit by paying the least-cost sustainable prices for these products, and CMS benefits from the numerous efficiencies that result from conducting an effective program, largely free of complaint, fraud, and corruption.

We believe that government plays an important role in establishing effective market rules. For the Medicare auctions, the impediments to reform are not special interests or a lack of knowledge, but bureaucratic inertia. This is an important setting and change of the prior administration's regulations is required to contain Medicare costs and assure quality services for Medicare beneficiaries. We are counting on your leadership to bring effective reform.

Many thanks for your thoughtful consideration of our concerns.

Sincerely, [244 auction experts]

The market design process

In sharp contrast to the design process followed by CMS, the modern auction design process begins with the government staff engaging auction experts via competitive RFP to help them in the auction design. Just as you would consult a bridge expert to build a bridge or consult a dermatologist to address a skin disease it makes sense to engage auction experts. Missing this initial step was I believe a main source of the CMS disaster that still continues after over ten years.

Once experts are engaged, the market design process involves a number of interrelated steps:

- Use auction theory to inform the basic design
- Use simulation to test the design
- Test critical features of design in experimental lab
- Test design in pilots in the field

· With each step refine the design to better achieve objectives

CMS failed at all five steps. The only one that was at least partially followed was the conduct of pilots in the field. However, CMS neglected to scientifically design the pilots and then examine the results of the pilots to refine the design to better achieve its objectives.

A Medicare auction based on best-practice and science

I now summarize the Market Pricing Program (MPP), which is a reformed Medicare auction based on best-practice and science. The draft legislation for Market Pricing Program is not being refined and should be introduced in the House soon.

The proposed design addresses each of the flaws identified in the CMS design.

The most important flaws: non-binding bids and the median pricing rule are easily fixed. First, we make bids binding commitments. This is done through rigorous qualification one month before auction. A deposit proportional to a bidder's capacity is made before bidding begins. Once the auction concludes the bid deposit is returned to losing bidders and transformed in to a performance deposit for winning bidders. Again the performance deposit is proportional to a winner's capacity. Second, the median pricing rule is replaced with the clearing price rule: the price that each winner is paid is the clearing price—the price at which supply and demand balance. More specifically the price is set at the last excluded bid, the lowest price that is rejected. In this way, the auction establishes a clearing price for each product in each region.

The MPP uses a simple and effective auction mechanism, the simultaneous descending clock auction (Ausubel and Cramton 2004, 2006). The auction format has been used for over ten years in many industries with great success and it was the approach used in the mock auction conducted at the Maryland Auction Conference in April 2011. The format is a generalization of an English auction, as Sotheby's or eBay would conduct, but the many related products are auctioned together.

There is one price "clock" for each product category and region. The prices initially are high. For each category and region and its associated price, the bidder says "in" or "out." If "out" the bidder provides an exit bid indicating the price the bidder wishes to drop out of the category. Once a bidder drops out of a category, the bidder cannot return to the category. This is called the activity rule. It prevents the bidsniping that is often seen on eBay.

The auctioneer lowers the price on each category for which there is excess supply. Again the bidders respond with "in" or "out." This process continues until supply and demand balance for all product categories.

Importantly, in the MPP, capacities are based on historic supply. This avoids the arbitrary pricing of the CMS format in which opaque decisions of CMS determine the prices.

An incumbent's capacity is its historic supply. Each qualified new provider is assigned a capacity of 1 block (either ½ percent or 1 percent depending on the particular product-region). Winning a particular product-region comes with both rights and obligations. Any provider may supply more than its capacity, but its capacity is assumed in matching supply and demand and in setting performance obligations.

Notice that capacities are determined in objective manner. The auction administrator (CMS) has no discretion in setting capacity and therefore price.

In the MPP format auction, competition comes from new entry. Given the relatively low entry costs, especially from providers supplying in other regions or other categories, ample new entry can be expected at prices above competitive levels. Further the financial guarantees (bid deposits) ensure that bidders will exit at prices below competitive levels.

Winning bidders and prices are determined as follows. As soon as supply falls to 100 blocks or less, the clearing price is set at the exit bid of the bidder that caused supply to fall to 100 or less. Each bidder still "in" wins its capacity. If supply is less than 100 blocks, the blocks won are scaled up to 100/Supply.

An important advantage of the MPP approach is that post-auction competition motivates quality. After the auction, the winners compete for Medicare beneficiaries by offering quality products and services. Medicare beneficiary choice is an important driver to motivate providers to provide high quality products and services.

An important simplification in the MPP design is that prices of individual products are relative to price of the lead product in the category. This avoids the bid-skewing problem observed in the CMS pilots (Katzman and McGeary 2008). In qualification stage, for each category of interest, each bidder reports the relative price of each product as a percentage of lead product's price. The auctioneer computes the relative price index for each product in each category as the capacity-weighted average of bidder reports. The auction then determines the price of each lead product in each category; other individual product prices are determined from the relative price index.

A sample reporting form is shown in the table below for the Walkers category.

Category: Walkers and Related Accessories								
HCPCS Code	HCPCS Code Description	Definition of a Bidding Unit	Current Ohio Fee Schedule Allowable	Index to Lead Product Price at Current Fee Schedule	Enter for each Non- Lead Product the % Relationship You Believe the Product should have to the Lead Product Price	Example of Pricing (You Enter Lead Product Price You Believe is Appropriate)		
Waren Andread Strategie	and the state of t	V1007/210-4-130004/100-4-10-4-10-4-10-4-10-4-10-4-10-4	Paragona (Heriotal Stream of			Enter Price Below		
E0143 LEAD PRODUCT*	Walker, Folding, Wheeled, Adjustable Or Fixed Height	purchase of one (1) new item	\$92.49	100.0%	N/A			
E0144	Walker, Enclosed, Four Sided Framed, Rigid Or Folding, Wheeled With Posterior Seat	purchase of one (1) new item	\$288.20	311.6%		\$0.00		
E0135	Walker, Folding (Pickup), Adjustable Or Fixed Height	purchase of one (1) new item	\$69.34	75.0%		\$0.00		
E0154	Platform Attachment, Walker, Each	purchase of one (1) new item	\$54.24	58.6%		\$0.00		
E0155	Wheel Attachment, Rigid Pick-Up Walker, Per Pair	purchase of one (1) new item	\$24.28	26.3%		\$0.00		
E0149	Walker, Heavy Duty, Wheeled, Rigid Or Folding, Any Type	purchase of one (1) new item	\$202.00	218.4%		\$0.00		

Product categories, products, and regions should be re-optimized for new approach. Indeed the product and region configuration should be revisited periodically, but especially during the initial design process. The approach can easily accommodate more product categories, products, and regions. The optimization of categories, products, and regions is an essential task in the product design step with major input from HME providers.

My recommended approach is to auction a representative 10% each year for two-year contracts. This approach does not disrupt the market structure excessively. Indeed to minimize disruption, it is desirable to auction only about two categories in each region (one-fifth of the current total). This keeps the emphasis on establishing competitive prices, rather than excluding suppliers.

Under this approach of auctioning a representative 10% each year for two-year contracts, 20% of the product-regions are under auction contracts. Only winning suppliers of the particular product-region may supply the particular product in the particular region. It is this possibility of exclusion that motivates competitive bids.

What happens for the remaining 80% of product-regions that are not under auctioned contracts? For these non-auctioned product-regions, we apply competitive bid-based prices using a simple econometric model. Thus, 100% of the product-regions are competitively priced: 20% directly from the last two auctions and the remaining 80% indirectly from an econometric model that estimates the competitive price for the particular product-region from the two most recent annual auctions.

Each year a different 10% is auctioned, so over 10 years each product-region is auctioned once. To be clear, in the auctioned product-regions, only the winners can supply during the two-year commitment

period. However, the winners still must compete to supply within the product-region. For the non-auctioned product-regions, any certified supplier can supply. This competition in non-auctioned product-regions is a strong motivator for a provider to supply quality goods and services.

The MPP auction format is easy for bidders to understand and participate in. This was demonstrated in the mock auction conducted at the Medicare Auction Conference in April 2011. First, the price process is easy for bidders to manage. Bidders interested in a particular category can focus on that category in all regions. Similarly, bidders interested in a particular region can focus on that region in all categories. Bidders with other interests can focus on the most relevant categories and regions for them. Second, proxy bids allow small bidders to bid as in a sealed-bid auction. That is, they can enter in the first round, their minimum price for each product-region they desire. There is no need from them to track every round of the dynamic bidding process.

The Market Pricing Program is highly transparent. Qualification and financial guarantees are reported publicly well in advance of the auction. Capacities are determined in objective manner. The auction rules including product definitions, performance obligations, and penalties are known two months before auction. Following each bidding round, excess supply at current prices as well as prices for next round are publicly announced. Winners and quantity won are immediately announced at the conclusion of the auction. Finally, an independent market monitor reports on auction outcomes and any problems within two weeks of the auction end.

The use of an independent market monitor is an important innovation that began in electricity markets following the California Electricity Crisis of 2000-2001. The original auction rules were designed by a committee of stakeholders and included numerous market flaws that ultimately led to market failure in 2001. An independent market monitor would have identified the market flaws in advance of the crisis and even if it did not, the independent market monitor would have identified the crisis and quickly propose fixes to get the market on track. Now all electricity markets in the US have an independent market monitor. The independent market monitor is one reason the US electricity markets, following the California Electricity Crisis, have been so successful and have become models of electricity market design worldwide. ¹¹

The proposed design is based on proven methods. The clearing-price approach is commonly used across all countries and industries, including health care. The design emphasizes beneficiary choice, which helps avoid the race to the bottom by motivating quality goods and services. Transparency is another

¹¹ One of the important duties of the independent market monitor is to prepare an annual State of the Market Report. This report provides extensive analysis of the operation of the market and critically evaluates the markets performance. Any problematic issues are raised and solutions are proposed. The reports of the independent market monitor of PJM, the largest US electricity market, provide an excellent example of the reports and the roles, see http://www.monitoringanalytics.com/reports/PJM State of the Market/2012.shtml. The contrast between the PJM state of the market report and that of CMS' (2012) annual report is dramatic. The CMS report provides no critique of the market, is not independent, is not conducted by experts, and does not raise or resolve the numerous serious issues raised by hundreds of prominent auction experts. Interestingly, the PJM report is produced by a small business of 25 employees (30 including contractors). CMS has 4,477 employees.

key feature of the MMP auction. Transparent auctions are commonly used in highly successful government auctions.

In sharp contrast, the CMS design with non-binding bids and the median pricing rule has never been used in any country or industry. CMS stands alone defending a mechanism with proven and well-understood failings.

Through theory, experiment, and practice, the Market Pricing program has been shown to achieve least-cost sustainable prices. An important advantage of the approach is that it motivates efficient least-cost providers that supply quality goods and services.

Figures don't lie, but liars do figure

Throughout my testimony and indeed throughout the vast set of materials that I cite I make every effort to be transparent, objective, and honest. Truth matters. All that I say is readily confirmed from the supporting papers, data, video, and transcripts that I provide at the end of my testimony. I mention this at the outset, because CMS has not used the same standard in the discourse on this issue. CMS conceals the data and makes misleading statements. When CMS uses numbers I am reminded of the saying that my Dad taught me: "Figures don't lie, but liars do figure." I elaborate on two important examples in the appendix. Below I briefly describe CMS' claim of substantial cost savings. These cost savings are a gross overestimate. The details are in the appendix and the supporting documents

Myth: CMS' Competitive Bidding Program will save \$42.8 billion over ten years

The 18 April 2012 HHS Press Office (2012) News Release states, "According to the report, the program saved \$202 million in its first year in nine metropolitan statistical areas – a reduction of 42 percent in costs and, as the program expands under the Affordable Care Act and earlier law, it could save up to \$42.8 billion for taxpayers and beneficiaries over the next 10 years." This is the second sentence of the News Release and the "\$42.8 billion savings" also is in the subtitle, "Health care law expands second round, program will save up to \$42.8 billion", so it is clear that the number is central to the argument.

Given that DME Competitive Bidding is an important pilot program within CMS, an organization with 4,477 employees and a budget of \$606.9 billion, you may think that there is a lot of analysis in the \$42.8 billion number. There is not. Here is the logic: The total DME market currently is about \$10 billion a year. A savings of 42 percent is estimated in the pilot program's first year, which covers about 9 percent of the US. Assume the same savings percentage throughout the country and assume the same savings in each year for ten years: then the roughly \$100 billion spend gets cut by 42 percent or \$42 billion. Easy.

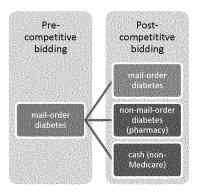
Here is the problem: the \$202 million savings number on which the house of cards is based is wrong. I do not have time to go into all of the serious problems with this number and others but let's look at one important example, which will be instructive: diabetes test strips. ¹² This is one of the most important products in the DME program. It accounts for \$51 million of the \$202 million total savings for all of DME. However, the \$51 million number is "simply not mathematically possible." (Milam 2012, p.2, bold-italics in original)

¹² I urge the Committee to look at Lewis (2012) for a critique of CMS' methodology.

Thomas Milam, an expert in the diabetes market and a member of the DMEPOS Competitive Bidding Program Advisory and Oversight Committee (PAOC), gives the correct calculation for diabetes test strips in his letter of 10 September 2012. There are basically three sources of "savings" in the \$51 million:

- Beneficiaries getting the test strips they need from a mail-order provider at the reduced postcompetitive-bidding price. Both Medicare and the beneficiaries enjoy this savings.
- 2. Substitution to non-mail-order. Beneficiaries are unable to get the test strips they need for their particular glucometer and so go the retail pharmacy for supplies. Non-mail order is not included in the DME Competitive Bidding Program and the prices are much higher, \$37.55 rather than \$14.65, a 256% increase. These much higher prices are born by both Medicare and the beneficiary. Both are made worse off.
- 3. Substitution to cash. Alternatively the beneficiary may decide that it is too difficult or impossible to get test strips from a contract supplier that CMS would allow. Instead the beneficiary pays cash, likely at the retail pharmacy price that is much higher than the mail-order DME Competitive Bidding price. CMS records this as a huge savings. This denial of access results in zero cost to Medicare, where in the pre-CB period Medicare paid the vast majority of the cost of the beneficiaries test strips. The result is a large apparent savings for Medicare and a large cost increase for the beneficiary.

These three possibilities are depicted below:



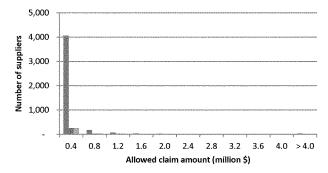
As shown in the figure only the first of the three possibilities—allowed mail-order diabetes supply—results in a cost savings. The other two possibilities—substitution to allowed non-mail order or cash purchase—result in cost increases either for both the Medicare and the beneficiary or just the beneficiary. The CMS data, the little that is available, confirm extensive substitution away from allowed mail-order (Milan 2012). As a result, the \$51 million cost savings is a gross overestimate.

For the other product categories access also is seriously impaired. The Accredited Medical Equipment Providers of America (AMEPA 2012) shows a 35% decrease in portable auction allowed post-CB; similarly, there is a 65% reduction in walkers allowed post-CB. At best these declines, which are comprehensively shown in Cramton (2012), show that the cost savings is a gross overestimate. However,

it is also likely, based on CMS data reported in Cramton (2012), that the loss in access has serious adverse health consequences. I am awaiting further data from CMS to confirm this result.

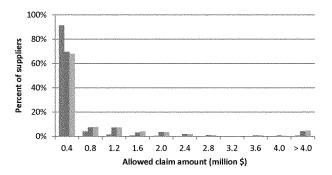
CMS' flawed program obliterates thousands of efficient small businesses

The chart below shows the number of contract suppliers both pre- and post-competitive bidding by supplier size, where supplier size is measured as by the company's total allowed claim amount for the year. I show the number of firms pre-CB (2010), post-CB based on the posting of winners in November 2010, as well as a revised posting of CB winners in the beginning of 2011. About 4,000 small businesses are wiped out under competitive bidding, over 90%.



™ Pre-CB (2010) W Original CB winners (2011) Revised CB winners (2011)

The next chart looks at the percent of supplies by size. As we can see, the vast majority of supplers both pre- and post-CB are small businesses. This is not surprising given the low economies of scale and the service advantage stemming from local service.



■ Pre-CB (2010) ■ Original CB winners (2011) ■ Revised CB winners (2011)

From the above it is clear that the current CMS competitive bidding program is bad for small businesses. However, it is bad for small and big businesses—all efficient (low cost) providers are harmed by the status quo. They either get thrown out of the market altogether or are forced to supply at a price that may well be below their cost.

The great injustice is that these businesses—both small and large—are not being wiped out because they cannot compete, but because the CMS auction is so flawed. The auction does not select the low-cost providers, but rather the suppliers that were "successful" in the low-ball bidding. This inevitable will lead to a "race to the bottom"—a frequent problem in poorly administered procurement auctions. Here the race would be especially rapid but for CMS' ability to manipulate the auction prices in a non-transparent way as describe earlier.

It breaks my heart to learn of the demise of one business after another as a result of unsustainable prices. Just a few days ago, I received an email from Esta Willman (2012) saying that she was shutting down her small business. For twenty-five years she and her husband have run Medi-Source Equipment & Supply, providing life-supporting oxygen and other durable medical equipment to beneficiaries in a rural area in San Bernardino County, California. I remember well having dinner with Esta in the Fall of 2010. We discussed the fatal flaws in the CMS program and how they could be readily fixed with modern auction methods. As a PAOC member, she was fascinated by the prospect of reform and fought for it until the end. The only thing she can cherish now is the love of the many beneficiaries who received quality supplies and services from her company for so many years and the knowledge that she worked tirelessly and without pay to reform the system that killed her company. Now the beneficiaries she served are without any local supplier of oxygen and other home medical equipment.

Is it wise for Congress to include specific design requirements and timetables in the reform legislation?

Generally, I am opposed to including specific design details and timetables in enabling auction legislation. Congress is not well-versed in the details of auction design and there is a real danger that including details in the legislation will hard-wire a flaw that then is difficult to change.

However, in the case of the DME auction, the administering agency, CMS has demonstrated gross incompetence with respect to auction design and implementation. CMS settled on a design roughly ten years ago and has pursued that flawed design through several pilots with only minor ineffective tweaks. For example, following pilots in early 2000, CMS switched from an average-price methodology to a median-price methodology, a switch that actually exacerbates the terrible incentive problem created by the poor pricing rule in conjunction with non-binding bids. Then when the 2008 Round 1 was held in pilot regions, Congress had to step in just days after the pilot and by law cancel the auction. As a result, CMS made a few minor tweaks such as tightening the *floor* on bids. The fact that CMS had to but in a tight floor on bids is clear evidence of strong incentives for low-ball bidding. Procurement auctions routinely have a *ceiling* on bids—or a clause to allow the buyer to reject all bids—to protect the buyer from an absence of competition, but floors are extremely rare.

It is not the case that complex auctions cannot be implemented effectively by government agencies. The agencies simply have to follow best-practice and science. This can be accomplished at extremely low

cost by retaining the services of experts. The best approach for such retention is through competitive bid. Indeed, very early on in this project in the Fall of 2010, I sent CMS a number of sample Request for Proposals from several governments seeking to retain expert auction services. I did this because CMS clearly did not even know that expert services were required, let alone how to acquire them.

Indeed, as I have previously testified before Congress, some agencies have done an outstanding job in designing and implementing complex auction markets (Cramton 2011d). The two leading examples are the Federal Communications Commission—spectrum auctions since 1994—and the Federal Energy Regulatory Commission—electricity markets since about 1998. In both cases, the agencies have sought and received significant expert advice.

In my most recent testimony to Congress (July 2011) on auction issues—the incentive auction legislation that Congress ultimate passed later that year—I said, "The incentive auction is complex. Its design is best left to experts. The FCC has an outstanding record of innovation in the auction arena and requires only limited guidance from Congress on the basic objectives and principles. It would be a mistake for Congress to prevent the FCC from adopting the best auction design by mandating auction details and other restrictions in the enabling legislation.

"Given the FCC's outstanding record in designing and implementing auctions, the legislation should provide the FCC with broad auction authority, focused on basic objectives and principles. To me, there are two key objectives: 1) transparency and 2) economic efficiency. What is needed is a statement of these objectives. Including specific details is apt to do more harm than good." I stand by those words.

In sharp contrast to the FCC and FERC, given CMS' dismal track record (see also Coulam et al. 2009), it is not only wise but essential that Congress specify each of the key features of an efficient auction based on best-practice and sciences together with a rigid and aggressive timetable. Doing less will lead to continued failure and will retard the use of effective market methods in other health care applications. The cost of such a failure likely is measured in trillions of dollars looking forward.

Congress must act

Unfortunately I am powerless to change this terrible injustice. Only Congress can insist on Medicare auction reform. By passing the Market Pricing Program, Congress can ensure an efficient, transparent, and fair market for durable medical equipment. The market—rather than illustrate government failure—can become a brilliant example of the government using market mechanisms in health care for the benefit of society. Taxpayers, providers, and beneficiaries will applaud your insistence.

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Appendix: Supporting material for the written record

On independence

I emphasize my independence because I have been told several times by Congressional staff that CMS staff have attempted to discredit my work by characterizing me as a "hired gun" to special interests or a "consultant seeking to sell auction services to CMS." These CMS staff should be ashamed at their baseless assertions. My work has been totally without pay aside from my first 12 hours on this project more than two years ago. I have spent well over 1000 hours on this project at huge opportunity cost to myself. I have more auction work from governments and companies at professional rates than I can handle. I would be delighted not to work for CMS on the design or implementation of Medicare auctions. If I were motivated by money, then I would have stopped my work on this project over one year ago, certainly by mid-April of 2011, when it became clear that CMS had no intention to reform their competitive bidding program.

On attempts to collaborate with CMS in Fall 2010

During the Fall of 2010 and the Spring of 2011, I worked hard to constructively collaborate with CMS on both the auction design flaws of the current program and how best to remedy these flaws. I believe my efforts are well documented in two short email streams (Cramton 2010a,b). My efforts included not only working with CMS but educating other government agencies that I thought would be helpful in assisting CMS in improving their program.

Figures don't lie, but liars do figure

Here are two examples, both of which come from the same CMS (2012) report that presents an update on the competitive bidding program after the first year in the nine regions that were under the pilot program. Both are "4 Pinocchio" statements.¹³ The statements are made with the intent to deceive and the misrepresentation is central to the writer's argument.

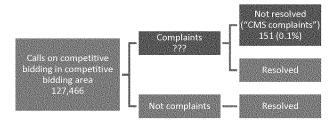
Myth 1: CMS' DME program had 151 complaints out of 127,466 calls in its first year

The summary of CMS' 17 April 2012 "Competitive Bidding Update—One Year Implementation Update" (CMS 2012) states, "CMS real-time claims monitoring has found no disruption in access to needed supplies for Medicare beneficiaries. Moreover, there have been no negative health care consequences to beneficiaries as a result of competitive bidding. CMS claims monitoring results are supported by the fact that the agency has largely received routine beneficiary or caregiver inquiries with only minimal complaints." These are sentences two-four in the lead-off one paragraph summary of the report, so it is clearly central to the writer's argument that the program is successful.

¹³ This is my judgment based on the *Washington Post*'s <u>Pinocchio Test</u>: 1 Pinocchio = "Some shading of the facts. Selective telling of the truth. Some omissions and exaggerations, but no outright falsehoods." 2 Pinocchio = "Significant omissions and/or exaggerations. Some factual error may be involved but not necessarily. A politician can create a false, misleading impression by playing with words and using legalistic language that means little to ordinary people." 3 Pinocchio = "Significant factual error and/or obvious contradictions." 4 Pinocchio = "Whoppers". What makes a "Whopper" is the statement is made with the intent to deceive and the misrepresentation is central to the speaker's or writer's argument.

I will talk about access and health consequences in the second myth. For now let's focus on the evidence CMS gives for the "minimal complaints" claim. CMS received 127,466 calls on the competitive bidding program in the competitive bidding areas during 2011, the first year of the program. This I do not dispute. But they go on and highly that of these 127,466 calls only 151 were complaints. This does not pass the laugh test. The reason is simple: even if CMS was that perfect agency that never receives a complaint, they should have recorded well in excess of 151 complaints due to errors in coding the calls.

To explain the "151 complaints" we must look more closely at what CMS means by a "complaint" which Encarta Dictionary defines as "a statement expressing discontent or unhappiness about a situation." CMS' definition is different: "inquiries that express dissatisfaction with the program and cannot be resolved by a call center operator." The CMS logic then looks like this:



The complaint number is rendered completely meaningless, because CMS fails to define what is meant by "resolved by a call center operator." For example, the definition of resolved may be, "the call center operator hung up on the beneficiary or the beneficiary hung up on the operator." That is certainly one way to "resolve" calls. Consider our perfect agency that never has a complaint, but miscodes non-complaint calls as complaints 1% of the time (that is there is minimal coding error). If the agency received 127,466 calls then it would wrongly code 1,275 of the calls as complaints, vastly more than CMS, who presumably does receive calls from unsatisfied beneficiaries about the DME program.

The bottom line: The only thing we learn from the "151 complaints" is that CMS knows little about numbers or thinks its audience is so naïve about numbers to accept such a claim without laughing.

Myth 2: CMS' Competitive Bidding Program will save \$42.8 billion over ten years

This example is presented in the main body of my testimony. Here I simply want to point out one weakness of the data used in Cramton (2012), which is acknowledged on page 3 of the report: "If there is a lag between the date of service and the date of receipt by CMS, then I would be underreporting 2011 claims by the length of the lag. For example, if the average lag between date of service and receipt by CMS is 30 days, then I should scale up claims by 365/(266 - 30) = 365/236. The size of the reductions

 $^{^{\}rm 14}$ lt is on the bottom of page 5 and the top of page 6 (CMS 2012).

¹⁵ I remember laughing out loud on 5 April 2011 when CMS Director Jonathan Blum triumphantly announced "only 43 complaints" out of many tens of thousands of calls on competitive bidding in the first quarter of 2011. My judgment: 4 Pinocchios.

in claims is so large that it seems implausible that this could be the result of long lags in the receipt of claims." To address this limitation, I have for many months sought through a Freedom of Information Request the same data fields but for the entire 2011 year and from an up-to-date claims database. Thus, far my request for data has not been filled. My request and the subsequent response is <a href="https://example.com/hereal-new-months-receipt data-hereal-new-months-receipt data-herea

On the competitive procurement of expert auction services

See Cramton (2010a). In my email I included four complete RFPs and stated, "The best approach for identifying the best experts is a well-written RFP and a competitive procurement of services. I have attached three recent RFPs as examples from three different industries (energy, telecommunications, and transportation) and two different countries (U.S and Canada). I encourage your staff to begin looking at these examples and think how they may need to be adjusted for the Medicare application in the event that CMS should decide to seek expert help in designing and implementing auction programs. Typically, this is done as a two-step process (design RFP followed by implementation RFP) and sometimes three steps (design RFP, testing RFP, and finally implementation RFP). The testing step in the three-step version is advisable when especially innovative auction methods are used, or the stakes are extremely high. Then experimental laboratory tests are desirable to test and fine-tune particular elements of the design.

I am sending these materials now, since I believe preparation of a suitable RFP is on the critical path to moving forward with improvements to your auction programs. Please let me know if you have any questions." I never received a reply and CMS made no effort to seek expert auction advice via RFP or otherwise.

On CMS' grade in auction design and implementation relative to other agencies

See Cramton (2011d). "Among all US agencies, the FCC gets the highest grade on auction design and implementation. At the other extreme is CMS, which gets the lowest grade among all US agencies for its design and implementation of the Medicare auctions for durable medical equipment. The CMS auction program is certain to fail at considerable cost to taxpayers and Medicare beneficiaries if Congress does not act to replace the current CMS auction with an efficient auction. Unlike the FCC, CMS requires much more direction from Congress. CMS over the last ten years has so far only demonstrated an inability to design and conduct auctions. Specific recommendations to the administration and Congress were provided in a June 2011 letter to President Obama from 244 concerned auction experts, including four Nobel laureates in economics. A wealth of supporting documents on this matter is available at www.cramton.umd.edu/papers/health-care. Like incentive auctions, Medicare auctions are of great importance to this committee; like incentive auctions, Congressional action is required and the proper course is clear."

Testimony of Tammy Zelenko President and CEO, Advacare Home Services, Bridgeville, Pa.

On Behalf of the American Association for Homecare

Before the Subcommittee on Healthcare and Technology House Committee on Small Business

On

Medicare's Durable Medical Equipment Competitive Bidding Program:

How Are Small Suppliers Faring?

September 11, 2012

Chairman Ellmers, Ranking Member Richmond, and members and staff of the House Small Business Subcommittee on Healthcare and Technology, my name is Tammy Zelenko. I am president and CEO of Advacare Home Services, a small business in Bridgeville, Pennsylvania. Advacare is a provider of home oxygen therapy, obstructive sleep apnea therapy, nebulizers, suction therapy, continuous passive motion therapy, hospital beds, wheelchairs and bathroom safety items. My company furnishes virtually all medically necessary physician-prescribed home and respiratory medical equipment and related services to Medicare beneficiaries. Through four locations in the Pittsburgh area, we provide high quality care to approximately 2,000 patients annually and employ 49 full-time associates.

I would like to thank the Subcommittee for holding this important hearing to examine the impact the Medicare competitive bidding program for durable medical equipment is having on small health care practices across the country. I am pleased to share my personal experience with the initial round of the Medicare bidding program and make constructive recommendations on how Congress can help support small health care providers and the patients they serve.

I am a member of the American Association for Homecare (AAHomecare) and I am testifying on their behalf. I also serve on the executive committee of the Pennsylvania Association of Medical Suppliers (PAMS), my state organization representing home medical equipment and service providers (HME), where I am the past president.

AAHomecare is the national trade association for home medical equipment service providers, manufacturers and other stakeholders in the homecare community. Nearly 80 percent of AAHomecare members are considered to be small businesses. AAHomecare members serve the medical needs of Americans who require home oxygen therapy, mobility assistive technologies (standard and complex wheelchairs), hospital beds, diabetic testing and medical supplies, inhalation drug therapy, home infusion and other home medical products, services and supplies.

We believe that home medical equipment is a vital component of the continuum of care and is a fundamental component to controlling health care costs by keeping beneficiaries in the most cost-effective and patient-preferred setting—their homes—rather than providing acute care in emergency departments and extended care institutional settings.

My goal before this Subcommittee today is to tell you about the negative impact the Medicare bidding scheme is having on small health care providers who are also small businesses. My aim is not to argue against competition. In fact, both the Association and I support healthy and fair competition.

HME providers compete every day to provide quality health care items and services to Medicare beneficiaries and embrace the opportunity to continue to compete to serve our patients. Competition breeds medical innovation, improved care and creates well-paying jobs in communities across the country. However, the competitive bidding program designed by the Centers for Medicare and Medicaid Services (CMS) is anti-small business, it is a job killer, and it will negatively impact the quality of care that our nation's most frail and elderly depend on to remain independent in their homes.

My testimony will highlight the flaws of the current competitive bidding program and recommend a sound, sustainable and budget-neutral alternative—the Market Pricing Program (MPP) for home medical equipment—that can be implemented on the same timeline as the current bidding program.

Advacare's Story

When I started Advacare Home Services, my goal was to grow a company that would provide only the highest quality of care to people in my community. I could compete with any provider because I offered better service. We provide trained and competency-tested service technicians and registered respiratory therapists in the home to instruct, educate, and train our patients and their caregivers on the use of home medical equipment so that patients with acute care or chronic needs could remain in their homes. We provide a comprehensive education, assessment and coaching program that empowers our patients to better understand their

disease, make proactive changes in their self-management techniques and help them remain independent.

We are often the eyes and ears of the elderly and the conduit between the patient, caregiver, physician, and community. We communicate critical information to the physician. We support patients in their home environment with self-assessment tools. We create a customized care plan based on physician orders and patient-specific goals. There are costs to providing this type of care, and I have spent the last 24 years investing my time, energy, resources, technology and money into building a reputation on quality and outstanding care in my profession.

I always felt that if I worked smart, not just hard, that I, too, could have the "American Dream." I come from a family of seven children. My father parked cars for a living, and I was the only child to go to college and receive a Master's degree. I put myself through college while working full-time at a home medical equipment company.

In 1986, I started out at my first home medical equipment company in the billing department, and worked my way through each of the departments and into management. In 1997, I was hired as the Director of Operations by seven local hospitals to start up their HME company.

As a small business owner, I was able to compete against the local, regional, and national providers within my market. Each year I gained market share, grew my practice, and received recognition due to the outstanding service that my company provided. However, all of that changed overnight when the bidding program went into effect. The bidding program, for me and thousands of providers like me, has created the biggest barrier for my company to survive.

I firmly believe that the government deserves to pay fairly for the items and services that HME providers furnish. Serving Medicare beneficiaries is a privilege, not a right. However, I am equally as passionate that the government should not be able to pick "winners" and "losers" and bar otherwise qualified providers from serving Medicare beneficiaries.

But even more troubling is the longer-term effect of this bidding program. Its design is neither sustainable nor based on sound economic principles. I am not aware of any auction or bidding program that is designed in the same manner as CMS' program.

In my role as a member of my state association, I get to speak with HME providers who share similar stories and no longer want to participate in the bidding program because it perverts the marketplace. It arbitrarily selects winners and losers, it arbitrarily sets reimbursement rates that are not sustainable, and it arbitrarily forces providers to trim the services they provide to frail and elderly patients to meet unrealistic reimbursement rates.

Competitive bidding has been in the design phase for a number of years. During this time, I recognized that change was coming and I would have to prepare and become more efficient. I just could not have anticipated that Medicare officials would design a program that is so antibusiness that it has been panned by every professional auction expert and economist who has looked at it. I began investing in technologies years ago to promote better efficiencies in preparation for competitive bidding. I invested in electronic medical record technologies. I purchased GPS devices for service technicians and state-of-the-art medical equipment and technology and invested in a new billing system and software. I believed these changes would prepare us for the bidding program. I was wrong.

This is the first year that I did not grow my company, the first time that I had to pass all of the healthcare premiums increases on to my employees, the first time that I could not offer reimbursement for continuing education.

Negative Impact on Small Businesses

The serious design flaws of the bidding program have had a substantial negative impact on my operations, to the detriment of: the patients Advacare services; my business; my staff; and, my local community. While larger regional or national HME providers have been able to subsidize some of the loss in revenue from the arbitrarily low bid prices through locations that are not yet subject to bidding, small businesses like mine cannot. Cost shifting should not be a survival technique and it cannot go on indefinitely as this program expands nationwide.

The following are some of the direct effects that the bidding program is having on small provider practices:

• Revenue, Staffing and Benefit Changes

- > Drastic decrease in Medicare revenue since the bidding program began;
- > Shifting health care cost increases to employees;
- Eliminating employer coverage of continuing education credits for respiratory therapists;
- > Limiting allowances for educational seminars and travel;
- Allowing staffing positions to go unfilled when employees left Advacare; and,
- > Subcontracted to a contracted oxygen provider in order to stay in the Medicare

• No Longer Able to Support Local Community

Advacare has been providing outstanding clinical care to Medicare beneficiaries for 15 years. We have supported our local communities and hospitals in a range of ways such as donating supplies to aid in disaster relief, participating on local foundation boards,

and contributing to local health care organizations and hospitals. The decreased revenue due to the low bid rates and not being awarded contracts means that I am unable to support the local community. Providers located outside of the area who won contracts are not contributing to the community, so my local organizations are suffering from the poorly designed bidding program as well.

· Sales and Marketing Impacted

Competitive bidding has created enormous barriers to gain new Medicare customers, making it very difficult to compete with the winning contractors.

Negative Impact on Patients

· Quality and Services Are Reduced

Before bidding, we competed on the level of service we provided. We furnished our patients with customized care plans to ensure proper levels of education, assessment, service and follow up to allow beneficiaries to receive care in their homes rather than more costly institutional settings. Because the competitive bidding rates are too low, we can no longer provide that level of service. Our respiratory therapists can no longer provide the clinical follow up on our oxygen patients that we have managed for years. The continuity of care that we had with the patient, caregiver, physician, and community resources no longer exists, and patient-centered care is compromised.

• Patients Are Forced to Switch Providers

We experience challenges every day working with Medicare beneficiaries who can no longer stay on Advacare's services, and we can no longer bill for their supplies. Advacare is forced to try to find a contracted supplier to take our patients who have been on our service for years even though patients do not want to switch providers.

Patients Must Receive Services from Multiple Providers

Often, our customer service department receives orders for multiple items all of which we could supply before the bidding program. Now, we can only provide the items that are not part of bidding, and we then help the referral source find other companies for items that Advacare can no longer provide. This means that beneficiaries must now receive HME items from multiple companies, which creates confusion and disrupts the continuum of care upon which they previously could rely.

Flaws in the Competitive Bidding Program

Experts in the design and operation of auctions have explained in great detail why the CMS bidding program will fail. CMS is the only group predicting that the program is sustainable over the longer term and operating flawlessly. They are basing this on a short-lived, small sample in nine markets—a program that even CMS officials call a "pilot." Yet, Round 2, with 91 markets, is more than 10 times as complex as Round 1. AAHomecare and small businesses like mine are on the front lines and can see fundamental flaws that need to be addressed immediately. And 244 experts from across the world have weighed in identifying similar problems and have told CMS, Congress and the Administration that the program will fail.

These are our main concerns:

1. Providers' Bids Are Not Binding Commitments

In Medicare's bidding program, bidders are not bound by the prices they bid. Any HME provider can decline to accept an offered contract from CMS after the prices, called Single Payment Amounts, are announced by the government. And because of CMS' decision about pricing, 50 percent of all bidders' prices will be lower than their best submitted bid. Medicare's rule undermines the credibility and integrity of bids, and, without binding commitments, encourages low-ball bids from providers.

To add insult to injury, if HME providers turn down contracts, their bid prices are still included in Medicare's calculation of bid amounts, and other bidders invited to participate are forced to choose between accepting the low price that they did not influence or losing their business altogether by not participating.

CMS states that 92 percent of contract awardees accepted their contract offer. But to decline a contract would immediately imperil a provider's practice because Medicare typically represents 40-60 percent of an HME provider's revenue. Now that we are in the second year of the Round 1 program, we are seeing both contracted and non-contracted providers exit the market, change their business model, close down or sell. What has propped this program up is its limited scope—it is being run in only 9 areas across the country. HME providers have been able to subsidize their competitive bidding markets with revenue from non-competitive bid areas. Yet, this cross-subsidization will evaporate as: 1) bidding is expanded to 91 additional areas in 2013, 2) private payors adopt competitive bid rates, and 3) CMS applies bid pricing to non-bid areas, including all rural areas in the U.S., as early as 2015.

2. The Pricing Calculation Is Flawed

Rather than paying contracted providers the clearing price (the last-accepted bid) which is the standard in bidding and reverse auction programs, Medicare's bidding program establishes prices at the unweighted median among the winning bids, resulting in 50 percent of the winning bidders being offered a contract price less than their bids. We know of no other auction or bidding program that has such a perverse rule where bidders are offered contracts at less than the amount they submitted during the bidding process.

3. Composite Bids Are Distorted

A composite bid is an average of a bidder's bids across many products weighted by the government's estimated demand. The composite bid methodology as designed by CMS provides strong incentives to distort bids away from market prices. Only heavily weighted (based on utilization) products within a category will impact the composite bid. Providers can "game" the system by bidding very little off the current Medicare allowable for certain products with little weight while bidding more aggressively on other items with a higher weight. This creates a program where individual products are not closely related to costs and providers participating in the program can "game" the system in order to manipulate the single payment amount. In addition, Medicare set a maximum for all items bid—again distorting the bidding process by not permitting bidders to fairly bid based on their true, fully-loaded costs.

4. Lack of Transparency Is Overwhelming

CMS has shared virtually no data with the public on the selection of contracted providers, calculation of historical demand (capacity), calculation of the single payment amount for products and services covered by bidding and outcomes-related findings to evaluate the program. Instead, CMS has made generalized statements that point to the so-called success of the program. Even the Agency's first year update after the implementation of the program is based on generalizations with little data to back up its findings.

Moreover, the savings numbers recently quoted by CMS appear to "double-count" savings resulting from anti-fraud and abuse initiatives that were implemented concomitantly with this program. For example, new provider screening tools, real-time claims monitoring and an avalanche of incremental pre- and post-payment audit activity have been implemented since the program began in 2011. It is surprising and shocking to us that Medicare has elected to audit contract winners in Round One markets so heavily when, in fact, CMS has stated that the program should, on a stand-alone basis, root out fraud and abuse.

Under the current program, pricing can be easily manipulated through subjective adjustments to the capacity that a provider lists on its bid forms. During the announcement of the Round One Rebid pricing, a CMS official stated the following about contract winners' financial stability. During a press call on July 2, 2010, the CMS official 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. 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."

This fact calls into question the validity of the payment rates established by the program and the supposed objective process that CMS established for the program and published in its Final Rule. The above public comment confirms that CMS may adjust a provider's stated capacity if it questions the provider's bid because it was considered low. By adjusting capacity, CMS manipulated the single payment amount and subjectively decided how many winners were needed. The bidding program then just becomes another way to apply administered pricing rather than letting the market set reimbursement rates. This subjectivity is playing with the very viability of numerous small businesses across the country.

5. The Bidding Program Is Designed to Be "Gamed"

Due to the methodology concerning how payment rates are calculated, the impact of non-binding bids and the ability to manipulate the capacity that a provider self-reports, the program is built to be "gamed." CMS even appears to acknowledge this fact in its first annual report on the bidding program when they state that, "we are strengthening our bona fide bid review process...to check that very low bids are sustainable by checking more of those bids." Questioning the sustainability of very low bids implicitly brings into question a program where the single payment amount offered by CMS is, by definition, lower than 50 percent of the accepted bids presented. If the bid amounts represent the lowest pricing while maintaining quality service, how can a program that reduces the pricing additionally be sustainable over the long term?

Under a "win at any cost" program, providers would do well to submit an unreasonably low bid—"a suicide bid"— in order to win a contract. These providers then would be assured of

a contract but they must hope that other providers bid more rationally so that the single payment amount would be higher than their submitted bid. From here, providers facing low reimbursement rates could agree to furnish competitively bid items but subsidize their revenue from non-Medicare or non-competitive bidding patients. CMS has never shared with the public how many of the 356 original contract providers have sold their businesses, gone out of business or simply did not bill Medicare for competitively bid items. This is a critical question for Congress to consider, because there were 6,922 unique HME providers submitting claims/providing services in 2010 in the nine bidding areas.

6. CMS Monitoring Is Weak and Non-Transparent

When the bidding program was first implemented, CMS required HME providers to provide the exact brand and model of equipment they were providing to Medicare beneficiaries. CMS also stated that it would begin to measure the patient satisfaction of beneficiaries who received HME services. This equipment report was intended to allow the Agency to determine if contracted providers began to substitute lower quality equipment under the program than was previously furnished to beneficiaries. However, CMS modified this requirement one quarter of the way into the pilot, so there is no way to monitor the quality of equipment Medicare beneficiaries are receiving. And to date, we have seen no beneficiary satisfaction data whatsoever, despite the program's 16-month implementation.

7. There Is No Due Process

Currently, there are no due process protections or appeals processes in place for providers to appeal CMS' methodology for establishing payment rates, making contract awards, designating bidding areas, deciding on the phased-in implementation approach, selecting items and services or the bidding structure and number of contractors. Numerous companies were initially qualified due to a technical error on CMS' fault, and yet it took over 120 days to resolve the issue—a date past the implementation date of 1/1/11.

8. Bidding Areas Are Too Large

CMS has created bidding areas that make it difficult, if not impossible for small providers to service. The Pittsburgh Metropolitan Statistical Area (MSA) covers more than 5,000 square miles and includes the city of Pittsburgh, seven surrounding counties and pieces of seven other counties. The Philadelphia MSA, which is part of the second round of competitive bidding, covers more than 9,000 square miles.

THE BIGGER PICTURE

The CMS program distorts the marketplace and, by ignoring the pricing methodology used in the original demonstration projects in Florida and Texas where the "clearing price" was used (i.e. setting the reimbursement rate using the highest contract supplier's bid), the program goes against the original intent of Congress when it voted to implement the program in 2003. It radically reduces the number of providers (competitors), thereby creating oligopolies in the marketplace at a time when our senior population is growing rapidly.

According to a recent Bloomberg Government report, "the bidding process employed by CMS will likely reduce the number of market participants and spur a wave of consolidation within the highly fragmented home medical equipment industry...As a result of the new program, the government awarded Medicare contracts to just 365 providers for 2011 in those same nine markets [of Round 1 of competitive bidding], an 85 percent reduction."

Moreover, it not only allows bidders to "game" the system's pricing rules but it actually encourages such manipulation during the bidding process. And it forces providers to reduce supportive services in order to meet drastically lower reimbursement rates that were obtained through a fundamentally flawed process.

These deficiencies, which I experienced first-hand, have been highlighted numerous times before the Congress. Meanwhile, CMS staff touts high cost savings and low negative beneficiary impact. However, the program is only running in nine markets, or six percent of the country. The competitive bidding program is particularly devastating to small businesses from day one. While larger regional or national providers, in the first year of a three-year fixed pricing contract, have been able to offset excessive and arbitrary price reductions in the bid areas with revenue from non-bid areas, this is not the case for small companies like mine.

AAHomecare does not stand alone in raising concerns with the current program. In fact, well over 200 economists, computer scientists, statisticians and auction experts from around the world have advised CMS that significant modifications need to be made to the bidding program to make it sustainable over time. Moreover, more than 30 consumer and beneficiary groups believe that the bidding program is flawed and needs to be changed.

AAHomecare has worked with auction experts to create an alternative to the current model that would give CMS a sustainable market-based pricing program for home medical equipment. This alternative preserves the concept of competition and ensures future beneficiary access.

Cost Effectiveness of Homecare

HME offers an efficient and cost-effective way to allow patients to receive care they need at home. The need for HME and HME providers will continue to grow to serve the ever-increasing number of older Americans. Homecare represents a small but cost-effective portion of the more than \$2.3 trillion national health expenditures (NHE) in the United States, and approximately 15.5 million Medicare beneficiaries require some type of home medical equipment annually, from rather simple bedside commodes for people who have hip replacements to high-tech ventilators for quadriplegics.

Yet, not all products are created equal: some require licensed or credentialed clinicians to be on staff or cost \$15,000 just to procure. And while Congress and the Office of Inspector General have shed light on products they believe to be overpaid, many others are unprofitable for us to provide even before the bidding program. The high cost of fuel, labor, rent and utilities and regulatory compliance associated with billing and collections, audits, HIPAA privacy, identity theft, IT security, Sarbanes-Oxley, waste disposal, beneficiary and employee safety, OSHA, DOT and FDA regulations continues to escalate year after year. Anyone who has ever required HME or had a relative who needed it can attest that our service includes much more than just the equipment.

The more that people receive quality equipment and services at home, the less that is spent on hospital stays, emergency room visits, and nursing home admissions. Home medical equipment is an important part of the solution to the nation's healthcare funding crisis. The facts bear this statement out as private health care plans have contracted for our services for decades and reaped the cost savings along the way. Even the current Administration is trying to develop programs to manage chronically ill Medicare patients in the home through new demonstration projects and the Innovation Center.

Fixing the Bidding Program

Congress's objective in requiring Medicare to use a competitive bidding model to establish payment amounts for HME was to reduce Medicare expenditures and ensure that beneficiaries have access to quality items and service. This objective cannot be met because CMS has designed a program that does not hold bidders accountable, does not ensure that bidders are qualified or capable to provide the products in the bid markets, and, due to the arbitrary nature of the capacity analysis, has produced bid rates that are financially unsustainable.

As I mentioned previously, auction experts and economists have warned that the Medicare bidding program is unsustainable in its current form. It will create significant barriers to access and will destroy the HME infrastructure that seniors and people with disabilities depend on as the program expands and providers cannot offset bid pricing with non-bid revenue.

Unfortunately, the recommendations of auction experts, beneficiary and consumer groups, the Medicare Program Advisory and Oversight Committee (PAOC)—the panel created by Congress to advise CMS on the design and implementation of the program—and AAHomecare and other interested groups have not been acted upon. We now look to Congress to fix systemic problems so that Congressional intent is followed.

To fix the fundamental flaws in the bidding program, an alternative market-based pricing program for HME has been developed, which has been specifically tailored to the HME marketplace. The proposal, known as the Market Pricing Program (MPP), would require changes to ensure a financially sustainable program. MPP uses an electronic state-of-the-art reverse auction to establish market-based reimbursement rates for HME around the country. These changes are consistent with Congress' original intent: to create a program that is based on competition while maintaining beneficiary access to quality items and services. The MPP would be implemented on the same timetable and apply to the same DME product categories as the current program, and will reduce government spending for DME items nationwide. It is intended to be budget-neutral.

The following are key components of the Market Pricing Program:

- MPP would require that providers stand by their bids if offered a contract. This feature
 is known as a "binding" bid.
- MPP would establish reimbursement rates at the "clearing price" (the last bid accepted) rather than the "median price," which CMS currently uses. Under the CMS methodology, half of all contract providers are paid less than they actually bid.
- 3. MPP would bid areas that are much smaller so that any provider could service an entire area subject to the auction.
- 4. MPP would bid the same product categories as the current competitive bidding program, but all products would not be bid in each area. MPP would bid 2 product categories for exclusive contracts in certain areas and apply the reimbursement rate to economically similar areas. This feature encourages competition, eliminates the incentive to submit unrealistic (suicide) bids, and allows providers to remain in practice until the next auction cycle commences.

Other important elements of MPP include:

Timeline

MPP would be effective on July 1, 2013. The design of the program would be developed through a collaborative, transparent process, involving all stakeholders (HME providers, CMS, beneficiaries), with the guidance of an auction expert and the oversight of the market monitor, to establish market rules, to set market-based and sustainable reimbursement

rates, and protect beneficiary access to, and choice of, quality HME products, services, and supplies. The use of an auction expert to help the Secretary of the Department of Health and Human Services design the auction program and a market monitor to help the Secretary ensure that the program is operating effectively and efficiently are common among public auctions.

Auction Operation

MPP would auction a representative 20 percent of the market (counties eligible for bidding) with two-year contracts. The remaining market areas eligible for the program would be served by any eligible providers furnishing HME at the reimbursement rates determined by the auction. The reimbursement rate established through the auction would apply to similar geographic areas (i.e., urban to urban, suburban to suburban) and be adjusted for regional characteristics.

Each year thereafter, MPP would auction a representative 10 percent of the market (counties eligible for bidding) with two-year contracts starting on July 1 of the year of auction.

An additional 10 percent of eligible market areas would be subject to auction each subsequent year until market pricing programs are occurring in 100 percent of eligible market areas throughout the United States. The process would continue and the Secretary, in consultation with the auction expert, would continue to select additional eligible market areas on an ongoing and rotating basis. This design would create the most accurate competitive market payment methodology in the Medicare program.

Rural Exemption

The same areas that are exempted under the competitive bidding program would be exempted under MPP.

Transparent Process Required

In establishing MPP, the Secretary would utilize an open and transparent process that includes all relevant stakeholders in the market. Provider and beneficiary education would be required in consultation with the auction expert and market monitor.

How MPP Benefits Small Businesses

For small businesses like mine, MPP has a number of key improvements over the current bidding program that will help my chances of survival. The smaller market areas mean that I will still be able to provide to patients that are nearby but not in the contracted area. The

Pittsburgh MSA includes seven counties. If CMS bid just one county under MPP, and pricing was applied to the other six, even if I did not win a contract, I would still have the opportunity to service patients in the other six counties at the market-based rate. Additionally, reducing the products bid in each contracted area to two items will allow me to continue servicing patients for all of the other categories, easing the burden of not being awarded contracts since I will no longer fear being completely excluded from the marketplace for every product category. Further, utilizing the "clearing price" methodology to set the market price means that I will not be paid less than my bid. Making bids binding will ensure that providers cannot game the system and then reject their contract award if the price is too low. Finally, the state-of-the-art auction system utilized in MPP will allow me to more easily understand my own business costs, and it will provide transparency throughout the bidding process for me and my competitors.

Conclusion

Small businesses are the backbone of the American economy. In these difficult economic times, Congress should take action to protect small providers and the patients and communities they serve. To do this, Congress must stop the current bidding program and replace it with MPP, which will allow small businesses to compete and ensure patients have access to the medically necessary HME items and services that they need.

Statement to the United States House of Representatives Committee on Small Business Subcommittee on Healthcare and Technology

Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?

September 11, 2012

Chairwoman Elmers, Ranking Member Richmond, and Members of the Subcommittee, the National Community Pharmacists Association (NCPA) is pleased to submit the following written comments for inclusion in the record of today's hearing on the Medicare Durable Medical Equipment Competitive Bidding Program (CBP). We commend you for holding this hearing given the impact that competitive bidding will likely have on beneficiary access to needed diabetic testing supplies (DTS) and other DME supplies as well as the ability of community pharmacies to serve the DME supply needs of Medicare Part B beneficiaries.

NCPA represents the interests of pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies across the United States. NCPA has a strong interest in this issue because independent community pharmacies hold one-half of all active DME supplier numbers and serve as a critical access point for DME supplies, especially DTS, for the large fragile population of Medicare Part B beneficiaries suffering from diabetes in the United States. According to a 2011 survey by NCPA, 67% of our members provide DME products to patients. It is important to note that independent community pharmacists provide DME not as a profit center, but in order to make certain that the beneficiaries they serve have access to the supplies they need at a single point of care. Only 6%-8% of an average independent pharmacy's annual sales are from DME.

NCPA's Primary Points

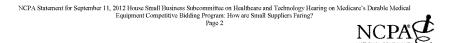
- Community pharmacists are indispensable. From face-to-face counseling to the DME they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs.
- 2. Independent community pharmacists must already comply with multiple criteria in order to participate in Medicare Part B including: obtaining expensive DME accreditation; possessing a surety bond; paying to obtain the actual product; complying with extremely burdensome documentation requirements; and working with a secondary payer in order to receive payment; all the while receiving much slower than-normal payments.
- Community pharmacists must bear all of these burdensome regulations even when only 6%-8% of an
 average independent pharmacy's annual sales are from DMEPOS. Therefore, independent
 community pharmacists generally sell diabetic testing supplies to provide a service to beneficiaries and
 not because of profit.
- 4. Forcing community pharmacists to participate in the CBP or to take the CBP reimbursement for DME, which will become a reality in 2016, would decrease beneficiary access and increase health care costs. At a time where Congress and CMS are trying to move towards a coordinated care approach, it is unacceptable to drastically reduce access to DME and drive up costs, which will lead to increased hospital stays and decreased quality of care.



- 5. According to an August 2012 survey that NCPA conducted of over 400 independent community pharmacists regarding consequences of a sharp reduction in payment for diabetes test strips, 92% of the pharmacies said they would likely drop out of the program if forced to either (1) take a reduction in payments for diabetes testing strips, or (2) take a competitively-bid chain or mail order price to continue to provide Medicare diabetes testing supplies.
- 6. The significant impact of independent pharmacies dropping out of the Medicare Part B program is certainly to be felt disproportionately in rural areas. Independent community pharmacies are far more likely than chain pharmacies to operate in traditionally underserved and rural areas where patient accessibility is a deep concern. Community pharmacies in these areas serve some of the frailest Medicare beneficiaries.
- 7. Prohibiting community pharmacies from delivering DTS to homebound Medicare patients is unconscionable. The way in which CMS has defined the term "mail order" will prevent community pharmacists from delivering DTS to homebound beneficiaries beginning on July 1, 2013. We urge Congress to address CMS' oversight and to ensure some of the frailest Medicare beneficiaries are not faced with the harsh reality that they have no way to receive the supplies they need to stay alive.
- 8. While CMS is considering drastically cutting DME reimbursement for non-mail order diabetes testing supplies via an inherent reasonableness authority, CMS is wasting millions of dollars on mail order diabetes testing supplies that are automatically shipped to patients that are never used. Waste is rampant in Medicare Part B mail order diabetes testing supplies. CMS turns a blind eye to this fact in its holy grail pursuit of lower mail order DTS prices. One should look no further than the One Year Implementation Update to Round 1 published this past April to see the large amount of waste being generated by mail order supplies.
- 9. CMS' recent efforts to use inherent reasonableness as a substitute for the CBP in an effort to drastically cut reimbursement for non-mail order DME is misused and would decrease access to care and beneficiary health. CMS has presented no evidence that the current fee schedule is grossly excessive as compared to the cost to independent pharmacies to purchase these supplies. Congress must take action to ensure that CMS cannot use this authority in a manner that would decrease access, decrease overall health care, and increase overall health care costs.
- 10. Congress should pass HR 1936, The Medicare Access to Diabetes Supplies Act. In light of the negative impact of a CBP for DTS on the ability of community pharmacies to continue to supply DTS, NCPA urges Congress to pass H.R. 1936 and permanently exclude small independent pharmacies from the CBP and CBP pricing.

Community Pharmacies Will be forced to Cease Supplying DTS When Faced with Drastic Reimbursement Cuts Decreasing Patient Access and Driving up Health Care Costs

While the Round 1 Rebid for mail order DTS in nine competitive bid areas (CBAs) has been in place for over a year, within the next year CMS will fully implement the national mail order competitive bidding program for diabetic testing supplies (DTS). For the time being, CMS has excluded, from competitive bidding, DTS supplied by retail pharmacies. We are grateful for this exclusion. However, by 2016, all DME suppliers, mail order and retail, will be subject to competitive bidding or competitive bidding pricing for DTS. In addition, unfortunately, in the context of the national mail order CBP, CMS is prohibiting retail pharmacies from providing home delivered DTS unless such a pharmacy wins a national mail order CBP contract.



From face-to-face counseling to the DME they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs. Community pharmacists are indispensable to helping combat diabetes, whether it is the counseling they offer, the medications they dispense, the lifestyle modification classes they provide, or the wide variety of testing supplies they carry. Also, it is oftentimes the case that independent pharmacists service very distinct and culturally diverse populations. Many of these beneficiaries do not speak English as their first language and are accustomed to seeking services from a community pharmacist they can effectively communicate with, which certainly can't be replicated by their mailbox or a 1-800 number.

Independent community pharmacists must already comply with multiple criteria in order to participate in Medicare Part B including: obtaining expensive DME accreditation; possessing a surety bond; paying to obtain the actual product; complying with extremely burdensome documentation requirements; and working with a secondary payer in order to receive payment; all the while receiving much slower than-normal payments. Community pharmacists must bear all of these burdensome regulations even when only 6%-8% of an average independent pharmacy's annual sales are from DMEPOS. Thus, community pharmacists generally sell diabetic testing supplies to provide a service to beneficiaries and not because of profit. Even CMS in the preamble to its 2010 Proposed Rule on competitive bidding noted the value of "a licensed pharmacist [being] on hand to offer guidance and consultation to the beneficiary."

The inability of small independent pharmacists to remain viable DTS suppliers is further demonstrated by comparing the average supply fee schedule reimbursement for retail DTS with the Round 1 CBP average reimbursement amounts for mail-order DTS. The average National retail single payment amount for diabetes testing supplies is \$37.67 whereas the average Round 1 Competitive Bidding Program single payment amount, across nine geographic regions, was \$14.62. Small business retail community pharmacies will not be able to continue providing DTS to Part B beneficiaries, when faced with over a 60% decrease in reimbursement.

Additionally, according to an August 2012 survey that NCPA conducted of over 400 independent community pharmacists regarding negative consequences for a sharp reduction in payment for diabetes test strips, 92% of the pharmacies said they would likely drop out of the program if forced to either (1) take a reduction in payments for diabetes testing strips, or (2) take a competitively-bid chain or mail order price to continue to provide Medicare diabetes testing supplies. In addition, 86% of respondents said that their average Medicare patient visits the pharmacy two or more times a month for counseling. The message from our survey is clear, drastically reducing payments for diabetes testing supplies to independent community pharmacies is financially unsustainable for these pharmacies and will diminish beneficiary access to DME.

This significant impact is certainly to be felt disproportionately in rural areas. Independent community pharmacies are far more likely than chain pharmacies to operate in traditionally underserved and rural areas where patient accessibility is a deep concern. A study conducted by the RUPRI Center for Health Policy Analysis and the North Carolina Rural Health Research & Policy Analysis Center found that 91% of all sole community pharmacies are located in rural communities, and that 22% are located more than 20 miles from the next closest retail pharmacy. In addition, rural community pharmacies generate \$26.9 billion in annual revenue and hire 71,000 full-time employees. Unfortunately, the number of retail pharmacies located in rural areas has declined. From March 1, 2003 to December 1, 2011, 852 independently owned rural pharmacies closed.²

NCPA Statement for September 11, 2012 House Small Business Subcommittee on Healthcare and Technology Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?

Page 3

Page 3

¹ Andrew D. Radford, Michelle Lampman. A Profile of Sole Community Pharmacists: Their Role in Maintaining Access to Medications & Pharmacy Services in Rural Communities. 2009 Medication Use in Rural America Conference. September 9, 2009.
² Kaitilin Boyle, Fred Ulrich, Keith Mueller, Independently Owned Pharmacy Closures in Rural America. RUPRI Center for Rural Health Policy Analysis: Rural Policy Brief, Brief No. 2012-4, July 2012, www.public-health.uiowa.edu/rupri.

Thus, as our Medicare population continues to grow, the amount of suppliers that can provide DTS to beneficiaries as well as the number of brands offered in the supply chain continues to decrease. Even with the decrease of suppliers that can provide DTS to beneficiaries and the number of brands offered in the supply chain, CMS is proposing drastic cuts in reimbursement for DME and prohibiting retail pharmacies from providing home delivered DTS unless such a pharmacy wins a national mail order CBP contract.

<u>Prohibiting Community Pharmacists from Delivering DTS to Homebound Medicare Patients will Decrease</u> <u>Access and Healthy Outcomes</u>

There is an urgent need for legislation to exempt small community pharmacies from the CBP for DTS and CBP pricing. In 2013, CMS will apply a national CBP to mail order DTS. In doing so, CMS has defined the term "mail order" to mean "any item . . . shipped or delivered to the beneficiary's home, regardless of the method of delivery." Conversely, CMS has defined the term "non-mail order" as "any item . . . that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront." Essentially, these two definitions prevent small independent pharmacies, which are not a part of the CBP, from providing home delivery, which is a valuable and necessary service for some beneficiaries who have difficulty getting to a pharmacy.

According to an August 2012 survey, 94% of independent community pharmacies regularly deliver diabetes testing supplies to patients (often free of charge) with almost 20% making 30 or more deliveries per month to different beneficiaries. Moreover, anecdotal evidence suggests that 40-50% of Medicare beneficiaries do not pick up their pharmaceutical drugs or supplies themselves, meaning they are either delivered to the beneficiary by the independent community pharmacy or picked up at the pharmacy by a caregiver.

As of July 1, 2013, these community pharmacists will no longer be able to deliver to homebound Medicare patients the DTS they desperately need. Three scenarios further demonstrate the problems with prohibiting community pharmacies from engaging in some home delivery of DTS.

First, many Medicare Part B beneficiaries that are in need of DTS are homebound and may not have a caregiver available to pick up DTS from the local independent pharmacy. Many beneficiaries, especially in rural areas, receive all their mail at a P.O. Box location that is miles from their home, and are unable to get to their P.O. Box more than once a week or every few weeks. In these instances, the beneficiary relies upon the independent pharmacy to deliver supplies to their home. This is done for the benefit and convenience of the beneficiary, and not to undermine the CBP.

The second scenario occurs when a small independent pharmacist temporarily delivers supplies to a patient. This scenario involves the "snowbird" patients, who live in the North during the summer and head south to places like Florida in the winter. Their pharmacist in the North, for the convenience and benefit of the patient, may be willing to mail winter supplies to the patient at their southern address. This is a temporary arrangement and is not done to undercut the CBP, yet the proposed definitions would prohibit small independent pharmacists from performing this helpful service. Notably, under either of the above scenarios the independent pharmacist obtains a receipt that the item was received by the beneficiary, the same documentation that the pharmacist receives from an in-store pick-up.

The third scenario involves community pharmacies that routinely deliver medications to assisted living facilities for residents. Again, under CMS' rule, these pharmacies will no longer be allowed to deliver supplies to these facilities, which is completely unacceptable and must be addressed. Almost 50% of all community pharmacists deliver DTS to assisted living facilities. Asking frail homebound patients, as well as those in assisted living facilities, to visit a store front to obtain their supplies while having their other medications delivered to their place of residence, makes no sense.

NCPA believes this was a severe oversight by CMS and urges Congress to act to address this issue. In light of the concerns raised by CMS's definition of the terms "mail order item" and "non-mail order item," NCPA urges Congress to act now to exempt independent community pharmacies from a DTS CBP. Such immediate legislative action is necessary to ensure that community pharmacies are able to continue to deliver DTS supplies to homebound beneficiaries, "snowbird" patients, and assisted living facilities. To do so would be consistent with the Medicare Part D program, which does not consider a small independent pharmacy providing home delivery of a Part D drug to be providing a mail order service.

CMS is Wasting Millions of Dollars on Mail Order Diabetes Testing Supplies

The result of small independent pharmacists potentially terminating their sales of DTS is that patients will be forced to use mail order, will lose access to care, and the patients and the health care system will incur nunceessary costs in the long-term. Through mail order, patients will also lose access to care because they will lose access to the valuable consultation, fitting and monitoring services provided by independent pharmacists.

Medicare Part B pays for billions of dollars each year in diabetes test strips – the majority of which are dispensed through mail order. Yet, community pharmacists continually hear stories from patients about how the mail order company continues to send strips to the beneficiary, even if they don't need them. Some patients indicate they have closets full of these strips! This means that either the mail order company is disregarding "stop orders" and has placed the person on automatic renewal even if they don't need the strips, or the person is not testing correctly, which could lead to further diabetes complications. This is a lose-lose situation for Medicare and the beneficiaries. Medicare pays for strips that aren't needed, while patients are not being managed well because they are getting their strips from a mail order firm rather than being managed by their community pharmacist.

Recently, CMS released a report touting positive health outcomes and significant savings from the Round 1 Rebid for mail order DTS. CMS claimed that the Round 1 Rebid yielded over \$51 million in savings with few beneficiary complaints and no negative health care outcomes. We believe that CMS's report does not paint a complete picture and is too quick to jump to conclusions.

For example, CMS claims that the Round 1 Rebid resulted in a decrease in overutilization of DTS. They reach this conclusion by looking at the decrease in mail order DTS utilization following implementation of the Round1 Rebid. However, CMS neglects to mention, per the Round 1 Rebid parameters, that beneficiaries in CBAs were not required to use mail order competitive bidding suppliers. Beneficiaries had the choice to move to retail suppliers outside of competitive bidding if they wanted. Accordingly, even though CMS found that mail order diabetic testing supply utilization decreased following implementation of the Round 1 Rebid, this could mean that patients in CBAs chose to go to retail over mail order in order to receive more face-to-face high touch

Even if CMS is correct that the Round 1 Rebid resulted in a reduction in DTS waste through a reduction in overutilization of DTS, such a reduction was only measured with regard to mail order suppliers. The fact that CMS found that beneficiaries had excess mail order supplies prior to the Round 1 Rebid reinforces our position that mail order waste, not retail waste, for DTS is the major waste problem in Medicare Part B. Accordingly, a similar reduction in DTS utilization may not be apparent, once the CBP expands to retail pharmacy. In contrast to mail order suppliers, small retail pharmacies do a better job of monitoring when and how often patients need refills and when and how often patients' testing regimens change. Mail order, on the other hand, through its autorefill policies, generates substantial stockpiling waste of DTS for patients and measures adherence through whether an auto-refill was delivered, not whether it was actually and appropriately used by the patient.

CMS' Actions to Cut DTS Reimbursement by its Inherent Reasonableness (IR) Authority as a Substitute for the CBP will Decrease Access to Care and Beneficiary Health

Recently, CMS has started exploring its inherent reasonableness authority to cut DTS reimbursement to community pharmacists as a substitute for competitive bidding. CMS announced in its notice, 77 Fed. Reg. 38,067, on June 26, 2012, that it would begin accepting oral and written comments as to whether the use of IR is justified. IR can be used as a substitute for the CBP where CMS wishes to make drastic cuts to DTS.

NCPA strongly disagrees with CMS' decision to use its IR authority to drastically cut reimbursement for DTS and urges Congress to act to make certain these drastic cuts do not take place. CMS' decision to cut reimbursement via the IR process on the assumptions that (1) retail pharmacies and mail order pharmacies purchase DTS at the same cost; and (2) the savings seen in placing mail order DTS in the CBP due to waste will also be present within the retail sector. In fact, CMS is using the information from the Round 1 Rebid for mail order supplies in determining that the fee schedule amounts in retail are grossly excessive.

CMS states in the notice of the IR meeting, "[a]lthough we recognize that there are pricing differences between mail order and non-mail order diabetic testing supplies because of the delivery methods for these supplies, information about the prices of mail order diabetic testing supplies can inform the analysis of prices for non-mail order diabetic testing supplies because several key cost components are identical for both, such as product acquisition costs and administrative costs, including claims processing and paperwork costs." CMS is acting under the assumption that there is no difference in purchasing in different pharmacy channels, and as such, CMS is viewing mail-order prices as reasonable for the retail sector. That is simply not the case. Product pricing in the retail and mail order channels is in fact different.

While CMS has presented no evidence that the current fee schedule prices are inconsistent with the purchasing costs for community pharmacists, independent community pharmacies cannot purchase diabetes test strips at the same prices as large self-warehousing chains or mail order pharmacies. Contrary to CMS' statements, there are different costs for acquiring the product. Since CMS uses the quantity of 50 test strips for the basis of pricing for the CBP, NCPA also looked at acquisition costs for community pharmacists for multiples brands of 50-count test strips. According to data that NCPA has collected, independent community pharmacists' average acquisition costs for multiple brands of 50-count test strips is multiple times more than the average supply fee schedule reimbursement for the Round 1 Rebid CBP (which was \$14.62). Moreover, only 6%-8% of an average independent pharmacy's annual sales come from DMEPOS. With the low margin on those supplies and drastic price reductions, many independent pharmacists will likely be forced out of the program and terminate sales of DTS.

Furthermore, the products which independent pharmacies and mail order stock are also very different. Community pharmacists are motivated to stock products which local physicians prescribe and local beneficiaries prefer. Thus, community pharmacists play a key role in the spectrum of providing tailored, personal care to the beneficiary. Due to the customized treatment that diabetes demands, DTS should not be treated as interchangeable.

On the other hand, mail order suppliers promote a limited range of products based on having the lowest cost, potentially questionable quality, and generally direct beneficiaries to these products. From its study AADE concludes, that "Julider the CBP, contract suppliers have powerful incentives to maximize profit margins by purchasing and offering a limited range of products, and only the lowest cost products available." Thus, the range of products offered between retail and mail order differs, the acquisition costs of these products differ, and the choice available to beneficiaries also differs.

NCPA Statement for September 11, 2012 House Small Business Subcommittee on Healthcare and Technology Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?

Page 6

NCPA

**Comparison of Medicare's Durable Medical Program: How are Small Suppliers Faring?

Page 6

³ Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey (November 2011).

Regardless of whether drastic cuts in reimbursement for DME are implemented by subjecting community pharmacy to CBP reimbursements or by inherent reasonableness, community pharmacists will nevertheless be forced to cease supplying DME. As a result, beneficiary access will suffer, adherence will decline, overall beneficiary health care will decrease, and health care costs will increase. Congress must act to make certain that CMS does not utilize its inherent reasonableness authority to drastically cut reimbursement for DME.

Congress Should Enact H.R. 1936, the Medicare Diabetes Access to Diabetes Supplies Act

In light of the negative impact of a CBP for DTS on the ability of community pharmacies to continue to supply DTS and in narrowing patient access to DTS, NCPA urges Congress to pass H.R. 1936 and permanently exclude small independent pharmacies from the CBP and CBP pricing. H.R. 1936 would exclude from a CBP and CBP pricing "blood glucose self-testing equipment and supplies furnished (regardless of method of delivery) by a retail community pharmacy (as defined in section 1927(k)(10)) that is not under common ownership with more than 10 other retail community pharmacies." Congress should pass H.R. 1936 because it will protect patients important face-to-face interaction with their independent pharmacists for effective diabetes monitoring and ensure that beneficiaries will have immediate access to the specific DTS that they need.

Along with excluding community pharmacies from any DTS CBP, the proposed legislation exempts community pharmacies from any pricing resulting from a DTS CBP. Such an exemption is necessary to protect meaningful beneficiary access to small independent pharmacies. Even if small independent pharmacies are excluded from a CBP, they may still terminate DTS sales and hinder beneficiary access to DTS if the prices established under such a program are applied to the community pharmacy market. This would make it cost prohibitive for our members to continue supplying DTS products. In the end, if Congress does not protect beneficiary access to small independent pharmacies, beneficiary compliance with testing regimens may be compromised, and the risk of diabetes-related complications may rise along with costs associated therewith.

Conclusion

If community pharmacies are not exempted from the CBP and CBP pricing for Part B DME supplies and DTS, in particular, then many will likely cease to provide such supplies, thereby narrowing beneficiary access to much-needed DTS. Independent community pharmacists are working hard to provide the best care and access to beneficiaries will eworking with CMS to improve quality of care and drive down long-term costs. The facts are, with drastic cuts to reimbursement for supplies, beneficiaries will no longer have access to the care they need and deserve.

This is not just an issue of convenience - this is about providing reasonable access to beneficiaries. If beneficiaries do not have reasonable access to their diabetic testing supplies, this decreases adherence, decreases the quality of care that beneficiaries receive, and drives up the overall costs of health care. We all have an interest and a part in making certain that beneficiaries have access to their diabetic testing supplies that they need.

NCPA has urged CMS to continue to exempt community pharmacies from the DTS CBP, to exempt community pharmacies from the CBP pricing, and to allow community pharmacies to continue to provide home delivery of DTS outside of the CBP. However, CMS has rejected our entreaties and, in large part, is bound by statutory dictates to implement a national CBP or national CBP pricing by 2016 for all DME. Given the statutory restraints faced by CMS, Congress must act to ensure that Medicare Part B beneficiaries continue to have access to high quality DTS and other DME supplies at their local community pharmacies.

Thank you for the opportunity to submit this statement for the record.

NCPA Statement for September 11, 2012 House Small Business Subcommittee on Healthcare and Technology Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?

Page 7

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Questions for the Record For Laurence D. Wilson, Director, Chronic Care Policy Group, Centers for Medicare and Medicaid Services Submitted by Chairman Sam Graves Hearing: "Medicare's Competitive Bidding Program: How Are Small Suppliers Faring? Subcommittee on Healthcare and Technology House Committee on Small Business September 11, 2012

Background

The Committee shares the Centers for Medicare and Medicaid Services' (CMS) commitment to a competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) which ensures high quality for beneficiaries, maximizes savings for taxpayers and beneficiaries, and ensures a level playing field for suppliers, many of whom are small businesses.

We are interested in CMS' decision to include transcutaneous electrical nerve stimulation (TENS) devices in the overly broad "General Home Equipment and Related Supplies and Accessories" product category. Including TENS devices in this category with unrelated products (such as hospital beds, group 1 and 2 support surfaces, commode chairs, patient lifts and lift seats) that treat unrelated conditions and which are not related to TENS devices, contradicts the product category definitions in CMS' competitive bidding final rule; forces suppliers, many of which are small, to bid on unrelated products (since a bidder must supply all products in a category); does not increase access or convenience for beneficiaries; eliminates the opportunity for TENS suppliers to bid against one another, which could increase taxpayer and beneficiary savings; and may undermine small suppliers who cannot furnish all products in the category, and may in fact discourage small suppliers who specialize in a single product from bidding.

According to CMS, DMEPOS product categories are "[a] grouping of related items that are used to treat a similar medical condition." In its final rule on competitive bidding, CMS stated, "We believe separate competitions for product categories will encourage participation by small suppliers that specialize in one or a few product categories" and "We do not plan to make product categories overly broad, and we do not intend to combine products from various policy groups into a single product category unless the product already falls in several policy groups."³

Questions

- 1. Why did CMS group together unrelated products that treat unrelated conditions into one overly broad category, called "General Home Equipment and Related Supplies and Accessories"?
- 2. In limiting most product categories to related products for related conditions, CMS seemed to encourage small businesses that specialize in a particular product to participate in the competitive bidding program. If so, why did CMS include TENS devices, which only treat acute and chronic pain conditions, in a broad category with other products having nothing to do with pain care, making it difficult for small manufacturers and suppliers to bid?

^{1 42} C.F.R. § 414.402.

² Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues; 72 Fed. Reg. 17,992, 18,031 and 18,057 (April 10, 2007) (codified at 42 C.F.R. pts. 411 and 413).

3 Id. at 18,031.

- 3. Has CMS met with representatives of the industries and small businesses included in the "General Home Equipment" category regarding their concerns about bidding in this overly broad category?
- 4. Going forward, has CMS considered establishing a separate product category for TENS devices, as CMS has done with negative wound pressure therapy pumps and related supplies and accessories?

Questions For the Record
For Laurence D. Wilson, Director, Chronic Care Policy Group,
Centers for Medicare and Medicaid Services
Submitted by Subcommittee Chairwoman Renee Ellmers
Hearing: "Medicare's Durable Medical Equipment Competitive Bidding Program:
How Are Small Suppliers Faring?"
Subcommittee on Healthcare and Technology
Committee on Small Business
September 11, 2012

Background

On November 10, 2011, CMS issued a final rule that revised the definition of durable medical equipment ("DME") to add a three-year minimum lifetime requirement ("MLR") which products must satisfy in order to be eligible for reimbursement under the Medicare DME benefit category. The final rule stated that the MLR would only be applied prospectively to new products classified as DME after January 1, 2012. The final rule also stated that, "To the extent that a modified product is not a new product (including an item that has been upgraded), the 3-year MLR will not be applicable." The final rule did not, however, provide any detail regarding the extent of changes that could be made to an existing DME product before such a "modified" or "upgraded" product would no longer be considered "new." Earlier this year, however, CMS indicated that it would be issuing additional guidance to provide further clarification on the grandfathering provision.

On May 4, 2012, nine House colleagues and I sent a letter to Secretary Sebelius expressing our views regarding the upcoming guidance. Specifically, we urged the Secretary to ensure that critical modified or upgraded medical devices from the DME category are subject to the final rule's grandfathering provision, including products that maintain and/or build upon the core clinical technology of existing DME products. On June 13th, we received a written response from Secretary Sebelius.

Questions

- 1. In her June 13th letter, Secretary Sebelius indicated that CMS would be issuing guidance in the "near future." When does CMS plan to issue such guidance?
- 2. In her June 13th letter, Secretary Sebelius stated that the grandfathering provision would apply to "technically refined" items, but not "significantly redesigned" products. I am concerned that Secretary Sebelius's response to our letter indicates that the guidance to be issued by CMS will take too narrow of an approach in defining the scope of the grandfathering provision. This will discourage innovation, as DME manufacturers will not be able to improve upon their technologies without the threat of losing reimbursement. This approach will also disproportionately affect smaller DME manufacturers, which produce medical products that are critical to the health of Medicare beneficiaries. What steps has CMS taken to ensure that this guidance will not have a negative impact on DME suppliers, particularly the smaller ones?

² 76 Fed. Reg. at 70290.

¹ 76 Fed. Reg. 70228 (Nov. 10, 2011).

Questions for the Record For Laurence D. Wilson, Director, Chronic Care Policy Group, Centers for Medicare and Medicaid Services

"Medicare's Competitive Bidding Program: How Are Small Suppliers Faring?" Subcommittee on Healthcare and Technology House Committee on Small Business September 11, 2012

Chairman Sam Graves

Background

The Committee shares the Centers for Medicare and Medicaid Services' (CMS) commitment to a competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) which ensures high quality for beneficiaries, maximizes savings for taxpayers and beneficiaries, and ensures a level playing field for suppliers, many of whom are small businesses.

We are interested in CMS' decision to include transcutaneous electrical nerve stimulation (TENS) devices in the overly broad "General Home Equipment and Related Supplies and Accessories" product category. Including TENS devices in this category with unrelated products (such as hospital beds, group 1 and 2 support surfaces, commode chairs, patient lifts and lift seats) that treat unrelated conditions and which are not related to TENS devices, contradicts the product category definitions in CMS' competitive bidding final rule; forces suppliers, many of which are small, to bid on unrelated products (since a bidder must supply all products in a category); does not increase access or convenience for beneficiaries; eliminates the opportunity for TENS suppliers to bid against one another, which could increase taxpayer and beneficiary savings; and may undermine small suppliers who cannot furnish all products in the category, and may in fact discourage small suppliers who specialize in a single product from bidding.

According to CMS, DMEPOS product categories are "[a] grouping of related items that are used to treat a similar medical condition." In its final rule on competitive bidding, CMS stated, "We believe separate competitions for product categories will encourage participation by small suppliers that specialize in one or a few product categories" and "We do not plan to make product categories overly broad, and we do not intend to combine products from various policy groups into a single product category unless the product already falls in several policy groups."

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Medicare Program, Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues; 72 Fed. Reg. 17,992, 18,031 and 18,057 (April 10, 2007) (codified at 42 C.F.R. pts. 411 and 413).

³ Id. at 18,031.

Questions

1. Why did CMS group together unrelated products that treat unrelated conditions into one overly broad category, called "General Home Equipment and Related Supplies and Accessories"?

Answer: CMS implemented this change as an improvement for the Round One Recompete. As we phase in statutorily-required competitions and contracts for furnishing items under the program, we believe that the phase in of larger, more consolidated product categories will be beneficial for suppliers and beneficiaries and promote competition In contrast, bidding narrow product categories of comparatively low-volume items would discourage competition and jeopardize beneficiary access and choice since few suppliers would be likely to bid.

The Round One Recompete product categories will promote one-stop shopping for beneficiaries, simplify the referral process and enhance the opportunities for winning suppliers, particularly small suppliers. Some contract suppliers in the Round One Rebid expressed concerns about winning in one product category and not another. Including several products in one product category addresses this concern for small suppliers whose business depends on furnishing a wide range of DME items in a specific metropolitan area. Also, numerous competitive bidding program small supplier protections, including a small supplier target, a capacity cap during bid evaluation, a network provision, and others, ensure that small suppliers have the opportunity to be considered for participation in the program. We note that we chose to phase in this change in the Round One Recompete, which includes nine competitive bidding areas (CBAs). This will allow us to monitor the change closely and evaluate the results before expanding this approach more widely across the country.

All of the items in the General Home Equipment product category, including TENS devices, are related because they are subject to the general quality standards, which deal with general durable medical equipment (DME) standards and services such as intake, delivery, setup and training on use of equipment. All of the items in this category are furnished by general DME suppliers, which typically deliver a wide range of items throughout the community using delivery trucks. Many of these suppliers are small suppliers. For example, in the area surrounding CMS headquarters in Baltimore, Maryland, there are 16 suppliers that offer TENS devices to Medicare beneficiaries and 13 of these suppliers also offer hospital beds and other items in the General Home Equipment product category. In addition, we do not believe it would be difficult for local DME suppliers that do not currently offer TENS devices to begin offering them. Local, community based medical equipment suppliers are experienced in delivering, setting up, servicing, repairing, and educating on the use of a wide range of DME items.

CMS is aware of a growing trend where specific brands of TENS products are being furnished through mail order to beneficiaries by a small number of large, remotely located manufacturers. Although small, community based DME suppliers are still furnishing TENS devices, the market has been steadily shifting to large manufacturers acting as both promoters and suppliers of their own products, thereby effectively limiting the beneficiary to a choice of only one brand of TENS device. CMS has carefully weighed this information with the needs of Medicare beneficiaries, the statutory requirement to phase in competitive bidding for DME, and the statutory

requirement to ensure that small suppliers have an opportunity to be considered for participation in the program. Including TENS devices in the General Home Equipment product category will help ensure that Medicare beneficiaries receive these items from local suppliers in their communities that can quickly address any concerns or needs beneficiaries may have related to their equipment and replacement supplies. It also greatly enhances opportunities for small, community based suppliers to furnish a greater volume and more diverse range of TENS products to Medicare beneficiaries. Our experience is that suppliers that specialize in furnishing a single type of DME item are typically very large businesses, not the small, community-based suppliers that are the foundation for the Medicare DME benefit.

2. In limiting most product categories to related products for related conditions, CMS seemed to encourage small businesses that specialize in a particular product to participate in the competitive bidding program. If so, why did CMS include TENS devices, which only treat acute and chronic pain conditions, in a broad category with other products having nothing to do with pain care, making it difficult for small manufacturers and suppliers to bid?

Answer: As indicated above, we believe that phasing in larger, more consolidated product categories is good for the program, its beneficiaries, referral agents, and suppliers. The product categories established for the Round One Recompete include groupings of items used to treat respiratory ailments, address mobility impairments, infuse drugs, provide enteral nutrition for tube-fed patients, treat wounds, and meet general home equipment needs. Small, community based suppliers can elect to compete for any or all of these product categories. Given the volume of TENS devices covered for use by beneficiaries in individual metropolitan areas, we do not believe that a product category made up of only TENS devices would generate viable competitions among small suppliers or sustainable business models in local competitive bidding areas. Grouping TENS devices into a product category with other general home equipment facilitates competitions between suppliers that can furnish a wide variety of DME.

3. Has CMS met with representatives of the industries and small businesses included in the "General Home Equipment" category regarding their concerns about bidding in this overly broad category?

Answer: Yes. CMS has had several meetings with the American Association for Homecare, the Advanced Medical Technology Association, and various manufacturers that also act as national suppliers of their specific brand of items. We have not met with or heard concerns from representatives of small, community based suppliers of TENS devices, hospital beds, or other items in the General Home Equipment product category.

4. Going forward, has CMS considered establishing a separate product category for TENS devices, as CMS has done with negative wound pressure therapy pumps and related supplies and accessories?

Answer: Given the comparatively low volume of TENS devices covered for use by beneficiaries in individual metropolitan areas, we do not believe that a product category made up of only TENS devices would generate viable competitions among small suppliers or sustainable business

models in local competitive bidding areas. In contrast, including TENS in a product category with other general home equipment will result in a robust competition among many suppliers and ensure that beneficiaries have access to all items in the product category, including TENS.

Chairwoman Renee Ellmers

Background

On November 10, 2011, CMS issued a final rule that revised the definition of durable medical equipment ("DME") to add a three-year minimum lifetime requirement ("MLR") which products must satisfy in order to be eligible for reimbursement under the Medicare DME benefit category. The final rule stated that the MLR would only be applied prospectively to new products classified as DME after January 1, 2012. The final rule also stated that, "To the extent that a modified product is not a new product (including an item that has been upgraded), the 3-year MLR will not be applicable." The final rule did not, however, provide any detail regarding the extent of changes that could be made to an existing DME product before such a "modified" or "upgraded" product would no longer be considered "new." Earlier this year, however, CMS indicated that it would be issuing additional guidance to provide further clarification on the grandfathering provision.

On May 4, 2012, nine House colleagues and I sent a letter to Secretary Sebelius expressing our views regarding the upcoming guidance. Specifically, we urged the Secretary to ensure that critical modified or upgraded medical devices from the DME category are subject to the final rule's grandfathering provision, including products that maintain and/or build upon the core clinical technology of existing DME products. On June 13th, we received a written response from Secretary Sebelius.

Questions

1. In her June 13th letter, Secretary Sebelius indicated that CMS would be issuing guidance in the "near future." When does CMS plan to issue such guidance?

Answer: We hope to issue this guidance soon, and note that we have already clarified in the June 13th letter that the three-year minimum lifetime requirement would not be applied to grandfathered items that are merely refined or upgraded versions of the same product.

2. In her June 13th letter, Secretary Sebelius stated that the grandfathering provision would apply to "technically refined" items, but not "significantly redesigned" products. I am concerned that Secretary Sebelius's response to our letter indicates that the guidance to be issued by CMS will take too narrow of an approach in defining the scope of the grandfathering provision. This will discourage innovation, as DME manufacturers will not be able to improve upon their technologies without the threat of losing reimbursement. This approach will also disproportionately affect smaller DME manufacturers, which produce medical products that are critical to the health of Medicare beneficiaries. What steps has CMS taken to

⁴ 76 Fed. Reg. 70228 (Nov. 10, 2011).

⁵ 76 Fed. Reg. at 70290.

ensure that this guidance will not have a negative impact on DME suppliers, particularly the smaller ones?

Answer: We do not believe the November 10, 2011, regulatory clarification or any sub-regulatory guidance based on that regulatory clarification will affect DME suppliers. The new regulations are designed to provide additional clarity to the definition of DME but do not represent a significant change in policy. Consistent with the law, longstanding Medicare policy specifies that equipment is durable if it can withstand repeated use and is the type of item which could normally be rented. To further clarify that the scope of the benefit does not extend beyond durable equipment, we added the minimum lifetime requirement to our regulations to prevent coverage of items that only last for short periods of time and are not items which could normally be rented. We note that the statute does not permit CMS to expand the definition of DME to include items that are not durable.

We do not believe that our past or present policies or regulations regarding the scope of the DME benefit under Medicare prevent manufacturers from improving technologies that fall within the scope of the benefit for DME. Indeed, the recent regulation should help manufacturers by providing a clearer articulation of the rules.



Statement

of the

Health Industry Distributors Association (HIDA)

to the

House Small Business Healthcare and Technology Subcommittee Medicare's Competitive Bidding Program for

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

September 20, 2012

On behalf of the interests of over 600 medical-surgical products distributor companies operating throughout the United States, the Health Industry Distributors Association (HIDA) commends the Small Business Healthcare and Technology Subcommittee for convening a hearing on Medicare's competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to explore the program's impact patients, providers and small business suppliers.

Founded in 1902, HIDA is the professional trade association representing medical-surgical products distributors. Our members deliver life-saving healthcare products to more than 290,000 points of care including over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the nation. HIDA's members are committed to promoting safety and cost savings within the healthcare supply chain.

The majority of distributors are small businesses. Over a quarter of the industry earns annual revenues under \$1 million dollars. The healthcare distribution sector employs 65,000 people nationwide. Distributors' average 1.3% annual profit margin is among the lowest in healthcare, requiring distributors to operate at extremely high levels of efficiency.

Small businesses are critical to the economic growth of the country. It is estimated that small businesses make up over 90 percent of the nation's durable medical equipment suppliers. Most of these suppliers deliver highly specialized products and services, which require a depth of industry knowledge. The competitive bidding program limits opportunities for these businesses by driving them out of the marketplace in a geographic area if they fail to win a contract during the bidding process, thus reducing patient access and threatening access and quality of care. The implementation of the competitive bidding program has had an impact on small business suppliers of medical-surgical products located in the Round One Rebid metropolitan statistical areas (MSAs). Approximately 450

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¹ Congress, House, Committee on Small Business, Subcommittee on Rural Development, Entrepreneurship and Trade, Hearing on the Impact of Competitive Bidding on Small Businesses in the Durable Medical Equipment Community, 111th Cong. 1st sess., February 9, 2009.

Health Industry Distributors Association Written statement submitted to the House Small Business Healthcare and Technology Subcommittee September 20, 2012 Page 2

suppliers located in these MSAs ended up closing their doors as a result of failing to win a contract or choosing not to bid during the Round One Rebid. This reality will be further compounded as the program rolls out to an additional 91 MSAs nationwide in July 2013.

HIDA is committed to efforts to ensure that Medicare beneficiaries, specifically those residing in skilled nursing facilities (SNFs), continue to have uninterrupted access to life-sustaining medical products. As such, we write to express our concerns about the competitive bidding program's impact on SNFs and the patients they care for. Specifically, HIDA recommends:

- Extending the grandfathering provision to include the enteral nutrients, equipment and supplies product category into the competitive bidding program;
- Excluding enteral nutrients, equipment and supplies from Round Two of the competitive bidding program until the program's impact on SNFs and their patients is fully evaluated and understood; and
- A third party validated study of the competitive bidding program's application to and impact on SNFs be conducted prior to the program's expansion nationwide; and

Transitioning to a competitive bidding program for DMEPOS items and services raises many serious questions related to cost, access and beneficiary protection. SNF patients are among the nation's most ill and frail. They require 24/7 direct clinical coordination and care by nurses, doctors and other trained healthcare professionals, including long-term care specific enteral nutrient suppliers. The level of care required to support the healthcare needs of these patients must not be inadvertently threatened or compromised.

Extend the grandfathering provision to enteral nutrients, equipment and supplies

We urge Congress to direct CMS to extend the grandfathering option to all products subject to future rounds of the competitive bidding program. CMS' grandfathering provision extends to most product categories subject to competitive acquisition and allows a non-winning supplier to continue providing products and services to beneficiaries in competitive bidding areas if that supplier agrees to accept the competitively bid reimbursement rates. Under the current statute, enteral nutrients, equipment and supplies are not included in the grandfathering provision. Grandfathering was promoted by CMS as a means to ensure that patients do not fall through the cracks, but that safeguard does not exist for enteral patients.

² Brown, Ken. "Competitive Bidding for Durable Medical Equipment: An Estimate of the Economic Impact on Iowa." (July 2012), available at: http://www.ygm.com/blog/index.php/2012/07/cb-toll-on-iowa-2590-jobs-lost-200-million-in-economic-activity-gone/

Health Industry Distributors Association Written statement submitted to the House Small Business Healthcare and Technology Subcommittee September 20, 2012 Page 3

Extending the grandfathering provision would provide a safety net and sense of continuity for some of Medicare's frailest beneficiaries in need of tube feeding.

Enteral nutrition therapy is not well-suited for competitive acquisition

HIDA recommends the exclusion of enteral nutrients, equipment and supplies from Round Two of the competitive bidding program until the program's impact on SNFs and their patients is fully evaluated and understood. Moving to a national competitive bidding program for DMEPOS items and services, specifically the inclusion of enteral nutrition therapy, raises many serious questions related to access, beneficiary protections, and market-based competition.

The level of care involved in delivering enteral nutrition therapy, commonly called tube feeding, must not be undermined by the competitive bidding process, nor should it compromise the life-sustaining nourishment to patients who cannot swallow because of severe or permanent medical problems. Patients are fed specialized nutritional formulas through a tube which is threaded through the nose, or a surgical opening, and leads directly to the stomach or intestine. Certain requirements must be satisfied in order to trigger Medicare Part B coverage of enteral nutrition in a SNF.

- 1. The beneficiary must have a permanent functional impairment of the gastrointestinal tract.
- 2. Enteral nutrition therapy must be deemed reasonable and necessary for the beneficiary.
- The beneficiary must require tube feeding to maintain weight and strength commensurate with his or her overall health status.

In these instances, Medicare Part B covers claims for enteral nutrition, along with the supplies and equipment necessary for administration (i.e., infusion pumps, intravenous poles, feeding supply kits and tubing).

Disregarding the qualifications and experience of a supplier of enteral nutrition therapy could lead to health complications and unintended consequences for beneficiaries. Many SNF suppliers have dicticians and clinical nursing consultants on staff. Typically, the enteral products are customized to SNF residents based upon each SNF's specific clinical protocol. As currently devised, the competitive bidding program allows suppliers with no previous experience or familiarity with institutional settings or the enteral nutrition product category to service SNFs. SNF patients are at risk of developing subsequent illnesses - requiring a more expensive form of care - if their nutritional status and food security diminish.

Given the complexities involved with the SNF provider setting and the enteral product category, CMS stated in its 2004 Report to Congress on the 1999-2002 Florida and Texas competitive bidding pilot demonstration projects that enteral nutrition therapy "was not well-suited for a competitive acquisition program." The agency recommended that the product category be excluded from future rounds of competitive bidding. Given this recommendation and

Health Industry Distributors Association Written statement submitted to the House Small Business Healthcare and Technology Subcommittee September 20, 2012 Page 4

the fact that the SNF setting was not the intended target of competitive bidding, we question why the agency chose to include enteral nutrition therapy in both the first and second rounds of the program.

Impact on SNFs must be assessed

A third party validated study of the competitive bidding program's specific impact on SNFs must be conducted before the program further expands. The Government Accountability Office (GAO) recently released a report to Congress reviewing the first year of Medicare's DMEPOS competitive bidding program; however, it fails to provide a complete analysis of the program's specific impact on SNFs and their patients' access to quality enteral nutrition therapy. As CMS moves toward expanding the competitive bidding program from nine to 100 MSAs, it is essential to assess how the program has impacted this vulnerable patient setting.

It is apparent that the competitive bidding program was designed with the home care setting foremost in mind, yet SNFs care for the bulk of Medicare beneficiaries receiving enteral feeding for life-sustaining nutritional support. Mr. Laurence Wilson, CMS' Director of Chronic Care Policy, acknowledged this reality in response to a question posed by Representative Bill Pascrell (D-NJ) on the program's impact on SNFs during the May 9, 2012, Ways & Means Health Subcommittee hearing on competitive bidding. Mr. Wilson stated that the only product category reimbursable under Medicare Part B impacting SNFs is enteral nutrition therapy (tube feeding).

Residents in SNFs often are more impaired than home care patients and they require a more complex regimen of care for enteral nutrition therapy than home care patients. Enteral patients in SNFs have dietary needs that change more frequently than most home care patients, thus requiring an enteral nutrition supplier that can readily address their special needs.

The competitive bidding program has interfered with a SNFs' ability to make decisions regarding the enteral nutrition needs of their residents. During the Round One rebid of the competitive bidding program a SNF had to submit and win a bid to continue providing enteral nutrition to its residents, or contract with a supplier from a list of bid winners in their respective MSA. Very few nursing homes won a bid to provide enteral nutrition to their own residents. The competitive bidding process has forced many SNFs to terminate long-standing relationships with their local long-term care specific enteral nutrient suppliers. These incidents raise a number of issues unique to the nursing home setting that must be evaluated prior to expanding the program nationwide.

Thank you for reviewing our concerns and considering our comments. We appreciate the opportunity to suggest important modifications to the competitive bidding program that should be implemented to ensure that patients and providers continue to have uninterrupted access to life-sustaining medical products.

Competitive Bidding for Durable Medical Equipment An Estimate of the Economic Impact on Iowa

Ken Brown, Ph.D. University of Northern Iowa Department of Economics

July 18, 2012

1 Introduction

Competitive bidding for durable medical equipment (DME) is currently being rolled out to 91 cities beyond the initial nine cities the program applied to beginning in 2011.

According to Medicare, competitive bidding in the first nine cities resulted in a reduction in reimbursements of 42% (Centers for Medicare & Medicaid Services, 2012) for the nine competitively bid DME categories in the program.

While none of the initial 100 competitively bid cities are in Iowa, starting in 2016 bid rates will be applied nationally, and Iowa will see a significant drop in DME revenues. This report estimates the economic impact of that reduction in revenues on Iowa. In addition, there are at least two other major employers in Iowa, VGM Group, Inc. in Waterloo and Medline Industries, Inc. in Dubuque, that will be affected by

¹ There are, however, a few Iowa suppliers in the Omaha, NE MSA to which competitive bidding will apply starting in 2013.

² It should be noted that, while competitive bidding is not scheduled to apply nationally until 2016, there is evidence that private payers are already applying bid rates identified in other locations to suppliers in Iowa. Further, some DME suppliers with Iowa locations are contracting their business footprint, and that contraction will likely result in a reduction in Iowa DME suppliers. Thus, while this report estimates an overall impact that is likely to occur beginning in 2016, the negative economic impact of competitive bidding on Iowa is already occurring.

competitive bidding for DME. These impacts are discussed in the "Other Impacts" section below.

2 Analysis

Total revenues in the DME market in Iowa in 2011 were approximately \$315.4 million.³ Overall, the nine competitively bid DME categories make up on the order of 75% of total DME revenues, implying that competitive bidding will apply to approximately \$236.6 million of DME revenues in Iowa. As mentioned above, during the first round of competitive bidding the average reduction in reimbursements for the bid categories was 42%. Altogether, this implies that, once competitive bidding applies to Iowa, Iowa will see a reduction in total DME revenues of about \$99.4 million.⁴

While DME revenues are estimated to fall in Iowa by \$99.4 million, a portion of that reduction will, in fact, be returned to Iowa consumers of DME. Since Medicare patients pay a 20% deductible, those patients paying the deductible will see their out-of-pocket expenses fall. According to a report by the Kaiser Family Foundation, 48% of Iowa Medicare beneficiaries have a Medigap policy that would cover the 20% deductible (Jacobson, Neuman, Rice, Desmond, & Huang, 2011). Therefore, of the \$99.4 million reduction in revenues, 52% of the 20% deductible will be returned to Iowa residents, reducing the overall loss in revenues to Iowa by \$10.3 million, bringing the total loss in revenues to \$89.1 million.

In economic impact analysis, this reduction in revenues is typically referred to as the "direct impact." This is not the end of the economic impact, however. In particular, to

³ According to statehealthfacts.org, per capita spending in Iowa on durable medical equipment in 2009 was \$103, and according to U.S. Census Bureau estimates, the 2011 Iowa population was 3,062,309 (U.S. Census Bureau, 2012). Together, these imply spending of \$315,417,827.

⁴ Of course, inflation and increased utilization of DME due to an aging population are likely to increase this number by 2016.

estimate the total economic impact one must also calculate the "indirect impact," which is also known as the "multiplier effect." For example, suppose a company exports a product for \$1,000. When the company receives the \$1,000 in revenue it will pay a portion of that out to employees in the form of wages. The employees will then turn around and spend a portion of that income on goods and services at other local companies, increasing the spending in the area beyond the initial \$1,000. This process continues as a portion of the revenues of each company continue to be spent in the local economy. Estimating the multiplier effect entails calculating how much additional spending beyond the direct impact takes place in the local economy.

The standard way to calculate the multiplier effect is to use input-output analysis. This can be done in a number of ways, but the most straightforward way is to use economic impact software designed for this purpose. This analysis uses one of the most popular software packages for this purpose, IMPLAN (MIG Inc., 2009).

Using IMPLAN to compute the indirect impact results in the following estimate of the overall economic impact on Iowa resulting from the reduction in DME reimbursements due to competitive bidding:

	Direct Impact	Indirect Impact	Total Impact
Output (\$M)	89.1	66.8	155.9
Employment	1,633	652	2,285

Overall, IMPLAN estimates competitive bidding for DME will reduce total output in the state by \$155.9 million and will reduce employment in the state by 2,285 jobs.

3 Other Impacts

In addition to the impacts calculated above, which pertain to the suppliers of DME

in Iowa, at least two other Iowa companies, VGM Group, Inc. (with its headquarters in Waterloo, Iowa) and Medline Industries, Inc. (with a substantial branch in Dubuque, Iowa), will be negatively impacted by competitive bidding for DME. Both VGM and Medline provide services to DME suppliers. As competitive bidding is rolled out across the country, many of these suppliers will go out of business, reducing these companies' client base. As that base diminishes, both companies will be forced to scale back operations, with additional losses to output and jobs in the state. Losses from these two companies could result in more than \$60 million in additional output lost and more than 400 additional jobs lost.

4 Conclusion

In summary, competitive bidding for DME will result in a significant negative economic impact on Iowa. Cuts in reimbursements to DME suppliers and reductions in the client base of VGM Group, Inc. and Medline Industries, Inc. will likely result in:

- more than \$200 million in reduced output in the state
- more than 2,500 jobs lost in the state
- a disproportionate impact on Waterloo, Iowa and Dubuque, Iowa due to the presence of VGM and Medline in those communities

While these negative impacts are straightforward to measure, other impacts are difficult to measure quantitatively. As I explained in a previous analysis, competitive bidding will result in the closure of DME suppliers in Iowa. These closures will reduce the proximity of patients to suppliers, reducing access to healthcare in much of Iowa. For example, in locations that once had a provider and now do not, the length of time to discharge from a hospital may increase. It might increase the wait time for wheelchair repairs. Or, it could reduce the frequency of delivery of portable oxygen

tanks or impact the ability of providers to respond promptly in cases of widespread power outages. While it is difficult to place a dollar amount on these impacts, these are nonetheless additional negative consequences associated with competitive bidding for DME.

All of these consequences have thus far been ignored as Medicare touts the expected savings from competitive bidding. These savings, however, are mostly an illusion. Imagine going to an auto dealer and looking at a car and the salesperson tells you the price is \$20,000. You tell the salesperson that you don't want to spend that much – in other words, that you'd like to save some money. So, the car dealer then shows you another car with manual rather than automatic transmission, with no air conditioning, etc. The salesperson tells you the price of this car is \$12,000. When you purchase the second car, while you will spend less money, all you are really doing is buying a lower-quality product at a commensurately lower price.

With DME, buying lower quality means two things. First, the patient will receive a lower-quality product that will cost slightly less. More importantly, second, the patient will see a significantly reduced level of service. As mentioned above, this could mean longer wait times for product repairs or reduced frequency in the delivery of portable oxygen tanks to name just two possible results. As a result, it is likely that the small reductions in spending by Medicare here will only result in reduced quality and access to healthcare in Iowa.

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Insight . Advocacy . Action

STATEMENT OF THE NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE (NASL)

FOR THE SUBCOMMITTEE ON HEALTH & TECHNOLOGY UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON SMALL BUSINESS

HEARING

ON

MEDICARE'S DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM: HOW ARE SMALL SUPPLIERS FARING?

SEPTEMBER 11, 2012

The National Association for the Support of Long Term Care (NASL) thanks Chairwoman Ellmers, Ranking Member Richmond and the Members of the House Committee on Small Business Subcommittee on Healthcare and Technology for holding this hearing regarding the Medicare durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

NASL is proud to represent providers and suppliers of products, medical supplies, diagnostic testing, professional services, therapy, and information systems for the long-term and post-acute care (LTPAC) industry. Our members include suppliers and manufacturers of durable medical equipment, prosthetics, orthotics and enteral nutrition, providers of physical, occupational, respiratory and speech-language pathology therapies, and health information systems developers.

We appreciate the Committee's concerns about the impact that competitive bidding has on small businesses, which we believe to be substantial. The competitive bidding program is complicated and demanding. Small suppliers are in greater need of assistance in dealing with the documentation and bidding requirements than are national suppliers. That assistance often has not been available. For example, a small supplier in the Cincinnati-Middleton area reports having posed a number of questions to the Competitive Bidding Ombudsman on detailed issues involved with the bidding process. The supplier received replies that were simply recitations of what is posted on the website, and which did not adequately address the issues raised by the supplier. Other suppliers have likely encountered similar experiences when trying to obtain information or raise issues related to the competitive bidding program. Thus, NASL believes that the Centers for Medicare & Medicaid Services (CMS) needs to be more responsive to individual supplier's concerns.

NASL remains concerned that the Medicare competitive bidding program needlessly forces quality suppliers out of the Medicare program. It is poorly structured and, we believe, ultimately is destined to fail, thus creating serious access and quality issues for Medicare beneficiaries in need of DMEPOS products and services. Briefly, our principal concerns are the following:

- Under the current competitive bidding system, 50% of the "winning" bidders must
 accept payment levels that are below their bids, which is directly contrary to the basic
 rules of competitive bidding programs conducted elsewhere in the federal government.
 Thus, the competitive bidding program does not accurately reflect the market for a
 particular product category in a particular geographic area. Despite the description of the
 program as market-based, it really is nothing more than an arbitrary fee schedule that is
 applied to a reduced number of participating DMEPOS suppliers.
- The combination of allowing non-binding bids and inviting inexperienced suppliers to bid for the contracts has resulted in further distortions of the market. The negative impact on the market was accentuated when some of the lowest bidders walked away from the program but their bids still influenced the competitive bidding payment amounts.
- CMS has not made public the level of information necessary to gauge how successful the
 competitive bidding program really is in terms of patient access to quality care. For
 example, CMS has not responded to the request of the Program Advisory and Oversight

Committee (PAOC) for information in 2011 that would enable the PAOC to assess the impact of the competitive bidding program on beneficiaries and suppliers. Preliminary analyses performed by outside economists have at least raised the question that the reduction in utilization of DMEPOS products and services in the competitive bidding areas may be adversely affecting Medicare beneficiaries' access to medically necessary care. Round Two of the program, which is a ten-fold increase in the scope of the competitive bidding program, should not be undertaken until CMS demonstrates that patient access to care has not been compromised.

In addition to these basic concerns that are shared by virtually all DMEPOS suppliers, NASL wishes to raise particular issues that result from the application of the competitive bidding program to products provided in nursing facilities. One of the product categories included in Round One and Round Two of the competitive bidding program, enteral nutrition, is primarily provided to residents of nursing facilities. This presents issues that go far beyond the scope of the competitive bidding program, as explained below.

Enteral nutrition involves the provision of nutrients by tube into a patient's stomach or intestine. It is prescribed by physicians for patients whose lower gastrointestinal tract functions normally but who are unable to swallow, who have a gastric obstruction or who cannot otherwise ingest adequate amounts of food and fluids by mouth. Medicare Part B covers enteral nutrition formulas, supplies and equipment under the prosthetic device benefit when enteral nutrition is necessary for the patient to maintain weight and strength commensurate with his or her general condition.

It is noteworthy that enteral nutrition was not tested successfully during the two demonstration projects that preceded the enactment of the *Medicare Modernization Act of 2003*, which created the competitive bidding program for DMEPOS items and services. In fact, enteral nutrition was removed from the Polk County, Florida demonstration, in large part, we believe, because most enteral patients in that county resided in nursing facilities. This created complications that CMS did not want to address at that time.

Nursing facilities have a special relationship with their residents. Especially for long stay residents, the nursing facility is the resident's home. The nursing facilities are responsible for providing complex nursing and rehabilitative therapy services involving an array of clinicians, providers and suppliers to meet patient health care needs, and the facilities are held accountable for the quality of the care and services. Nursing facilities must meet detailed conditions of participation to participate in the Medicare and Medicaid programs as well as a wide array of additional federal and state requirements regarding patient safety and quality of care. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, and the suppliers' understanding of the fragile and medically complex patient that rely on nursing facilities for care.

For these reasons, many nursing facilities were extremely concerned that the competitive bidding program would force them to admit unfamiliar suppliers into their facilities to provide services, supplies and equipment to their residents. NASL agrees with nursing facilities on this point –

that the facilities must be able to select the suppliers that the facilities believe can best enable them to meet resident needs and comply with applicable standards. Unfortunately, the competitive bidding program has interfered with their ability to make these decisions regarding the enteral nutrition needs of their residents, and has disrupted ongoing relationships that had worked to the benefit of their residents. The fact that grandfathering (i.e., permitting non-winning bidders to continue to provide care to their current patients if they accept the competitively bid rates) was not extended to enteral nutrition ensured that every nursing facility that did not win a bid, or every nursing facility whose enteral nutrition supplier did not win the bid, had to find a new enteral nutrition supplier.

In addition, the provision of enteral nutrition therapy in nursing facilities differs from the provision of enteral nutrition therapy in patients' homes. Residents in nursing facilities often are more impaired than home care patients and require a different regimen of care. Enteral patients in nursing facilities have dietary needs that change more frequently than most home care patients, and thus require the services of enteral nutrition suppliers that can readily address their special needs. An enteral supplier that has had no experience working with the complex medical needs of nursing facility residents may not be an adequate replacement for a supplier that has had years of such experience.

Suppliers with no experience or understanding of the complex nature of the nursing facility and the patient that relies on the facility for 24-hour care may seek to lower costs by providing lower quality products. As an example of this, if beneficiaries can no longer be provided with certain types of enteral pumps this may lead to increased trips to the emergency room for gastric feeding tube replacement, and they will also incur the associated expense of emergency-level transportation services. Let alone the inconvenience, trauma and a predisposition to pressure ulcers due to time spent on a gurney associated with an ambulance trip to a hospital emergency department could present challenges for many beneficiaries.

We do not believe there has been adequate scrutiny of the application of the competitive bidding program to nursing facility residents. We urge Congress to require CMS to provide the data to the Government Accountability Office for its required analysis of the competitive bidding program, and the public, to address the following issues:

- Changes in treatment patterns of enteral nutrition patients in nursing facilities in competitive bidding areas, and whether the use of new enteral nutrition suppliers has increased nursing facilities costs for the care of their enteral nutrition patients;
- Observations from nursing facilities' clinicians as to any diminution in quality of enteral nutrition therapy provided to their residents;
- Incidence of re-hospitalization of nursing facility residents in need of enteral nutrition in competitive bidding areas in 2011, compared to the re-hospitalization rates in those areas in 2010; and
- Whether the new enteral nutrition suppliers providing enteral nutrition to nursing facility residents had previous experience in treating nursing facility residents.

In addition, we request that Congress require CMS to grandfather all patients and products involved in the competitive bidding program in any future expansion or extension of the program.

Additional Recommendations

We join with numerous other commenters in advocating for the adoption of the concept of the Market Pricing Program developed by the DMEPOS industry. We believe that better definitions of the professional services and related costs for the provision of DMEPOS, along with a fairer and more reasonable bidding regimen that will accurately capture market prices, will be a dramatic improvement over the current competitive bidding program.

If Congress decides to continue with the current competitive bidding program, then we urge Congress to correct the deficiencies in the program we have identified in this statement. In addition, we urge Congress to modify the planned product categories for the Round One Recompete, scheduled to go into effect in 2014 for the original nine competitive bidding areas. CMS intends to group certain unrelated product categories into larger categories. For example, CMS intends to create a new "General Home Equipment and Related Supplies and Accessories" category that will encompass hospital beds and related accessories, group 1 and 2 support services, transcutaneous electrical nerve stimulation devices, commode chairs, patient lifts and seat lifts. Many suppliers provide some but not all of these items. As a result, this will lead to several disturbing problems:

- This approach unfairly favors large, "one-stop shop" operations, which ultimately will be anti-competitive.
- Specialty or niche suppliers that have significant experience and enviable track records for
 quality for one or several of the items will be at a distinct disadvantage in the bidding for
 all of the items in this category.
- To survive in this bidding process, small or niche suppliers will have to increase the
 degree of subcontracting to cover the wide array of products in the category.
 Subcontracting increases the possibility of patient and provider confusion, disruptions in
 care and similar issues.
- For those suppliers that choose not to subcontract to provide the full array of items in
 this category, they must attempt to become proficient and efficient in product areas with
 which they do not have experience. We believe the Medicare program should be
 providing incentives to suppliers to provide services and products in areas where they
 excel, instead of encouraging suppliers to experiment in other product areas.

The DMEPOS competitive bidding program must be designed to produce savings for the Medicare program, and not diminish the quality of products, supplies and services for patients. Therefore, we thank the subcommittee for bringing attention to the issue by holding this hearing and urge Congress to complete a full analysis of the competitive bidding program before it expands the program to 91 Metropolitan Statistical Areas. NASL, an organization that represents suppliers and manufacturers of durable medical equipment, prosthetics, orthotics and enteral nutrition, stands ready to be a resource, as you carry out the important work related to the competitive bidding program and assessing the impact of the program on small businesses.



DMEPOS Competitive Bidding is set to be implemented January 1, 2011 in nine of the United States' largest metropolitan areas (Round One). The program is to be expanded by 91 cities the following year (Round Two).¹ Competitive bidding is set to cost more than 80,000 American jobs in bid areas over the next three years, with totals likely to exceed 100,000 in all areas.

93 percent of local providers will not be awarded competitive bidding contracts2.

As a result of the original bidding process, only 7 percent of local providers were awarded contracts. Through regulatory analysis of CMS-1561-IFC, CMS expressed the likelihood that re-bid results are likely to very closely resemble those stemming from the original bidding process.

42 percent of non-contract providers are likely to go out of business.

The average DME provider counts on Medicare for 42 percent of their revenue³. If 42 percent of all revenue is taken from a sector of an industry, it's likely the resulting consolidation will result in a reduction of an approximately equal percent of existing companies.

39 percent of all suppliers located in competitive bidding areas are likely to go out of business.

The 42 percent reduction in revenue for the 93 percent of providers who will not be awarded contracts will result in a 39 percent reduction in providers and associated jobs.

12,000 employees are set to lose their jobs through the first round of bidding.

The average DME employs 10 FTE⁴. The reduction of nearly 1,200 supplier locations will result in nearly 12,000 lost jobs in 2011 within the nine Round One competitive bidding areas.

¹ CMS-1270-F expands the program by 70 cities, while Senate Health Care Reform provisions propose an additional 21

² 2008 Competitive Bidding Results

³ HME News 2009 Financial Survey

⁴ Based on an average of \$120,000 in revenue per FTE and 2008 National Health Expenditure data

More than 80,000 employees will lose their jobs through the implementation of the first two rounds of competitive bidding.

Competitive bidding implementation in the nine Round One areas, 70 Round Two areas and 21 areas likely to be added through health care reform legislation will collectively result in more than 80,000 lost jobs within the 100 bid areas.

The closing of branch location of CBA-based providers outside of bid areas will likely bring job loss totals to more than 100,000 by 2014.

The competitive bidding program will start a domino effect, with the number of lost jobs attributed to its implementation likely to far exceed 100,000. Providers centrally located within a bid area and satellite branches outside of bid areas will close, resulting in lost jobs even outside bid areas.

Medicaid and private insurers will reduce payment rates due to the program, further expanding the effect on providers.

Generally Medicaid and private insurers follow Medicare's lead when setting reimbursement rates for DME. Bid rates will undoubtedly result in significant reduction in payment from all payers, only reinforcing the fact that more than 100,000 jobs will be lost as a result of direct and indirect effects of the program.

Even contract suppliers will lose on average 33 percent of their Medicare business, and 14 percent of their overall patient base.

For the 7 percent of local suppliers receiving contracts, the average DME will only receive four of six bid product category contracts, based on original Round One results.

Finances will not allow for significant shifts in jobs from non-Medicare suppliers to Medicare-contracted suppliers.

Analysts and economists have concurred. The anticipated reductions in Medicare reimbursement will be such that suppliers awarded contracts will not have the financial wherewithal to take on additional staff. There will be no measurable shift in employment from "losing bidders" who are forced out of business to "winning bidders" who must take on the entire Medicare market.

All of this could be prevented by passing H.R. 1041,

budget neutral and bi-partisan legislation to repeal the DME competitive bidding program. SUPPORT FOR H.R. 1041 WILL SAVE MORE THAN 100,000 AMERICAN JOBS and ensure continuing beneficiary access to quality care.



Competitive Bidding Will Cost More Than 80,000 Jobs

\ W /	Provider					Mail-									Out-of-			
Salara Salara Salara	Locations	Population		Standard	Complex	Order	Enteral	CPAP/	Hospital		Support		Contract	In-State	State	Lost		
MSA	*	>65*	Oxygen	PMD	Rehab	Diabetic	Nutrition	RAD	Beds	Walkers		Contracts	Suppliers		Suppliers	Locations	Lost Jobs	
Round One																		
Charlotte, NC	161	184,074	26	20	7	10	22	10	1.2	18	-	125	30	26	- 4	57	567	
Cincinnatti, OH	186	296,367	12	15	6	15	18	11	12	13	-	102	24	21	3	69	692	
Cleveland, OH	192	373,855	18	13	7	15	23	14	12	13	-	115	27	24	4	71	706	
Dallas, TX	520	550,311	37	27	7	12	30	19	19	28	-	179	43	37	6	203	2,028	
Kansas City, MO	224	267,862	14	10	8	8	17	12	1.2	20	-	101	24	21	3	85	853	
Miami, FL	955	1,022,022	85	1.9	9	17	39	33	32	30	14	278	66	58	9	377	3,769	
Orlando, FL	171	284,126	33	1.2	7	13	24	17	12	20	-	138	33	29	4	60	598	
Pittsburgh, PA	406	505,549	17	18	7	13	20	14	11	17		117	28	24	4	160	1,603	
Riverside, CA	264	428,429	15	46	8	9	13	12	10	19		132	31	27	4	99	994	11,8
ound Two																		
Akron, OH	66	114,054	6	5	5	3	6	5	5	5		41	10	8	1	24	242	
libuquerque, NM	59	108,604	6	5	5	. 3	6	5	5	5		40	9	8	1	21	213	
Allentown-Bethlehem-Easton, PA	67	140,590	8	5	5	4	7	5	5	6		47	11	10	1	24	241	
Asheville, NC	59	83,207	5	5	5	3	5	5	5	S		38	9	8	1	21	215	
Atlanta-Sandy Springs-Marietta, GA	411	461,346	25	19	8	13	24	17	16	21		143	34	30	4	160	1,601	
lugusta-Richmond County, GA	62	70,476	5	5	5	3	5	5	S	S.		38	9	. 8	1	23	227	
ustin-Round Rock, TX	82	128,257	7	5	5	4	7	\$	5	. 6		4.4	10	9	1	31	306	
akersfield, CA.	53	79,278	5	s	5	3	5	5	5	5.		38	. 9	. 8	. 1	19	190	
aton Rouge, LA	1.14	87,700	5	. 5	5	3	5	5	- 5	5		38	9	8	. 1	45	446	
eaumont-Port Arthur, TX	48	62,959	5	. 5	5	3	5	5	- 5	5		38	9	. 8	. 1	17	169	
irmingham-Hoover, AL	151	173,257	9	7	5	5	9	б	6	8		\$6	13	12	. 2	59	586	
indgeport-Stamford-Norwalk, CT	42	122,535	. 7	. 5	5	4	6	5	5	6		42	10	9:	1	14	140	
ape Coral-Fort Myers, FL	56	145,102	. 8	6	5	4	8	5	5	7		48	31	10	1	19	194	
harleston-North Charleston, SC	64	74,619	- 5	5	5	3	5	5	5	5		38	9	8	1	24	236	
hattanooga, TN-GA	74	82,084	5.	5	5	3	5	5	s	S		38	9	8	1	28	278	
hicago-Naperville-Joliet, IL-IN	759	1,229,600	67	50	21	36	65	46	43	57		382	91	79	12	285	2,855	
olorado Springs, CO	42	62,527	5	5	5	3	5	5	5	5		38	9	8	1	14	143	
olumbia, SC	104	87,823	5	5	5	3	5	s	5	5		38	9	8	1	40	404	
olumbus, OH	156	208,832	11	9	5	6	11	8	7	10		66	16	1.4	2	60	597	
Payton, OH	73	139,863	8	5	5	4	7	5	5	- 6		46	11	10	1	27	266	
Peltona-Daytona Béach-Ormond Beach, FL	51	120,502	7	5	5	3	6	5	5	6		42	10	9	1	18	178	
Penyer-Aurora, CO	158	257,466	14	11	5	7	14	10	9	12		81	19	17	2	59	593	
Detroit-Warren-Livonia, MI	660	657,057	36	27	11	19	34	24	22			204	49	42	6	259	2,594	
I Paso, TX	77	85,177	5	5	5	3	5	5	5	5		38	9	8	1	29	290	
lint, MI	55	65,782	5	5	5	3	5	5	5	s		38	9	8	1	20	198	
resno, CA	71	98,259	5	5	5	3	5	5	5			39	9	8	1	26	265	
Grand Rapids-Wyoming, MI	79	98,908	5	- 5	5	3	5	5	5	. 5		39	9	8	1	30	298	
Freensboro-High Point, NC	63	105,666	6	5	5	3	6	5	5			39	9	8	1	23	230	
Sreenville, SC	67	90,441	. 5	· 5	. 5	3	5	5	5			38	9	8	.1	25	248	
Hartford-West Hartford-East Hartford, CT	125	192,633	10	. 8	5	6	10	7	6			62	15	13	- 4	47	471	
louston-Baytown-Sugar Land, TX	412	489,090	27	20		14	26	18	16			152	36	32	- Ø1 5	160	1,598	
					9	24	20						30	34				

ROT	3

Indianapolis, IN	212	212,075	12	9	5	- 6	11	8	7.	10	67.	16 .	14	2	83	832	
Jackson, M5	97	68,755	5	5	5	3	5	5	5	5/	38	9	8	1,	37	374	
Jacksonville, FL	92	152,591	9 .	7	5	5	9	6 .	. 5	7.	53	13	11	2	34	340	
Knoxville, TN	91	108,090	6	5	5	3	6	5	5	5	40	9 -	8	1	35	348	
Lakeland-Winter Haven, FL	43	114,846	6	5 1	5	3	6	5	5	5	41	10	8	1/	14	145	
Las Vegas-Paradise, NV	149	272,523	15	11	5	- 8	14	10	9	13	85	20	18	3	55	552	
Little Rock-North Little Rock, AR	96	88,833	.5	S	5	3	5	5	5	5	38	9	8	1	37	370	
Los Angeles-Long Beach-Santa Ana, CA	1,970	1,469,249	80	60	25	43	77	54	50	68	457	109	95	14	788	7,876	
Louisville, KY-IN	126	183,060	10	7	5	5	10	7	6	8 -	59	14	12	2	48	478	
McAllen-Edinburg-Pharr, TX	162	78,059	5	5 .	5	3	5	5	5 -	. 5	38	9	8	1	65	647	
Memphis, TN	189	158,664	9	6	5	5	8	- 6	5	7	5.2	12	11	2	75	749	
Milwaukee-Waukesha-West Aliis, Wi	139	231,314	13	9	S	7	12	9	8	11	73	17	15	2	52	520	
Minneapolis-St. Paul-Bloomington, MN	381	358,033	19	15	б	10	19	13	1.2	1.6	111	27	23	3	150	1,503	
Nashville-Davidson-Murfreesboro, TN	181	181,932	10	7	5	5	10	7	6	8	58	14	1.2	2	71	709	
New Haven-Milford, CT	83	140,984	8	6	5	4	7	5	· s	6	47	11	10	1	31	308	
New Orleans-Metainie-Bogalusa	208	139,486	8	6	5	4	7	5	5	6	46	11	10	1	83	833	
New York-Northern New Jersey-Long Island, NY-NJ-	3,111	2,801,847	152	115	48	81	1.47	104	94	129	871	207	181	27	1,231	12,308	
Ocala, FL	28	83,565	5	5	5	3	5	5	5	S	38	9	8	1	8	85	
Oklahoma City, OK	168	157,101	9	6	5	5	. 8	6	5	7	51	12	11	2	66	661	
Omaha-Council Bluffs, NE-IA	115	106,156	6	s	5	3	6	5	5	5	39	9	8 -	1	45	449	
Palm Bay-Melbourne-Titusville, FL	42	119,506	6	5	5	3	6	5	5	6	42	10	9	1	14	140	
Raleigh-Cary, NC	106	92,856	5	5	5	3	5	5	5	5	38	9	8	. 1	41	412	
Richmond, VA	125	184,803	1.0	8	5	5	10	7	6	9	59	14	12	2	47	473	
Sacramento-Arden-Arcade-Roseville, CA	99	260,851	14	11	5	8	14	10	9	12	82	19	17	3	34	345	
Salt Lake City, UT	92	101,118	5	5	5	3	5	5	5	S	39	9	8	. 1	35	353	
San Antonio, TX	158	240,431	13	10	5	7	13	9	8	11	76	18	16	2	60	598	
San Diego-Carlsbad-San Marcos, CA	167	383,781	21	16	7	21	20	14	13	18	119	28	25	4	60	598	
San Francisco - Oakland - Fremont, CA	209	586,436	32	24	10	17	31	22	20	27	182	43	38	-6	72	719	
San Jose-Sunnyvale-Santa Clara, CA	90	209,223	11	9.	5	6	11	8	7 .	10 .	66	16	14	2	32	320	
Scranton - Wilkes - Barre, PA	167	124,995	7	5	5	4	7	5	5	6	43	10	9	1	66	664	
Syracuse, NY	62	103,732	6	5	5	. 3	, s	5	5	s .	. 39	9	. 8	1	23	226	
Tampa - St. Petersburg - Clearwater, FL	256	561,504	31	23						-				_	92	923	
					10	16	29	21	19	26	175	42	36	5			
Toledo, OH	77	103,312	6	S	5	3	. 5	ş	5	S	39	9	8	1	29	289	
Tulsa, OK	152	130,406	7	S	5	4	7	5	5	6	44	10	9	1	60	600	
Virginia Beach-Norfolk- Newport News, VA	139	208,832	11	9	5	6	11	- 8	7	10	66	16	14	2	53	526	
Visalia-Porterville, CA	36	44,817	5	5	5	3	5	5	5	S	38	9	8	1	12	118	
Wichita, KS	83	86,948	5	. 5	5	3	5	s	5	5 .	38	9	8	1	32	316	
Youngstown-Warren-Boardman, OH	98	121,687	7 introduciones	5 Medalyziechys	5 99/24/69/6/69	d description	6	S Marie Come	5 0/5/1/2016/37/0	6	42 (expressions)	10 Sinominateria	9 Obdobenic	1 20012801240	37	375	54,788
Senate Additions to Round Two																	
Albany-Schenectady-Troy, NY	73	137,793	. 7	6	5	4	7	5	5	6,	46	11	9	1	27	267	
Baltimore-Towson, MD	369	380,677	21	16	7	21	20	14	13	18	118	28	25	4	145	1,447	
Boise City-Nampa, ID	49	63,447	5	5	5	. 3	5	5	5	5	. 38	9	8	1	17	173	
Boston-Cambridge-Quincy, MA-NH	307	664,430	36	27	11	19	35	25	22	31	207	49	43	6	111	1,110	
Buffalo-Niagara Falls, NY	140	218,557	12	9	5	- 6	11	8 .	7	10	69	16	14	2	53	528	
Honolulu, HI	70	143,014	8 .	. 6	5 .	4	8 .:	5	5.	7 .	47	11	10	1	25	253	
Oxnard-Thousand Oaks-Ventura, CA	58	96,983	5	5 /	5:	3	5	s	5	5	38	9 .	8	1	21	210	
Philadelphia-Camden-Wilmington, PA-NJ-DE	568	918,746	50	38	16	27	48	34	31	42	286	68	59	9	214	2,137	
Phoenix-Mesa-Scottsdale, AZ	202	548,084	30	22	9	16	29	20	18	25	170	41	35	5	70	700	

40 404	25 253	52 523	37 366	29 287	67 670	14 141	114 1,142		18 184		444	10%	184 156 1,302 224 79,074	184 156 1,302 224 79,074 Contracts		
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260,023	86,374	271,225	161,445	208,367	348,180	111,316	435,560	248,348	161,786		557,540	557,540	557,540 117,475 26,813,207	557,54 117,47 26,813,20	557,54 117,47 26,813,20	557,54 117,47 26,813,20 Inc.
113	88	142	86	82	182	42	300	8	48		346	346	346 52 20,671	346 52 20,671	346 62 20,671 eeks Group,	346 62 20,671 eeks Group,
Portland-Vancouver-Beaverton, OR-WA	Poughkeepsie-Newburgh-Middletown, NY	Providence-New Bedford-Fall River, Ri-MA	Rochester, NY	Sarasota-Bradenton-Venice, Ft.	Seattle-Tacoma-Bellevue, WA	Springfield, MA	St. Louis, MO-IE	Stockton, CA	Tucson, A2		Washington-Aribgson-Alexandria, DC-VA-MD	Washington-Adington-Alexandria, DC-VA-MD Worcester, MA	Washington-Arington-Alexandria, DC-VA-NID Worcester, MA	Washington-Adhigton-Alexandra, DC-Va-MD Wareeyter, MA	Washington-Adhington-Aleksandria, DCVA-MD 346 Worteyer, MA 20071 *Provider and beneficiary rank provided by The Weeks Group, Inc	Washington Arlington Alexandria, DC-VA-AID Worzester, MA *Provider and beneficiary socials provided by The N



DURABLE MEDICAL EQUIPMENT (DME) COMPETITIVE BIDDING

Will Cost More Than 100,000 Jobs

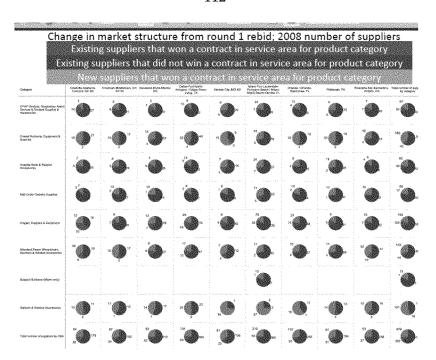
DMEPOS Competitive Bidding is set to be implemented January 1, 2011 in nine of the United States' largest metropolitan areas (Round One). The program is to be expanded by 91 cities the following year (Round Two).¹ Competitive bidding is set to cost more than 80,000 American jobs in bid areas over the next three years, with totals likely to exceed 100,000 in all areas.

Assumption #1: Overall, 93 percent of local DME suppliers will not be awarded competitive bidding contracts.

<u>Sources:</u> (a) Official CMS Round One Rebid Contract Supplier Listing (https://www.cms.gov/DMEPOSCompetitiveBid/01A2 Contract Supplier Lists.asp) compared to the total number of eligible suppliers (as of 1/1/2011) for Medicare Part B DMEPOS within each competitive bid metro area per the official Medicare Supplier Directory (www.medicare.gov/supplier/home.asp). (b) Peter Cramton, Professor of Economics, University of Maryland, Provider volumes in 2007-08 from the Medicare 5% Limited Data Set Standard Analytic File.

Change in Market Structure (nationwide market share) in all product categories in 9 Competitive Bidding Areas from Round 1 Rebid
2009 nationwide market share is shown. Establing suppliers that won contracts in the Round 1 Rebid are in green; existing suppliers that iost are in red. Shows that
significant number of existing suppliers by volume will be excluded from supplying Medicare beneficiaries.
Source: Complied by Peter Campion, 9 Nov 2010. Provider volumes in 2009 and 2008 from <u>HARGABBERN, Comp</u>; winning suppliers from CM3 at https://com.pi/sont/i.com/hargabern/.

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Drygen Kupples & Equipment			les (C)		nes Series		.0"	0	"O"	50% 20%
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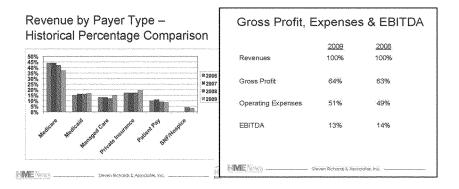


Assumption #2: The average DME location employs 10 FTE

<u>Sources:</u> (a) National Health Expenditure Projections 2009-2019 (https://www.cms.gov/NationalHealthExpendData/downloads/proj2009.pdf) for total Durable Medical Equipment expenditures in all sectors projecting \$28.1 billion in CY 2011, (b) CMS "Categories of DMEPOS Suppliers" indicating approximately 23,000 NPI numbers (locations) applicable to the provision of the DME product categories included with the bidding program and representing approximately 13,000 unique companies, and (c) overall average Revenue Per DME Employee 2010 Survey (Steven Richards and Associates, Inc.) at \$125,000. (10 FTE * \$125,000 * 23,000 = \$28.7B)

<u>Assumption #3:</u> About 40% percent of all suppliers located in competitive bidding areas are likely to go out of business.

<u>Sources:</u> (a) Steven Richards and Associates, Inc. 2010 Survey indicates Medicare, as a payer type, to overall DMEPOS supplier revenue is approximately 39% with all payer EBITDA margin of 13%. (b) HMEdatabase.com; the nine product categories included in the bidding program make up approximately 73% of all Medicare reimbursements. (c) TCF Bank credit analysts suggest a significant percentage (40-50%) of DMEPOS suppliers who incur 29% (.39 Medicare* .73 Medicare products affected by program) revenue reductions will be unable to withstand the three year contracting period with current 13% margins.



Medicare DME Market

• Top-20 products by 2009 reimbursement

	T	Share of	Reimbursement	Beneficiaries	Beneficiaries
Product	Rank	Reimbursement	(SM)	total (k)	allowed (k)
Blood glucose/reagent strips (A4253)	1	27%	701	2,849	2,768
Oxygen concentrator (E1390)	2	14%	377	441	407
PWC gp 2 std cap chair (K0823)	3	13%	342	130	119
Budesonide non-comp unit (17626)	4	7%	188	121	117
Neg press wound therapy pump (E2402)	5	4%	114	60	56
Enteral feed supp pump per d (84035)	6	4%	98	67	64
Lancets per box (A4259)	7	3%	89	2,463	2,385
EF spec metabolic noninherit (84154)	8	3%	66	32	31
Hosp bed semi-electr w/ matt (E0260)	9	2%	58	172	163
Cont airway pressure device (E0601)	10	2%	55	213	203
EF complet w/intact nutrient (B4150)	11	2%	49	43	40
Powered pres-redu air mattrs (E0277)	12	2%	44	26	24
High strength Itwt whichr (K0004)	13	1%	38	105	95
Stationary liquid 02 (E0439)	14	1%	35	43	36
Diab shoe for density insert (A5500)	15	1%	34	346	330
Portable gaseous 02 (E0431)	16	1%	32	245	217
EF calorie dense>/=1.5Kcal (84152)	17	1%	30	29	28
Pwr seat combo w/shear (E1007)	18	1%	26	5	4
Walker folding wheeled w/o s (E0143)	19	1%	24	326	293
Standard wheelchair (K0001)	20	1%	21	152	137

Source: www.HMEdatabase.com

Assumption #4: More than 80,000 employees will lose their jobs through the implementation of the first two rounds of competitive bidding. (Competitive bidding implementation in the nine Round One areas, 70 Round Two areas and 21 areas to be added through health care reform legislation.)

<u>Sources:</u> (a) Medicare Supplier Directory (<u>www.medicare.gov/supplier/home.asp</u>) search of all DMEPOS suppliers within metropolitan statistical areas (MSA) subject to the bidding program in Rounds 1 and 2, utilizing a 40% three-year failure rate, times 10 full time employees per supplier location.

Statement of Charles R. Plott, Professor of Economics and Political Science, California Institute of Technology

Before the U.S. House of Representatives Committee on Small Business September 11, 2012

My name is Charles Plott and I am the Edward S. Harkness Professor of Economics and Political Science at the California Institute of Technology. My research specialties are in the theory and behavior of auction systems including the design and testing of new forms of auctions. I am a member of the National Academy of Science, the American Academy of Arts and Sciences, a Distinguished Member of the American Economic Association, a Fellow of the Econometric Society, and I have served as president of the Economic Science Association, the Society for the Advancement of Economic Theory, the Public Choice Society, the Western Economics Association, and the Southern Economics Association. I have consulted with many governments and businesses and I have published over 160 scientific papers.

My testimony is in response to the questions as posed to me by the Committee.

1. I was asked to summarize my paper "The CMS Auction: Experimental Studies of a Median-Bid Procurement Auction with Nonbinding Bids", written with Brian Merlob and June Zhang and published in *The Quarterly Journal of Economics, vol. 127, no. 2, 2012, pp. 793-828.* I was also asked to comment further on the fundamental issues I see with the Competitive Bidding program as it pertains to the DMEPOS established by CMS.

I became aware of the properties of the CMS auction through a letter that called attention to the rules. The letter was addressed to auction experts and was sent by Professor Peter Cramton of the University of Maryland. I independently initiated a study of the auction rules. I found that some of the CMS auction rules reflect standard procedures but two rules protruded as features that would necessarily lead to an unsuccessful auction. The possible incongruence between the CMS auction rules and the intuition drawn from a substantial body of well tested auction theory led to the research reported in the paper. The

experimental economics methods I applied were a natural tool to illustrate the potential tension between the purpose of the rules and their consequences if put into place.

My focus is on the major architectural features of the auction, several of which are standard in the world of auction procedures. The auction proceeds as a sealed bid auction using a "one price" structure in the sense that if identical items are purchased, then suppliers are paid the same price independent of the terms of the tendered bid. Bids are arranged from low to high. The fixed procurement goal is applied to determine the winners to be those with the lowest bids. These features are well known and function well within standard frameworks. Several other features are natural and dictated by the scale and scope of the auction.

The issues of concern stem from two central features of the CMS auction that are not part of traditional auctions: (1) The price is set at the median of the winning bids, and (2) winning bids may be withdrawn after the price is announced should the winners find the price unacceptable. These two features make the CMS auction substantially different from traditional procurement auctions.

My study is structured around comparisons between the performance of auctions based on the CMS auction rules and auctions based on other auctions rules. The comparisons are based on four natural policy goals: (i) The auction should be successful in procuring the units demanded; (ii) The auction should be efficient from a social point of view in the sense that units are purchased from the lowest cost producers; (iii) The auction should not be wasteful from the government's point of view; and (iv) The auction should produce a competitive price that is capable of creating a healthy supply industry.

Different auction tests were created and studied through the use of experimental economics methods frequently used to compare the basic principles of auction behavior and performance. Auction architectures performing poorly in simple cases studied experimentally provide a realistic warning about problems that can surface in complex cases. Furthermore, if the behavior observed in the simple case is understandable in terms of theory, or even partial theory, then there is reason to take that theory seriously when applied to more complex cases. Theories that are less successful in the laboratory can be analyzed to determine why they lack reliability.

The major test results can be summarized as follows:

- Reliable procurement auction architectures exist. Our study focused on the
 "excluded bid" pricing process, which met all of the four natural policy
 goals. Procurement policies were met. The auction was efficient. Prices
 approximated competitive so a healthy industry could be maintained and
 the cost was as low as possible given that goal.
- The CMS auction architecture failed the tests on all dimensions. The theory that motivated the concerns of the CMS auction critics is supported by the tests and that theory explains the poor performance. To be a winner in the auction, a supplier needs to bid lower than other suppliers. But unlike other auctions the bids are not constrained from below by the cost of supply because the bid can be withdrawn if the supplier does not like the resulting price determined by the auction. A winning low bid provides the bidder with an option to sell at the market price if the bidder likes the price and refuse otherwise. Excessively low bids are part of strategic bidding. A pattern of excessively low bids emerged from the test auctions and that resulted in an announced price below the cost of many bidders. Since the winning bids were consistently below cost, prices, based on the median of already excessively low prices, were certainly below cost. The procurement failed dramatically in the tests.

The CMS rules violate two basic principles. One is often termed "no cheap talk" meaning that the incentives assure that participants must deliver on offers that are accepted. The principle is observed operating around us in daily commerce. A bid on a home is often accompanied with a payment to prevent frivolous offers. Offers tendered in stock and bond exchanges are enforced rigorously. Except in special circumstances offers cannot be conveniently cancelled after acceptance. Common sense suggests that cheap talk, if allowed, can undermine a competitive negotiation process. The second principle is related to a concept of "revelation". Successful auctions rely on forces of competition to guide competitors toward revealing the best terms they can offer. This "revelation" property can take many forms but it must be designed into the process. The CMS architecture is an example of the absence of the principle and, as a consequence, the offers in the test auctions had little resemblance to costs.

• For the CMS auction there is no simple "fix" in the sense that some slight change in the rules might correct the problems. The removal of one of the rules does not produce a well-functioning auction process. One can imagine an auction in which the price is determined by the median of the lowest bidders but bidders cannot withdraw bids. Testing such an auction reveals a perversity of such rules as bidders place very high bids in an attempt to avoid winning and being forced to sell at a low auction price. That is, a price determined by the median of the low bidders can still be unacceptable and the way to avoid being forced to sell below cost is to place a bid far above cost knowing that you can only win if others bid high and so the price will be high. With such rules the cost of the procurement goes up dramatically but efficiency does not because the least cost bidders need not be winners.

An alternative modification of the CMS auction might be to replace the median price rule with the excluded bid price determination, while keeping the withdrawal rule. That change does not improve the auction performance. Competition drives prices to levels lower than bidders are willing to accept and the auction does not succeed.

• The problems with the CMS auction become exacerbated with scale. Additional suppliers, relative to procurement goals, simply add to the excessively low prices, bid withdrawals and procurement failure.

The best form of auction in tests conducted in this study was the excluded price auction. It was implemented as a sealed bid auction but the auction exists in many forms. Those include descending price auctions, clock auctions, and other forms of continuous auctions. Simultaneous auctions and combinatorial auctions have both been successful.

2. The auction tests were conducted using standard methodology of experimental economics. The methods are widely used for testing new forms of auctions and also testing other competitive processes. Examples include the FCC auctions of the electromagnetic spectrum, pollution permit markets, auctions of public properties, regulation, and other competitive systems. Rules that seem desirable when viewed in isolation, in abstraction or from the view of a single bidder can have completely different properties when placed in the context of a system. Competitive processes are systems and the rules must be considered in terms of unforeseen consequences that result from the interactions of

competitors operating within the rules. Experimental economics evolved to meet the challenge of the required tests. Many economics laboratories exist in the United States as well as most other countries.

Experimental methods are used to focus on very simple cases created and studied under laboratory environmental conditions. As is the case with any economics or engineering example, field trials can be so complex that at the end of the trial it is impossible to determine exactly what happened and why. Simple experiments are used to test for the most basic proof of principle prior to going to a field trial. Experiments are used to expose and test the basic principles at work. Once principles are understood, they become tools to assess what will take place in more complex environments. The questions posed in the tests we performed are whether or not the auction works as anticipated or desired and whether or not it is working for understandable reasons.

The tests we conducted were in the form of auctions in which subjects were given financial incentives to win. The structures of the incentives were such that the experimenter could compute both the theoretically efficient allocation and the theoretical competitive price. At the conclusion of the test, we could study the outcome of the auction to determine the degree to which the auction approximated these measures. The subjects were recruited from subject pools at Caltech and the University of Maryland. These subject pools have been successfully used in many important auction systems tests, including the FCC auctions, among others.

The auctions were first tested at Caltech's Laboratory for Experimental Economics and Political Science. The data for all auction forms were tested and analyzed. The study then moved to the Experimental Economics Laboratory at the University of Maryland. Instructions and the conduct of the experiment were handled from Caltech with Maryland personnel observing and watching for any technical problems. The tests at the University of Maryland replicated the findings in the Caltech laboratory. In addition, a set of new parameters were also employed at the Maryland facility to test the robustness of previous results. All results replicated and scaled as predicted by theory. Embedded in the procedures were special conditions that could be compared to results from auctions produced by many laboratories over many years. All results compared favorably to those produced elsewhere in the research community.

- 3. My knowledge of what transpired in the CMS field trials is limited to conversations, newspaper reports, and a report of the data produced by Professor Peter Cramton. However, I can say what one would expect to find based on the performance of the auctions we studied.
- (i) Auction bids would be low relative to expectations. That would include patterns of bids below costs.
- (ii) Winning bidders would be hesitant to deliver at the at the announced auction price. The response of the auctioneer would be to attempt to force delivery by whatever means available, including threats of exclusion from future auctions. This activity follows the realization that the bids reflected "cheap talk".
- (iii) To the extent that bidders could not be forced to supply at stated prices the procurement would fall short of needs.
- (iv) Without a profitable market, firms would begin leaving the market in search of alternative products to produce and support their enterprise.

LAST CHANCE FOR PATIENT CHOICE
AND
AMERICAN ASSOCIATION OF HOMECARE
AGREED-UPON PROCEDURES ENGAGEMENT



Independent Accountant's Report on Applying Agreed-Upon Procedures -

Last Chance for Patient Choice and American Association of Homecare Waterloo, lowa

We have performed the procedures described in Schedule A, which were agreed to by Last Chance for Patient Choice and American Association of Homecare, solely to assist you with respect to certain home health care products which may be part of a competitive bidding system maintained by Medicare. This agreed-upon procedures engagement was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants The sufficiency of the procedures is solely the responsibility of the specified parties of the report. Consequently, we make no representation regarding the sufficiency of the procedures described below either for the purpose for which this report has been requested or for any other purpose.

Our procedures and findings are described in Schedules A, B, C and D.

We were not engaged to, and did not, conduct an audit, the objective of which would be the expression of an opinion on the information. Accordingly, we do not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported to

This report is intended solely for the information and use of Last Chance for Patient Choice and American Association of Homecare and is not intended to be and should not be used by anyone other than these specified parties.

HOGAN-HANSEN

HOGAN - HANSEN

Waterloo, Iowa August 8, 2012

Part I

Make 100 calls to Medicare Help Line 1-800-633-4227 at varying times of the day with at least two calls per day and calls made in the morning, afternoon and evening. Weekend calls are to be attempted, but if the service is not available on the weekend, that should be documented and then the 100 calls should all be made during the business hours.

For each call, inquire about available providers of oxygen, hospital beds or wheelchairs in the following areas of the country:

City or State	Zip Code
Tucson	85725, 85734
Cincinnati	45042, 45051
Cleveland	44023, 44039
Minnesota	54723, 54021
Tennessee	37172, 38569
Louisiana	70471, 70115
Nebraska	51502, 68463
St. Louis	62248, 62074, 62040, 62202
Rhode Island	02357, 02872
San Antonio	78002, 78886
San Diego	91901, 92197
Seattle	98007, 98490
New York	07717, 07977
Chicago	60151, 60568
Hartford	06002, 06043
Springfield	01071, 01116
Baltimore	20723, 21035
Albany	12084, 12175
Poughkeepsie	10941, 12504
Rochester	14454, 14502
Allentown	18015, 18210
Scranton	18419, 18510
Little Rock	72034, 72099
Cape Coral	33924, 33971
Atlanta	30028, 30092
Baton Rouge	70722, 70739
Jackson	39042, 39082
Greensboro	27265, 27350
Tulsa	74028, 74070
Greenville	29611, 29681
Nashville	37055, 37122
Flint	48507, 48532
Grand Rapids	49058, 49316
Wichita	67020, 67026
San Jose	95123, 95118
Stockton	95211, 95205
El Paso	79911, 79928
Omaha	51536, 68018
Dayton	45322, 45373

122

Agreed-Upon Procedures

City or State	Zip Code
Huntington	41144, 45619
Colorado Springs	80863, 80917
Denver	80013, 80031
Honolulu	96791, 96822
Boise City	83636, 83646
Albuquerque	87035, 87072
Las Vegas	89012, 89128
Portland	97018, 97034
Salt Lake City	84036, 84061
Seattle	98029 98042

During each call, inquire about a competitive bidding system and whether that impacts the area we are calling about and if it will affect the availability of services in future years.

Document the number of rings before the phone is answered.

Document the time, in seconds, that it takes to reach a human being to speak to.

See Schedule C for the results of the procedures applied.

Part II

Make one call to each of the providers listed in Schedule D at varying times of the day with at least two calls per day and calls made in the morning, afternoon and evening. Weekend calls are to be attempted, but if the service is not available on the weekend, that should be documented and then the 100 calls should all be made during the business hours.

For each call, inquire about whether the business is a provider of oxygen, hospital beds or wheelchairs.

Document the number of rings before the phone is answered.

Document the time, in seconds, that it takes to reach a human being to speak with.

See Schedule D for the results of the procedures applied.

123

Schedule B Summary of Results of the Agreed-Upon Procedures

	Calls Ma	ide To
	Medicare	Providers
Average number of phone rings before being answered	0	1.64
Average number of phone commands to reach a live person	2.00	0.27
Average number of seconds between phone answer and talking to a live person	300.67	19.85
Percentage of calls answered by a live person in less than 1 minute	0%	90.00%
Percentage of calls answered by a live person in less than 2 minutes	28.00%	100%
Percentage of calls where a competitve bidding area was answered "Yes"	4.00%	N/A
Percentage of cails where a competitvely bid product was answered "Yes"	2.00%	N/A

Results of Calls to Providers

	Provider	Yime Called (AM, PM, Evening)	Rings Prior To Answer	Number of phone commands to reach a live person	Seconds between phone answer and talking to a live person	Product inquired about	Did they have the product we called about
1	BJC Home Medical	AM	2	0	3	Oxygen	Yes
2	HealthCare Equipment & Supply	AM	3	2	60	Hospital bed	Yes
3	Med Resources	AM	1	0 .	2	Wheel chair	Yes
4	Pharmas Medical Equipment	AM	1	1	46	Oxygen	Yes
5	IV & Respiratory Care	MA	0	0	2	Hospital bed	Yes
6	Mobility First	PM	1	0	2	Wheel chair	Yes
7	Advanced Medical DME	PM9	2	ð	9	Hospital hed	No -said they specialize in c-pap and bi-pap equip.
8	Support Sevices, Inc.	PM	1	0	7	Oxygen	No
9	A & B Medical Supply	PM	c	0	17	Hospital bed	Yes
10	Therapeutic Specialties	PM	1	0	17	Wheel chair	Yes
1.1	Care Pro Home Medical	PM	1	1	21	Oxygen	Yes
12	Kelly's Medical Supply	AM	1	0	\$	Wheel chair	Yes
13	NuCare Home Medical	AM	2	9	17	Hospital bed	Yes
14	Hammer Medical Supply	AM	2	1	90	Oxygen	Yes
15	Iowa Healthcare	AM	0	1	85	Hospital bed	Yes
16	Palmer Home Medical Supply	AM	2	0	10	Wheel chair	Yes
17	Heritage Medical Equip & Supply	PM	0	1	35	Oxygen	Yes
18	A-1 Home Healthcare	PM	1	G	5	Hospital bed	Yes
19	Madison CO. Med Equipment	PM	1	0	s	Wheel chair	Yes
20	U of IA Comm Homecare	PM	3	o	11	Oxygen	Yes
21	Handi Medical Supply Inc.	PM	0	1	63	Wheel chair	Yes
22	Allina H & C Home Oxy & Med Sup	AM	4	0	21	Hospital bed	Yes
23	Rice Home Medical	AM	4	1	63	Wheel chair	Yes
24	Med City Mobility	AM	i	o o	3	Oxygen	No
25	LTC Wheelchairs	AM	1	o o	9	Hospital bed	No.
26	Healthline Medical Equipment	PM	ž	0	9	Oxygen	Yes
27	Reliable Medical Supply	PM	1	à	3	Hospital bed	Yes
28	Wheelchair Plus	PM	2	ò	12	Oxygen	No
28	Corner Medical	PM	4	0	28	Wheel chair	Yes
		PM	1	0	8	Hospital bed	Yes
30	Sandford Healthcare Assoc LLC	AM	1	0	10	Oxygen	Yes
31	Hometown Healthcare Inc			0	. 21	Hospital Bed	Yes
32	Hometown Medical LLC	AM	2	0			Yes
33	Hattiesburg Medical Supply	AM	2	-	10	Manual Wheelchair	res Yes
34	Grace Healthcare	AM	1	0	9	Oxygen	
35	Mobility Medical Inc	MA	1	0	6	Hospital Bed	Yes
36	A & A Home Health Equipment Inc	AM	1	o	3	Manual Wheelchair	Yes
37	DME South	AM	1	0	5	Oxygen	Yes
38	Thrift Home Care	MA	2	c	11	Hospital Bed	Yes
39	Premier Medical Equipment Inc	AM	1	0	4	Manual Wheelchair	Yes
40	A&8 Medical Supply of Crowley LLC	AM	2	0	13	Oxygen	Yes
41	Kens Thrifty Way Pharmacy	AM	1	0	2	Hospital Bed	Yes
42	DuraMed, Inc.	PM	1	1.	44	Manual Wheelchair	Yes
43	Life Care Medical Inc	PM	1	0	4	Oxygen	Yes
44	Access Respiratory Homecare LLC	PM	1	o	ş	Hospital Bed	Yes
45	Carmichael's Cashway Pharmacy Inc	PM	1	0	10	Manual Wheelchair	Yes
	Nurses Unlimited Healthcare Services	PM	2	ø	5	Oxygen	Yes
47	Universal Med Supply	PM	1	1	35	Hospital Bed	Yes
	Xmed Oxygen & Medical Equipment	PM	3	0	17	Manual Wheelchair	Yes
	AA Mebility	PM	1	0	4	Oxygen	No - said they do provide hospital beds and wheelchairs
	Dallas Life Support Systems Inc	PM	3	0	18	Hospital Bed	No - said they do provide oxygen
	Specialty Medical Sales	AM	2	0	6	Manual Wheelchair	Yes
	Major Medical Supply	AM	1	0	3	Oxygen	Yes

125

Schedule D

Results of Calls to Providers

	Provider	Time Called {AM, PM, Evening}	Rings Prior To Answer	Number of phone commands to reach a live person	Seconds between phone answer and talking to a live person	Product inquired about	Oid they have the product we called about	
53	Grand Mesa Medical Supply LLC	MA	1	0	7	Hespital Bed	Yes	
54	Rocky Mountain Medical Equipment Inc	AM	1	1	45	Manual Wheelchair	Yes	
55	All Saints Home Medical	MA	2	0	12	Oxygen	Yes	
56	Norman Regional Home Medical Equipment	AM	1	0	5	Hospital Bed	Yes	
57	CareSource LLC	AM	1	0	8	Manual Wheelchair	Yes	
58	Advanced Care Medical Equipment	AM	Z	0	7	Oxygen	Yes	
59	Home Health Warehouse LLC	AM	2	0	10	Hospital Bed	Yes	
60	Bel Regional Home Medical Inc	PM	0	1	41	Oxygen	Yes	
61	Green Bay Home Medical Equipment	PM	1	0	3	Manual Wheelchair	Yes	
62	Knueppel Healthcare Services Inc	PM	0	1	66	Hospital Bed	Yes	
63	ThedaCare At Home	PM	0	1	72	Manual Wheelchair	Yes	
64	Home Realth United Home Medical Equip	MA	2	0	5	Oxygen	Yes	
65	Family Medical Equipment & Supply	MA	1	0	56	Hospital Bed	Yes	
66	Memorial Home Services of Central IL	MA	1	1	59	Manual Wheelchair	Yes	
67	Iroquois Home Care	AM	4	0	20	Oxygen	Yes	
68	Lakeland Pharmacy	AM	1	9	4	Hospital 8ed	Yes	
69	The Home Healthcare Store	MA	3	0	11	Manual Wheelchair	Yes	
70	Anthem Health Services	AM	1	0	6	Oxygen	Yes	
71	Continued Care of Long Island, Inc.	AM	2	0	8	Hospital 6ed	Yes	
72	Home Respiratory Care	AM	1	1	44	Manual Wheelchair	Yes	
73	Homecare Concepts Inc	AM	1	1	75	Oxygen	Yes	-
74	Fidelity Health Care	AM	2	0	13	Hospital Bed	Yes	i
75	Hastings Home Health Center Inc	AM	3	1	49	Manual Wheelchair	Yes	خ
76	Integrated Medical Inc	MA	1	0	5	Oxygen	Yes - but specific item not covered by Medicare b/c lost competitive bid	•
77	Dependable Medical Equipment	AM	2	0	11	Hospital Bed	Yes	
78	Alliance Home Care & Mobile Diagnostics	MA	1	0	7	Manual Wheelchair	Yes	
79	Med One Healthcare LLC	AM	7	0	44	Oxygen	Yes	
80	All Med Equipment Service Inc	AM	1	0	3	Hospital Bed	Yes	
81	Keelers Medical Supply Inc	AM	2	0	9	Manual Wheelchair	Yes	
82	Aero Mobility Inc	AM	1	0	6	Oxygen	Yes	
83	Broadway Medical Service & Supply Inc	AM	1	0	9	Hospital Bed	Yes	
84	Calox Inc	PM	3	0	9	Manual Wheelchair	Yes	
85	Enice Home Medical Equipment	PM	1	2	27	Oxygen	Yes	
86	Experea Healthcare	PM	1	0	0	Hospital Bed	Yes	
87	Home Respiratory Care	PM	2	0	0	Manual Wheelchair	No	
88	Horizon Medical	PM	2	1	25	Oxygen	Yes	
89	Ellis Home Oxygen & Medical Equipment	AM	2	0	6	Hospital Bed	Yes	
90	Baird Respiratory	PM	1	3	90	Manual Wheelchair	Yes	
91	GSH Home Med Care	PM	0	1	38	Oxygen	Yes	
92	Medical Necessities and Services LLC	PM	11	1	105	Hospital Bed	Yes	
93	King Drugs and Home Care	PM	2	0	\$	Manual Wheelchair	Yes	
94		, PM	2	0	10	Oxygen	Yes	
95	Medical Necessities Inc	PM	1	0	3	Hospital Bed	Yes	
96	Naples Oxygen	PM	5	0	5	Manual Wheelchair	No Van	
97	Browning's Pharmacy And Healthcare	PM	1	0	5	Oxygen	Yes	
98	Perkins Medical Supply	PM	2	0	6	Hospital Bed	Yes	
99	Rx Stat Inc	PM	2	0	8	Manual Wheelchair	No	
100	Airway Oxygen Inc	AM	3	0	10	Oxygen	Yes	

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	٥	~	115	Dayton 45373	Electric Hospital Bed	Medicare number	Medicare number	, to	No.
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		7	324	Colorado Springs 80863	Electric Hospital Bed	No	2	Yes	No
		~		Colorado Springs 80917	Manual Wheelchak	No	No.	Yes	No
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		~	362	Salt Lake City 84063	Electric Hospital Bed	No	ş	Per	No
		~	353	Seattle 98029	Manual Wheelchair	No	No	Yes	No
		~	366	Seattle 98042	Owygen	No	No	Yes	No
Average	٠	2.00	300.67						
			(S.D.) minutes						

Last Chance for Patient Choice

August 13, 2013

Background and Explanation of Hogan-Hansen Study on Medicare's ability to accept beneficiary calls

Background

CMS (Medicare) implemented their competitive bidding scheme in nine MSAs effective January 1, 2011. Implementation of this bidding scheme resulted in a dramatic alteration to the home health care infrastructure – an 80% reduction in healthcare suppliers of oxygen, wheelchairs and hospital beds; reductions in levels of service provided, change in quality of equipment and assistive devices; dramatic reductions in access to home healthcare equipment and services among beneficiaries; and, changing of suppliers for thousands of people; among other impacts. The frail elderly and the disabled populations in these nine markets were the population which suffered the impacts of CMS's implementation of this bidding scheme.

On April 17, CMS issued a report titled, "Competitive Bidding Update—One Year Implementation Update" in which it reported on the results of the program and specifically made the following claims about impact on beneficiaries and beneficiary complaints:

"The results of CMS's real-time claims monitoring is supported by the low number of beneficiary complaints the agency has received. Since implementation, CMS has been carefully monitoring complaints coming into its regional offices, its toll-free number 1-800-Medicare, and to the Medicare Competitive Acquisition Ombudsman's office. CMS received 127,466 beneficiary inquiries regarding the competitive bidding program during 2011. This represented less than 1 percent of total call volume at the 1-800-Medicare call center. The vast majority of inquiries were about routine matters, such as questions about the program or finding a contract supplier. The number of overall beneficiary complaints, defined as inquiries that express dissatisfaction with the program and cannot be resolved by a call center operator, continues to be minimal. All complaints were assigned to program experts for prompt resolution. In the fourth quarter of calendar year 2011, CMS received six beneficiary complaints. This is a minute fraction of the 2.3 million Fee-for-Service beneficiaries residing in the nine competitively bid MSAs for 2011."

Table 3: Beneficiary Complaints by Quarter, 2011	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total
Beneficiary Complaints	43	73	29	6	151

Concern over CMS's inability or unwillingness to engage beneficiary feedback
Patient advocate groups and medical equipment industry groups adamantly disagreed with
CMS's finding and report. The CMS findings were not in any way consistent with the stories

and observations of these groups. Multiple beneficiary and industry groups have brought forward multitudes of complaints and concerns from beneficiaries. It is our belief that there have been and continue to be large numbers of beneficiaries negatively impacted by the CMS bidding scheme. We believe there are numerous problems with CMS's alleged monitoring of complaints. One of these problems is that it is exceedingly difficult for beneficiaries to access CMS offices to ask a question, to seek assistance, to wage a complaint or resolve a problem.

Independent Study

We engaged an independent accounting firm to perform a survey of accessibility and effectiveness of the CMS 1-800-Medicare question and complaint system. The survey results demonstrated a shocking lack of accessibility to CMS and explain, in part, why CMS alleges to have not received many complaints. Among the findings:

- On average, its takes a caller to CMS over 5 minutes before they reach a live person with whom to speak.
- This 5 minute timeframe contrasts with an average of less than 20 seconds it takes to reach a live person at any of 100 random DME providers, day and night.
- Further, in calls to DME providers, 90% of the callers reached a live person in less than
 one minute. In attempting to reach CMS, 0% of callers reached a live person in under
 one minute.
- In calls to DME providers, 100% of the callers reached a live person in less than two
 minute. In attempting to reach CMS, only 28% of callers reached a live person in under
 two minute.
- It is inconceivable that any organization, especially one serving an elderly population, would establish a user/customer/beneficiary support system where callers must wait more than 45 seconds to reach a live person. CMS's level of disregard for its beneficiary callers either constitutes gross incompetence or deliberate avoidance of beneficiary input and questions.
- The independent accounting firm also asked the CMS phone team whether or not the new competitive bidding rules would apply in their zip code and whether or not those rules would change anything about DME providers they could access or DME equipment they would use. In all 100 calls, the caller used a round 2 bid MSA as their home, but 96% of the time CMS told them that zip code was not in round 2 of competitive bidding. In all 100 calls, the caller indicated needing either oxygen, a wheelchair or a hospital bed. In 98% of the calls, CMS indicated that the DME product was not covered by competitive bidding now or in the future.

Last Chance for Patient Choice

1111 San Marnan Drive, Waterloo, Iowa 50701

A Market Pricing Program to Fix Medicare's Bidding System for Home Medical Equipment and Services (HME)

The congressional objective in requiring Medicare to use competitive bidding to establish payment amounts for home medical equipment (durable medical equipment) was to reduce Medicare and beneficiary expenditures and ensure that beneficiaries have access to quality items and service. This objective cannot be met because the Centers for Medicare and Medicaid Services (CMS) has designed a program that does not hold bidders accountable, does not ensure that bidders are qualified to provide the products in the bid markets, and produces bid rates that are financially unsustainable. More than 240 market auction experts and economists have warned that the Medicare bidding program is unsustainable in its current form. It will create significant barriers to access and will destroy the HME infrastructure that seniors and people with disabilities depend on.

To fix these serious problems, independent auction experts and economists proposed a market-based pricing system for HME. The proposal, known as the Market Pricing Program (MPP), would require CMS to make fundamental changes to ensure a financially sustainable program. It uses a state-of-the-art auction system to establish market-based reimbursement rates around the country. These changes are consistent with Congress' original intent: to create a program that is based on competition while maintaining beneficiary access to quality items and services. Key components of the MPP are:

- MPP includes the same HME items as the competitive bidding program and is implemented across
 the country in the same timeframe as the bidding program;
- Two product categories are bid per geographic area. Eight additional product categories in that same area would have prices adjusted based on auctions conducted simultaneously in comparable geographic areas;
- Bid areas are smaller than metropolitan statistical areas (MSAs) and more homogeneous;
- Bids are binding and cash deposits are required to ensure only serious bidders participate;
- The bid price is based on the "clearing price," not the "median price" of winners; and,
- The same areas that are exempted under the competitive bidding program will be exempted under

The Medicare DMEPOS Market Pricing Program Act of 2012

Overview

This legislation would replace the current Medicare DMEPOS competitive bidding program with a sustainable market pricing program (MPP) that is based upon sound economic principles that are embraced universally by auction experts across the country. The market pricing program would be implemented on the same timetable and apply to the same DMEPOS product categories as the current program, and it will reduce government spending for DMEPOS items nationwide. It is intended to be at least budget-neutral.

Bill Summary

Stop the Current Program

- The Round One rebid Medicare DME competitive bidding contracts and prices will continue through June 30, 2013, and then terminate (six months early), when the MPP pricing will take effect.
- In the nine Round 1 Rebid areas, the Secretary shall offer contracts to DMEPOS suppliers that submitted a bid for one or more of the Round One product categories, but whose bid(s) were rejected solely because of price considerations. Those bidders who accept a contract must accept the single payment amount in effect for the particular product category(s).
- The Secretary will take no further action to implement Round Two in the 91 new bid areas under the current competitive bidding program.

Establishment of the DMEPOS Market Pricing Program (MPP)

Use of Experts to Design and Monitor the MPP

- The Secretary shall, within two months of enactment, contract through a competitive process
 with an Auction Expert for the design and implementation of the MPP, and separately, also
 through a competitive process, contract with an expert to serve as Market Monitor for the
 MADD
- Both the Auction Expert and Market Monitor may not be a current government employee, a current or former CMS employee, or a current or former CMS contractor involved in the competitive bidding programs undertaken to date by CMS.
- Both the Auction Expert and Market Monitor must have successful experience designing and implementing auctions of similar complexity in the public sector.
- The Secretary shall make available to the Auction Expert and Market Monitor all confidential information on the relevant markets.
- The Secretary and Auction Expert are required to operate the MPP with full transparency and to post on a public Internet site operated by the Secretary all information pertinent to the MPP.

Timeline

2012:

- Within two months of appointment, the Auction Expert shall develop a draft auction design as
 the starting point for the collaborative rulemaking process.
- Within four months of appointment, the Secretary and Auction Expert shall convene a design
 conference to include all stakeholders, including CMS and other federal personnel, DMEPOS
 suppliers, beneficiaries and the DMEPOS competitive bidding Program Advisory and Oversight
 Committee (PAOC). The conference shall be recorded and available over the Internet.

Within three months following the design conference, the Secretary and Auction Expert will publish the final MPP design, which, to assure transparency, shall include all financial and other qualifications for bidders, the eligible market areas and product categories to be auctioned, the protocols and timing for the conduct of the auction, the methodology by which prices will be set for the non-lead products within a product category, the methodology by which an auction price will be transferred to the same product in an economically similar eligible area in which no auction for that product was held, and an appeals process to protect suppliers.

2013:

- The auctions will commence no later than March 1, 2013.
- The auctions will consist of multiple rounds of bidding (descending price), concluding when supply (from DMEPOS providers) meets demand (expected utilization) and thereby establishing the clearing price.
- A cash deposit or irrevocable letter of credit bid bond, in an amount determined by the Secretary and Auction Expert, is required for a bidder to be qualified to participate. These deposits are returned to unsuccessful bidders and retained for the successful bidders as a guarantee of performance on the contract.

Implementation of the MPP by July 1, 2013

- MPP prices determined through the auction will be effective July 1, 2013, for all areas of the country not excluded by current law.
- The Secretary and Auction Expert will select a sufficient sampling of market areas for auction that will establish valid nationwide prices.
 - The first auction will cover a sample of at least 20 percent of the country and include a variety of geographic and socio-economic areas.
 - > Succeeding annual auctions to cover a sample of at least 10 percent of the country.

Product Categories to Be Auctioned

- Same as in current program: oxygen, standard power wheelchairs, manual wheelchairs, enteral
 nutrients, CPAP, hospital beds, walkers, diabetic supplies, negative pressure wound therapy
 and support surfaces (Group 2).
- Secretary retains current authority to compete additional categories.
- Secretary is precluded from including in MPP adjustable skin protection cushions for wheelchairs, complex rehabilitative power wheelchairs and complex manual wheelchairs (HCPCS K0005 and E1161).
- No more than two product categories may be auctioned for exclusive contracts in any one market area (defined as a city/county/aggregation of counties).
- Any qualified and willing supplier may provide non-auctioned categories in market areas at the clearing price as determined from auctions in other market areas via MPP.

Price Determination

- A "lead product" is determined for each of the product categories.
- Other products are proportionately referenced (in terms of price) to the lead product price through a process designed by the Auction Expert with input from stakeholders.
- The "lead product" is auctioned (descending price) until supply (providers' capacity) equals demand (expected utilization).
- At this point, the "clearing price" is determined and all remaining bidders are offered, and must accept, a contract at this price.
- The Secretary and Auction Expert, using an econometric model developed from the auction process, which spans a full range of geographic and socio-economic factors nationwide, determine and announce prices for all market areas not specifically excluded from MPP.
- Prices are effective July 1, 2013, and each July 1 of succeeding years for all areas not under the
 two-year exclusive contracts. This process annually adjusts prices to reflect true costs and
 rewards the most efficient providers.
- Successful bidders (i.e. those whose bids are below the clearing price) will be offered a twoyear contract for that market area, and these suppliers must accept and perform the contract.

Bidding Requirements

- All bidders must provide a cash deposit or irrevocable letter of credit (LOC) from a qualified
 institution as a bid guarantee of good faith and ability to perform. This bond will be retained as
 a performance guarantee for winners and returned for unsuccessful bidders.
- The capacity of each bidder will be determined based upon the bidder's historical supply. Any
 new-to-the-market-area or new (start-up) suppliers having no historical supply will be assigned
 a standard base capacity of one percent market share.

Miscellaneous MPP Provisions

- A product-specific grandfathering period may be set by the Secretary on the recommendation
 of the Auction Expert with oversight of the Market Monitor, with qualified suppliers to furnish
 products under contract in market areas.
- Small businesses are defined as \$3.5 million or less in annual revenues and shall represent at least 30 percent of total capacity in each market area.

Role and Responsibilities of the Market Monitor

- Reporting to the Secretary, the Market Monitor evaluates and reports on the design, implementation and functioning of MPP for the purpose of identifying weaknesses or problems and recommending adjustments and changes.
- The Secretary shall provide the Market Monitor with access to all confidential information on the relevant markets.

- The Market Monitor shall review and report on the draft and final auction designs and participate in and report on the designs and design conference.
- The Market Monitor shall monitor supplier performance and beneficiary experience to ensure supplier compliance with standards established in the MPP and beneficiary access to quality products and services and shall provide regular reports to the Secretary on the these matters and the overall operation of MPP.
- The Market Monitor shall provide an annual report to Congress on the development and operation of the MPP process, identifying potential problems and recommending solutions.

Other Provisions

- The PAOC is made permanent, subject to the Federal Advisory Committee Act (FACA), and terms of PAOC members extended for an additional 3 years.
- Negative Pressure Wound Therapy—Standards will be collaboratively developed in consultation
 with the stakeholders as part of a new appendix to the Medicare DMEPOS Quality Standards.

Response to the Congressional Hearing on Medicare's Durable Medical Equipment Competitive Bidding Program

19 September 2012 Peter Cramton

Summary

On 11 September 2012, the Subcommittee on Healthcare and Technology of the United States House Committee on Small Business led by Chairwoman Renee Ellmers (R-NC) and Ranking Member Cedric Richmond (D-LA) held a hearing on Medicare's Durable Medical Equipment Competitive Bidding Program, which is in its pilot stage, but soon is to expand to over one-half of the country. The program is administered by the Centers for Medicare and Medicaid Services (CMS). Under the 2003 Medicare Modernization Act, Congress mandated CMS to identify providers and price home medical equipment through competitive bid. The hearing included four witnesses:

- Lawrence Wilson, Director of the Chronic Care Group with CMS, testified on behalf of CMS; he is
 one of the CMS staff that runs the Medicare Competitive Bidding Program. He described the
 DME Competitive Bidding Program as "successful."
- Peter Cramton, Professor of Economics, University of Maryland, testified as an auction expert,
 who has designed and implemented auctions in many industries and countries over the last
 twenty years. He argued that Congress must insist that CMS replace its fatally flawed auction
 program with an efficient auction based on best-practice and science and thereby achieve leastcost sustainable supply of quality home medical equipment for beneficiaries.
- Tammy Zelenko, President and CEO of Advacare Home Services, testified as one among the
 thousands of the small businesses that have participated in the Medicare auction. She described
 the serious problems of the program for any business, stating, "let us be clear: This bidding
 program is anti-small business. It is a business and job killer."
- Randy Mire, owner of Gem Drugs, explained the important role of independent community pharmacies in the delivery of Medicare-funded health services and goods to beneficiaries.

The hearing helped illuminate the serious problems with the current program. As an auction expert and someone quite knowledgeable with both CMS' current program and the stakeholders' Market Pricing Program, which replaces the current program with a modern efficient auction, I provide comments on CMS' testimony.

I identify two points of agreement with CMS (details are provided in the main body of this statement):

CMS' Competitive Bidding Program is not an auction. This is a harsh critique given the 2003
Congressional mandate that requires that CMS identify providers and price services with an
auction (competitive bid). To me as an auction expert (and not a lawyer), CMS' program is in
violation of the law.

CMS' Competitive Bidding Program has such poor bidding incentives that a provider's rejection of
a supply contract is unrelated to its bid. In contrast, in an efficient auction, the provider is
motivated to bid its cost, and therefore the decision to reject a contract is entirely determined
by its bid: reject the contract if and only if the contract price is below the bid (the bidder's cost).

I also identify several points of disagreement with CMS and explain why CMS is wrong (again details are provided in the main body of this statement):

- CMS claims it has worked closely with stakeholders to design and implement the program. It has
 not. It has dictated the terms. For otherwise it would not be possible to come up with a program
 that all stakeholders agree is badly flawed. CMS stands alone in supporting this program.
- CMS claims to be open to improvements as the program expands. Then why for two years has
 CMS made no reform of the program in light of the unanimous agreement among experts and
 other stakeholders on the flaws of the program. Certainly CMS should explain why the
 stakeholders are wrong. CMS to date has not questioned the validity of the stakeholders'
 critique.
- CMS claims the program encourages small business participation. In fact, the program—even
 when implemented in less than 9 percent of the country—has led to the elimination of about
 4,000 companies as contract suppliers, about 90% of the total.
- 4. CMS claims that the dramatic drop in utilization post-competitive bidding was the result of rampant overutilization, which the program has corrected. Instead, the drop in utilization is a result of access problems—the beneficiaries are unable to get the supplies they need from the Medicare program and so are getting their supplies outside the program.

In response to critique of its Competitive Bidding Program, CMS has countered with two assertions: (1) the program is saving Medicare and beneficiaries a lot of money, and (2) there are no adverse health outcomes as a result of the program. Neither assertion is supported by fact.

To see this consider the following thought exercise: Suppose CMS decided to set the price of two auctioned products—oxygen and mail-order diabetes test strips—to \$0. This is easily accomplished by CMS setting the floor and ceiling for these two products to \$0. Then all bids received would be zero and the median price would be zero. What would happen? Clearly even those who accept the price of zero and become contract suppliers will refuse to supply these products at such a price. Thus, utilization falls to zero together with the price. The result is a huge apparent "cost savings" for Medicare, when in fact what is observed is a denial of access. The apparent cost savings for beneficiaries is also a mirage. The beneficiary whether a diabetic, an oxygen patient, or both, still gets her home medical supplies; she simply gets the supplies outside the Medicare Competitive Bidding Program and pays substantially more as a result. What happens with diabetes is especially interesting. Not even Medicare saves money, since the beneficiary unable to get her test strips via mail order instead goes to the retail pharmacy, where both Medicare and the beneficiary pay about 260% more.

In the Round One Rebid, CMS wisely chose to set the price above zero so as to induce a majority of suppliers to sign the supply contract. But the impact of CMS' program is the same as in the thought exercise above: false cost savings and denial of access. The Medicare auction requires significant reform.

Two points of agreement

CMS: "This is not an auction"

Mr. Wilson. "This [the CMS Competitive Bidding Program] is not a procurement, a government procurement, it is not an auction."

In response to Mr. Wilson's statement that the CMS Competitive Bidding Program was not an auction I testified:

Mr. Cramton. "In the words of Mr. Wilson, he said, quote, 'This is not an auction.' This is one thing I completely agree with Mr. Wilson about, it is not an auction, and that is a very damning critique for the following reason: In 2003, Congress passed legislation that required that CMS conduct a competitive bidding program for durable medical equipment. Competitive bids and auction are the exact same thing. So he is saying that CMS is not abiding by the law, and I would agree with him on that point. It is one of the few things I agreed with him on: it is an arbitrary pricing process...only worse since it excludes over 90% of the market (rather than any willing supplier)."

CMS' slow progress with auctions is one clear indicator that its problems are not limited to auction design but also auction implementation.

Given this history it is not surprising that Mr. Wilson said, "This [Market Pricing] program would seem to require about 8 years to implement." There is no need for the auction implementation to take so long. One year is a better estimate of what would be required provided Congress specifies an aggressive timeline so that the implementation is done on a fast track and with the aid of experts.

CMS: "The winners rejected supply contracts not based on their bids" Implication: Bids are not related to costs

Mr. Wilson. "[W]hen you looked at their bids they didn't not accept because their bid was higher than the price or lower than the price, it sort of cut both ways. So it was obviously for some other business associated reason."

There is only one reason to reject a supply contract: the provider cannot supply the product category without loss; that is, the CMS price is below the provider's cost.

Mr. Cramton. "The current system does not elicit the true costs from the providers. Mr. Wilson stated that in his response, and I quote, "The winners rejected or accepted not based on their bid." That is, the consideration was just what Ms. Zelenko said. The consideration in accepting or rejecting was whether she thought she could provide the goods and services at the price. So it has nothing to do with her bid. And in a competitive, efficient auction, the trick of making an efficient auction is to elicit the bidder's true costs, and then, in fact, the acceptance or rejection would be based upon the bid. And that is

exactly what an efficient auction does when it identifies the clearing price. Those that bid below the clearing price are accepted; those that bid above are rejected."

This issue also illustrates the lack of transparency in the CMS auction. If the experts had the bidding data (perhaps with the bidders' names removed to preserve confidentiality of the bids), then we could easily see whether a bidder's rejection of a supply contract was related to its bid, as Mr. Wilson says. Assuming he is right then the pilot supports the fact that there are serious problems with the bidding incentives in the CMS auction, as demonstrated in theory and the experimental lab, and seen in the field with the need to a floor and ceiling on bids. It is telling that Mr. Wilson does not realize that his empirical observation indicates a serious problem with the auction.

Four points of disagreement

CMS: "CMS worked closely with stakeholders to design and implement the program." Mr. Wilson. "CMS worked closely with stakeholders to design and implement the program in a way that is fair for suppliers and sensitive to the needs of beneficiaries."

Despite this supposed collaboration with stakeholders, CMS managed to come up with a design that stakeholders—beneficiaries, providers, non-CMS government leaders, and auction experts—all agree is flawed.

Mr. Cramton. "So there is unanimous consent on this, and, in fact, I have been working on this for 2 years. I have talked to people around the world, and, indeed, I have never heard anybody disagree with the remarks that I presented today and that are presented in my <u>written testimony</u> before you."

CMS: "We are open to improvements as the program expands."

Mr. Wilson. "We continue to be open to further improvements as the program expands."

- Then why in the face of overwhelming practical scientific evidence of severe problems, does CMS
 make no significant changes to the program as the program expands to one-half of the country. The
 most serious flaws, non-binding bids and the median pricing rule where were identified by 167
 auction experts in September 2010 and sent to CMS not only by the experts but by numerous
 Congressman.
- Why does CMS not release any of the essential data necessary to properly evaluate the pilot program? Remarkably the absence of data even extends to the DMEPOS Competitive Bidding Program Advisory and Oversight Committee (PAOC) established by Congress to monitor the program. For example, listen to Barbara Rogers, Medicare beneficiary, PAOC Member, and President/CEO of the National Emphysema/COPD Association, who spoke at an update to Congress on the Competitive Bidding Program, "Well, I will tell you, when I go to bed at night and I turn my life over to my ventilator—I get emotional here—when I do that, it's not a widget to me. You know, it is my life. And people's life and death are affected by this program. And it's my experience that CMS has no concept, or else they don't care. When I ask CMS as a PAOC member for information or suggestions, 90 percent of the time I'm given two answers. It's a legislative issue, we don't deal with

it; or it's confidential and we can't tell you. So to me, who are they accountable to? You know, they don't seem to be accountable to anybody. $^{\prime\prime}$

Why does CMS not commission an independent assessment of its pilot so that there is some
possibility they might be able to improve it? A basic tenant of science is peer review. There is a good
reason for this. Only through peer review can one have any faith in assertions, especially coming
from those with a conflict of interest.² The designer and implementer of a program cannot be relied
on to provide an objective critique of its own program. This is common sense. CMS' one-year "

Mr. Cramton. "If one takes a look at the 1-year report that CMS did, which I think was released on April 17th of 2012—it is on my Website, it is on their Website—you will see a 16-page report that does not address any of the issues that all of the experts agree are extremely serious problems with their program. Not one word about any of the issues. So it is not a critique, it doesn't give data, it just makes an assertion."

· Then why does CMS appear to misunderstand a basic element of the Market Pricing Program?

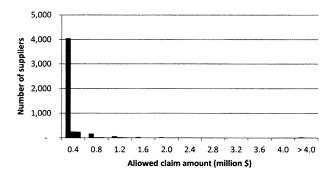
Mr. Wilson. "We talked about choice a little bit today. This assigns patients essentially to certain small suppliers, it has a small supplier target that says they get 30 percent of the business. The only way to implement that is to assign a patient to a supplier and take away their choice. That is a concern for me. So I think there is some issues and concern there that need to be addressed, but I don't see replacing a system that is working for one that has some problems."

• In fact, Mr. Wilson appears to misunderstand a basic element of the Market Pricing Program, an early draft of which was available in January 2011. A key tenant of MPP is beneficiary choice, which is supported in a variety of ways, the most important being that the beneficiary gets to select among any auction winner in the 20% of cases that are currently under auction contract and can select among any qualified supplier in the remaining 80% of the cases. The hundreds of stakeholders that developed MPP are well aware of the benefits of beneficiary choice and take it seriously—in sharp contrast to CMS' Competitive Bidding Program. These features have been part of the Market Pricing Program, since January 2011 and were in fact part of the proposal initially presented to Mr. Wilson on 1 November 2010.

CMS: "The Competitive Bidding Program encourages small business participation" Mr. Wilson. "Most importantly, the regulation established a special 30 percent target for small supplier participation in the program. CMS was very pleased that we exceeded this 30 percent target in the nine Round One areas with 51 percent of contracts going to small suppliers."

¹ <u>Competitive Bidding Congressional Update—What You Need to Know,</u> Longworth House Office Building, sponsored by U.S. Representative Sue Myrick (R-NC), 24 May 2011. [Video of panelists, <u>Transcript of entire event</u>]
² For more on conflict of interest see my written testimony at p. 17.

The reality is that the CMS Round One Rebid was a disaster for small businesses. Even when applied to less than 9 percent of the US population, CMS' Competitive Bidding Program excluded many thousands of small business providers. The facts are shown in the chart below (page 12 of my written testimony):



■ Pre-CB (2010) ■ Original CB winners (2011) ■ Revised CB winners (2011)

Yes, 51 percent of the remaining providers (CB winners) are small businesses, but this is little consolation to the 90 percent who were eliminated by an auction process that auction experts describe as "bizarre" in the *New York Times*. The painful reality is that 51 percent of nearly zero is nearly zero.

CMS: "There was rampant overutilization under administrative pricing"

Mr. Wilson. "[T]here was rampant overutilization under the prior system [administrative pricing]."

This bold claim is central to CMS' argument. There is no denying that utilization has dropped dramatically in the nine competitive bidding areas.⁴ There are two possible sources for the drop in utilization:

³ Ayres, Ian and Peter Cramton, <u>"Fix Medicare's Bizarre Auction Program"</u> (with Ian Ayres), Opinion Pages, New York Times. 30 September 2010.

⁴ See for example AMEPA (2012), <u>"Reductions in Allowed Claims Prove Limited Patient Access."</u> and Cramton, Peter (2012) <u>"The Hidden Costs of a Flawed Medicare Auction,"</u> University of Maryland, January 2012. [<u>Data</u>] The "Hidden Costs" study was based on a FOIA request to CMS. Analysis of the data is limited as a result of the significant lag between the time CMS receives a claim and the time it is recorded as an allowed claim. To address this limitation I sent a follow-up data request, requesting the same data fields but updated to better reflect the full set of allowed claims in 2011. The data request was completed by PDAC and underwent two months of quality control checks. At this point PDAC normally sends the data directly to me, however, CMS apparently requested that the data be sent to them instead. CMS received the data on 17 August 2012. One month has gone by and I still have received nothing. This is one more example of the complete lack of transparency of the program. There is no reason why basic information like what I asked for is not immediately made available to the public. Congress should insist on a much higher level of transparency. The saga of my effort to get basic data from CMS is documented in <u>Follow-up FOIA Data Request</u>.

- 1. a decline in fraudulent claims—what CMS refers to as overutilization, or
- a decline in access—those with legitimate claims getting home medical equipment outside of the CMS Competitive Bidding Program.

CMS has attempted to back up its overutilization claim in its <u>one-year update</u>. This critical issue is addressed in a single paragraph of the CMS one-year update at page 5: "CMS's monitoring revealed declines in the use of mail-order diabetes test strips and continuous positive airway pressure (CPAP) supplies in the competitive bidding areas. In response to these declines, CMS initiated three rounds of calls to users of these supplies in the nine competitive areas, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. This would suggest that beneficiaries received excessive replacement supplies before they became medically necessary. CMS concludes that the competitive bidding program may have curbed inappropriate distribution of these supplies that was occurring prior to implementation."

CMS provides no further details of the survey, such as when was the survey conducted, what questions were asked, or what were the responses to questions. We somehow are to believe that the drawing down of beneficiary inventories is simply the result of "curbed inappropriate distribution of supplies." This argument is illogical. The behavioral response of access difficulties is first to run down inventories—it is not surprising that beneficiaries keep some inventory on hand of supplies necessary for their survival—and second to purchase the needed supplies outside of the Medicare program. If an oxygen patient cannot get her oxygen within Medicare post-competitive bidding, then she will get it outside of Medicare. The alternative in many cases would be to perish. Thus, the CMS survey is entirely consistent with access problems in both diabetes and oxygen, two of the largest products under competitive bidding. Even if we assume as CMS asserts that beneficiaries are simply running down massive inventories, then the "cost savings" as calculated by CMS is clearly a mirage, since utilization should spring right back to historic levels once the inventories are exhausted.

Conclusion

Congress and the White House must act to reform the Medicare auction. If we do not effectively apply market methods to health care, Medicare is unsustainable.