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

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

Unofficial Transcript of Hearing with links to video
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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.

[0h00m01s]*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 1st, 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 beginning 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.

[The statement of Chairwoman Ellmers follows:]

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[0h04m43s] *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 effectiveness 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.

[The statement of Mr. Richmond follows:]

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[0h07m33s] *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 MEDICAID SERVICES, BALTIMORE, MD

[0h08m41s] *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 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 suppliers.

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, 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 taxpayers 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 a $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 open 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.

[The statement of Mr. Wilson follows:]

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[0h13m49s] *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' nonbinding?

[0h14m15s] *Mr. Wilson.* Chairwoman, that is an important issue that we looked at very closely. We were certainly—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.

[0h15m42s] *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?

[0h16m14s] *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 manufactures, invoices, and 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.

[0h17m45s] *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 information that you have just given us?

[0h17m59s] *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.

[0h18m55s] *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?

[0h20m07s] *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 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 not just a—it is very small and it is not just an occurrence in the nine competitive bidding areas, but it is a more general trend.

[0h22m38s] *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—

[0h22m56s] *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.

[0h23m45s] *Chairwoman Ellmers.* Okay, great. I do have a couple more—

[0h23m47s] *Mr. Wilson.* I—

[0h23m48s] *Chairwoman Ellmers.* Oh, I am sorry, I thought were you finished.

[0h23m49s] *Mr. Wilson.* I am.

[0h23m50s] *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.

[0h24m05s] *Mr. Richmond.* Thank you and thank you, Director Wilson, for being here.

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 then that data being lost or 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?

[0h24m56s] *Mr. Wilson.* Thank you. I think the problems that you are describing are ones that we experienced in our 2008 round, Congressman, 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 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 improvements.

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, 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, 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.

[0h27m13s] *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 ban together and form networks to bid. How many actually did that?

[0h27m28s] *Mr. Wilson.* We had 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.

[0h27m47s] *Mr. Richmond.* Are you all doing anything to encourage it or to educate the small suppliers on the ability to do that or the advantages to doing that?

[0h27m57s] *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.

[0h28m29s] *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?

[0h28m57s] *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.

[0h29m34s] *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?

[0h30m00s] *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.

[0h30m35s] *Mr. Richmond.* And right now, do you all currently have bids out right now?

[0h30m40s] *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 some time 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.

[0h31m08s] *Mr. Richmond.* Okay. Madam Chairwoman, thank you and I yield back.

[0h31m11s] *Chairwoman Ellmers.* Okay, at this time I would like to introduce my colleague from Iowa, Mr. King, for his questions.

[0h31m18s] *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 18th, 2012, and a Hogan-Hansen study on Medicare's ability to accept beneficiary calls, that is August 13, 2013.

[0h31m47s] *Chairwoman Ellmers.* Without objection, so ordered.

[The three reports follow:]

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[0h31m50s] *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 happens to patient choice?

[0h32m31s] *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.

[0h33m02s] *Mr. King.* Can—

[0h33m03s] *Mr. Wilson.* I think importantly to get that consistency, if I may, you are talking about, sir, 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.

[0h33m27s] *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 in 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.

[0h34m58s] *Mr. Wilson.* It does not provide us the authority to do what you described, sir.

[0h35m02s] *Mr. King.* What prohibits you then from enforcing such an authority at the discretion of the executive branch?

[0h35m09s] *Mr. Wilson.* If that authority were put in place?

[0h35m10s] *Mr. King.* If it doesn't specify that authority, what is out there in statute that would prohibit you from asserting that authority?

[0h35m21s] *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.

[0h35m32s] *Mr. King.* Did you want to do that? Was it something you looked at from the beginning though and you wanted to put more standards in?

[0h35m40s] *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.

[0h35m58s] *Mr. King.* Now—

[0h35m59s] *Mr. Wilson.* But I think it is worth considering.

[0h35m59s] *Mr. King.*—you do write the specifications for the bid, correct, and you have the statutory authority to do that?

[0h36m06s] *Mr. Wilson.* Yes, sir, to write specifications.

[0h36m08s] *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?

[0h36m37s] *Mr. Wilson.* Well, I am not aware of any suicide bids. We put in a process to address that issue, it is called bona fide bid process.

[0h36m43s] *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 indulge me.

[0h36m51s] *Chairwoman Ellmers.* Without objection, please continue.

[0h36m53s] *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?

[0h37m31s] *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 is 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 affect 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.

[0h38m13s] *Mr. King.* I will just say this, large companies will like this, small companies with not. Thank you, and I yield back.

[0h38m18s] *Chairwoman Ellmers.* Thank you. At this time I would like to introduce my colleagues from Pennsylvania, Mr. Thompson, for his questions.

[0h38m24s] *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?

[0h41m26s] *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 rulemaking, 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 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.

[0h42m59s] *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 a 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?

[0h43m49s] *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.

[0h44m32s] *Mr. Thompson.* Thank you. Thank you, Chairwoman.

[0h44m35s] *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?

[0h45m32s] *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 tells the staff not to think about where we are make 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 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 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.

[0h46m40s] *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?

[0h46m59s] *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.

[0h48m48s] *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.

[0h49m28s] *Mr. Wilson.* Thank you.

[0h49m35s] *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 ECONOMICS, UNIVERSITY OF MARYLAND, COLLEGE PARK, MD; TAMMY ZELENKO, PRESIDENT/CEO, ADVACARE HOME SERVICES, BRIDGEVILLE, PA, ON BEHALF OF THE AMERICAN ASSOCIATION OF HEALTH CARE; AND RANDY MIRE, OWNER, GEM DRUGS, RESERVE, LA, ON BEHALF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION STATEMENT OF PETER CRAMTON, PH.D.

[0h51m49s] *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 auction 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 Caltech 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 is 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.

[0h57m34s] *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.

[0h57m50s] *Mr. Cramton.* Thank you.

[The statement of Mr. Cramton follows:]

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[0h57m50s] *Chairwoman Ellmers.* At this time I do—our next panelist is Ms. Zelenko, and actually Mr. Thompson from Pennsylvania is going to introduce her.

[0h57m59s] *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

[0h58m27s] *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 providers 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 locations, 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.

[1h03m40s] *Chairwoman Ellmers.* Thank you for your testimony, Ms. Zelenko. [The statement of Ms. Zelenko follows:]

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[1h03m43s] *Chairwoman Ellmers.* At this time we will be introducing our last panelist Mr. Mire, and my colleague Mr. Richmond will do that.

[1h03m52s] *Mr. Richmond.* Madam Chairwoman, it is my pleasure to introduce our next witness, which is 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

[1h04m43s] *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 Pharmacy.

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 to the care for 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 my patients know how to use the products properly.

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, community pharmacies are not exempt from the competitive bidding program—and 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 a 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 is a bipartisan legislation introduced by Representatives Schock and Welch that 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 beneficiaries 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—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 you may have.

[1h09m53s] *Chairwoman Ellmers.* Thank you.

[The statement of Mr. Mire follows:]

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[1h09m54s] *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?

[1h10m25s] *Mr. Cramton.* Correct.

[1h10m26s] *Chairwoman Ellmers.* Okay—as established by CMS, and do other experts agree with you?

[1h10m35s] *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.

[1h14m13s] *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?

[1h14m31s] *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.

[1h15m23s] *Chairwoman Ellmers.* And just briefly, it sounded to me from your testimony that you are in favor of the market pricing plan. Is that—

[1h15m32s] *Ms. Zelenko.* It eliminates the problems that we have discussed with the current bidding program.

[1h15m40s] *Chairwoman Ellmers.* And so something, a solution like that would be something you would support?

[1h15m43s] *Ms. Zelenko.* Yes, it is.

[1h15m45s] *Chairwoman Ellmers.* Okay. Mr. Mire, what impact has the DME competitive bidding been on your pharmacy as a business owner?

[1h15m54s] *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 it is a lot of problems that the patients are experiencing.

If I were to say, you know, 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 are like, okay, well, you know, maybe we will just stay bedridden and so forth, and they begin to get more issues, bedsores. And they miss that 101 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.

[1h17m13s] *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.

[1h17m43s] *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?

[1h18m26s] *Mr. Mire.* Actually, sir, there was no one to even point out the program. Nobody never 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, you know, I found that out today.

[1h18m58s] *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?

[1h19m17s] *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.

Unfortunately, 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.

[1h20m10s] *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?

[1h20m57s] *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.

[1h21m55s] *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. And I guess I am asking for your opinion on 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?

[1h22m26s] *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.

[1h24m22s] *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.

[1h25m38s] *Mr. Richmond.* Thank you and I yield back.

[1h25m40s] *Chairwoman Ellmers.* Thank you for those responses.

And now I will turn to my colleague Mr. King for his questions.

[1h25m47s] *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.

[1h26m19s] *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—

[1h27m08s] *Mr. King.* Where did you fit in the rank order? How many bidders and generally how big of dollars are we talking about?

[1h27m13s] *Ms. Zelenko.* I will need to get back to you on that, and I can put it in writing.

[1h27m16s] *Mr. King.* The number of bidders, don't you have a kind of range so we have got a concept to work with today?

[1h27m21s] *Mr. Cramton.* No data. The data is not available. Ms. Zelenko. That is part of it.

[1h27m25s] *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?

[1h27m35s] *Ms. Zelenko.* Correct.

[1h27m36s] *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.

[1h27m53s] *Ms. Zelenko.* Correct.

[1h27m54s] *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?

[1h28m06s] *Ms. Zelenko.* Yes, it is.

[1h28m07s] *Mr. King.* You have to be qualified.

[1h28m08s] *Ms. Zelenko.* You do have to be qualified.

[1h28m10s] *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?

[1h28m29s] *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—

[1h29m20s] *Mr. King.* Were you astonished to hear Director Wilson testify that they didn't have the statutory authority to require bonding?

[1h29m23s] *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.

[1h29m53s] *Ms. Zelenko.* You do.

[1h29m53s] *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.

[1h30m08s] *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?

[1h30m21s] *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.

[1h30m51s] *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?

[1h31m57s] *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?

[1h32m20s] *Ms. Zelenko.* Oh, absolutely. It is an enormous amount.

[1h32m21s] *Mr. Thompson.* Well, any idea of a percentage?

[1h32m22s] *Ms. Zelenko.* Well, offhand I can't give that to you, but I can—

[1h32m28s] *Mr. Thompson.* It is significant.

[1h32m29s] *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.

[1h32m51s] *Mr. Thompson.* Right. These gas prices probably don't help your business at all either.

[1h32m54s] *Ms. Zelenko.* And we cannot pass on any of this.

[1h32m56s] *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 are 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?

[1h33m37s] *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 actually thousands of years. It is really the fundamental market clearing 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 an 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.

[1h36m51s] *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—

[1h37m13s] *Mr. Cramton.* Yes.

[1h37m13s] *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?

[1h37m42s] *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.

[1h40m08s] *Mr. Thompson.* Thank you.

[1h40m09s] *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:]

******** COMMITTEE INSERT ********

[1h42m12s] *Chairwoman Ellmers.* This hearing is now adjourned. [Whereupon, at 11:54 a.m., the Subcommittee was adjourned.]