Public Meeting

Linda Howard:
Good morning, everyone. Welcome to CMS. For some of you, welcome back to CMS. We're going to bring our meeting to order now. My name is Linda Howard, and I'll be your moderator today. I work in the Office of Strategic Operations and Regulatory Affairs, which has nothing to do with diabetes or the management of diabetes in any way. But I do have to tell you that today is a very special day. It's my 65th birthday.

[laughter]

[applause]

So Medicare is a little more important to me now than it was in the past.

[laughter]

I want to start off with some housekeeping items. First of all, we have restrooms -- most important thing -- down the hall on the left. You passed it as you came in. There is also a phone there. We have a cafeteria on our lower level, and a gourmet coffee stand there. If any of you need assistance in arranging for taxi service today, please see the concierge in the lobby. CMS is a non-smoking campus. There's a smoking area outside the building near the guard stations, at the entrances to the campus. We ask that you please put your cell phones and Blackberry on silent. Please note that this meeting is being recorded. There will be transcription available on our website after the meeting. If you're a speaker, whether you are participant or CMS staff member, please be sure to step up to the microphone so that everyone can hear you. We appreciate your cooperation in adhering to speaking timeframes. All commenter's will have up to 10 minutes. I will signal with a bell when a speaker has one minute left. Note I am over there. It's a little bell. Listen for it. One minute, and then you'll have to wrap up. Speakers may not call on other speakers or designate unused minutes to others. Calling on speakers is my job. If you have additional speakers from your group, please sign up by the doors outside of the auditorium. I will call a break today, based on the progression of the meeting. Due to recent world events, you may notice an increase in security on our CMS campus. Our CMS chief of security has asked us to provide a reminder that the CMS complex is not open to the general public. As a guest to the complex, your access is limited to this meeting area, the lobby through which you entered, and the cafeteria on the lower level. If you are found outside of those areas without proper escort, you may be escorted out of the facility. We will accommodate as many speakers as we can before the meeting adjourns at 1 PM. You will be called in the order in which you signed the commenters list. For those individuals who do not have the opportunity to speak today, you may submit written comments. It is likely that the comment period will be extended until after the audio and transcription files are available on our website. At this point, written comments will be accepted until 5 PM on July 30th. As I said, we may extend that. Comments can be sent through email to dmepos@cms.hhs.gov. When the meeting is adjourned for the day, all visitors are expected to leave the premises. These procedures are for the protection of everyone in the building, including you, our visitors.

We want to welcome you here this morning. It's a little humid. Typical Baltimore Washington weather. We have many -- many of you meeting participants may have had a phone conversation or meeting at one time or another with members of our staff. So our first order of business is to introduce you to the CMS panel today. First, the director of our Chronic Care Policy group, Laurence Wilson. The Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, DMEPOS, policy, Joel Kaiser. Our Technical Advisor for the Division of DMEPOS policy, Karen Jacobs. And our public meeting coordinators and policy analysts for the division of DMEPOS policy, Elliot Klein and Hafsa Vahora [spelled phonetically], who is taking the sign ups outside the door. We also have Michael Keane this morning, Director of the Division of Competitive Bidding.

At this time, I'd like to ask the Director of the Chronic Care Policy Group, Laurence Wilson, to give opening remarks. Laurence?

Laurence Wilson:
Thank you, Linda. And, before I give my opening remarks, with regard to the issue of the day, I just wanted to say a few words about Linda to thank her for her service to Medicare. Linda has worked for us at CMS for a number of years. And when you get to be 65, you don't say how long people have been at CMS, but a number of years. She's been here since I came to CMS. She's worked on skilled nursing facility policy, durable medical equipment policy, physician self referral or stark policy, and arranged a physician in hospital policy issues. For us, she has been a moderator recently for many of our coding [spelled phonetically] meeting, DME meetings, and many other public meetings that we have. So I think she's provided a great service to the public, as well as CMS staff. And so, really what I wanted to do was just to thank her for all of her service, and also present her Medicare card to here on the date of her 65th birthday. So Linda, please use it in good health.

[laughter]

[applause]

So with that, let me just say for CMS, welcome to our complex here in Baltimore. I'm Laurence Wilson, again, I'm Director of the Chronic Care policy group. Days like today are very important. Public participation in the policy development process is critical. We rely on that at CMS to ensure appropriate administration of the Medicare program and many of the other issues that the agency is tasked with. Diabetes, of course, is a growing epidemic in our country. That includes a growing number of Medicare beneficiaries as well. It's critical for the policy makers at CMS to ensure access to the necessary testing and treatment for this growing disease. The purpose of the meeting -- oh, and the -- at the same time that we do that, we also must ensure consistent with our mission that we are prudent stewards of taxpayer dollars, and pay appropriate for -- pay appropriately for the important components of care, such as diabetic testing supplies. The purpose of the meeting today is to initiate a process consistent with our legal requirements to consider whether changes to the fee schedule amounts for diabetic testing supplies, furnished by non-mail order suppliers or what we term retail entities, should be adjusted to more reasonable levels under the Inherent Reasonable Statue and regulations. So the question that we're asking today, and that we're seeking input on, is whether the current fee schedule is reasonable, or

whether Medicare should propose some more -- or some other price. IR or inherent reasonableness is a two step public process. The first part of the process involves seeking public input as we consider whether or not to even propose such an adjustment. The second part of the process is, if we were to make such a decision to propose something, actually, proposing a policy, listing our methodology in the federal register and seeking a second round of public input, and then, consider public comments over a 60 day comment process, doing a final notice very much like a rule and moving forward with implementation. So really, a two step process. So, consistent with that, we are not proposing a specific methodology or data source today. And I would emphasize, we've not made a decision yet, to move forward and advance such a proposal. We're really just engaging stakeholders to obtain input on the reasonableness of the current fee schedule amounts as part of the deliberative phase of the process. After hearing from affected suppliers, CMS will make a determination regarding whether to propose adjustments to the payment amounts. A specific proposal to do so would, again, be set forward in the federal register, and, after a period of public comment, as I mentioned, a final policy would be crafted. Again, we very much appreciate your participation in this first or initial phase of the process. Our policy staff, technical staff, physicians, and other from CMS are here to listen, and we look forward to your input. So again, thank you very much for participating today.

Linda Howard:
Thank you, Laurence. Now, our Director of the Division of DMEPOS in CM's Chronic Care Policy group, Joel Kaiser, will provide an overview of inherent reasonableness of fee schedule amounts for non-mail-order diabetic testing supplies. Joel?

Joel Kaiser:
Thank you Linda, and, once again, congratulations on the well deserved milestone. I want to thank everyone for coming today, to participate in the process. I'm going to walk you through the slides that will explain the inherent reasonableness process and talk about, you know, what the issues are that we want to discuss and get supplier feedback on today. I'm going to have to put this up here so I can see. Too dark down there. I want to repeat -- the purpose of the meeting is to obtain consultation from representatives of suppliers regarding the inherent reasonableness of the Medicare fee schedule amounts for non-mail-order diabetic supplies. For those of you who don't already know, inherent reasonableness is the term commonly used to describe the authority provided by the statute for adjusting grossly excessive or grossly deficient payment amounts. That is, payment amounts that are not inherently reasonable. For a long time -- long time folks associated with the Medicare program, you might remember the reasonable charge days, where inherent reasonableness was a process that was developed administratively under the reasonable charge process when the reasonable charges weren't so reasonable. It then was later extended to fee schedule amounts by the OBRA-87 legislation. Receiving consultation from suppliers likely to be affected by any change in payment is a mandated step in the process for using this authority. I would say the most important thing I could say, as part of my presentation, and main discussion point today that we need to hear supplier feedback on, is that the threshold for a grossly excessive determination is any amount that must be adjusted by 15 percent or more to produce a realistic and equitable payment amount.

On to competitive bidding. Competitive bidding is the program that applies to all DME items other than covered class III equipment, that is, items that are classified as class III items by the

FDA; Group 3 complex rehabilitative power wheelchairs and related accessories, and inhalation drugs administered through nebulizers. When phasing in items, the statute mandates that high volume, high cost items be phased in first. For diabetic testing supplies, we have phased in those supplies, furnished on a mail order basis. The decision to phase in mail order diabetic testing supplies under the program first does not eliminate the mandate to phase in competitive bidding for non-mail-order diabetic supplies.

So given the volume, non-mail-order diabetic supplies is a high priority category for phasing. As you can see from this list, most of the major high volume high cost items have already been phased in. The national single payment amounts that will be established through the competitive bidding program for mail order supplies will take effect July 1, 2013. A revised definition of mail-order, that includes all deliveries of supplies to the beneficiary will also take effect on this date. In addition, contract suppliers will be allowed -- I'm sorry, will not be allowed to automatically switch the beneficiary to a different model, monitor, and tester. We call that the anti-switching rule. The national mail-order contracts and payment amounts will apply to all diabetic testing supplies other than those the patient obtains in person at a local pharmacy or storefront.

So, competitive bidding for non-mail-order diabetic testing supplies. This would involve awarding contracts to enough local pharmacies and storefronts capable of meeting demand for non-mail-order diabetic supplies in each competitive bidding area. Based on the competitive bidding regulation, we could have as few as five suppliers per area. All other local suppliers would be unable to receive payment for furnishing non-mail-order diabetic supplies. Adjustments in the payment amounts can be achieved through either competitive bidding or inherent reasonableness. With inherent reasonableness, all non-mail-order suppliers would have the option to continue furnishing the items to Medicare beneficiaries.
Diabetic supplies is the only category of items that has been bifurcated for competitive bidding purposes. This creates a unique situation where adjustments in payments for one mode of delivery is achieved before the other. As the price adjustment for mail-order becomes national in scope, the price discrepancy also becomes national in scope, making it important to address pricing for the other mode of delivery. Since many of the components of the costs of mail order diabetic supplies are similar, or identical, to the cost of non-mail-order diabetic supplies, we also feel that this creates a very unique opportunity for use of the inherent reasonableness authority. As we phase into competitive bidding programs, each time we phase in a round of competitive bidding, we announce the product categories that will be bid in each round. On April 17th, we announced the product categories for the re-compete of round one, those nine round one areas. We decided not to phase in mail-order -- I'm sorry -- non-mail-order diabetic supplies as part of the round one re-compete because wanted to consider this unique opportunity to use the inherent reasonableness authority first.

So, with the IR option, we can potentially reduce the price discrepancy between mail-order and non-mail-order diabetic supplies sooner than if we pursued the competitive bidding option. This allows all contract suppliers -- I'm sorry, all enrolled suppliers, such as community pharmacies, to continue furnishing diabetic supplies to Medicare beneficiaries who prefer to pick up their supplies in person and that allows them to have a face to face conversation with a pharmacist if they prefer to do that. And this could be something that someone wants to do as opposed to

speaking over the phone with the supplier. So that's why we think this is an important choice to maintain for beneficiaries.

Walking through the steps of the inherent reasonableness process, which are outlined in the regulation. First thing we have to do -- or one of the things we have to do, is a thorough impact analysis. This is where we consider the potential impact of special payment limits, payment adjustments, on quality, on access, on beneficiary liability, on assignment rates, and on participation of suppliers. Participation meaning that suppliers elect to be participating suppliers and accept assignment on all claims. Another important step is the step we're having today, the supplier consultation, where we consult with representatives, as I said, of suppliers likely to be affected by any change in payment. The third step is where we get into the formal federal register notice process. If we make a determination that Medicare payment amounts are not inherently reasonable, then we do a -- go through a federal register notice and comment process, which starts with publication of proposed -- of a proposed notice. And a proposed notice would explain the factors we consider in making a determination, number one, that the payment amounts are grossly excessive or deficient. And number two, our proposed payment amount or methodology for establishing an amount that's realistic and equitable. We explain all the factors and data that we consider in making these determinations, and the potential impacts. Then we allow for 60 day comment period, for the regulation no less than 60 days, on the proposed payment limits.

I do want to make a special note here, at this time, that we have seen some press on this issue. And some of the press does have some inaccuracies. It indicates that IR adjustments are limited to changes of 15 percent per year. I would point out that that limit only applies to adjustments made by CMS contractors by carriers. That limit does not apply to adjustments made by CMS. After the 60 day comment period, we publish the final notice. And the final notice, again, explains the factors in the data considered, this time, in making the final decision on whether to make an adjustment and what the new payment amount or methodology would be. We respond to the public comments and we provide the effective date for the change.

And now, we're going to have our public comments on the issue today. And we request your consultation on the issue of whether the current fee schedule amounts for non-mail-order diabetic testing supplies are grossly excessive. I would remind you that, per the regulation, grossly excessive is defined as any adjustment that needs to be made in a payment amount of 15 percent or greater to arrive at a realistic and equitable payment amount. And I would close with saying, please note that a decision not to pursue inherent reasonableness adjustments does not eliminate the mandate to phase these items in, under the competitive bidding program. Thank you.

Linda Howard:
Thank you, Joel. Now, we're going to proceed with our comments. Everyone should have registered at the entrance of the auditorium, and had the opportunity to sign the commenters list. If not, anyone wishing to comment can sign up there at any point during the meeting. We ask that when you come to the microphone in the center you please state the name of your company or organization. You will have a maximum of 10 minutes to comment. And as I said earlier when you are at the nine minute point, I will ring the bell, so you have a minute to wrap up. Our first commenter is Alan Rudy. Alan?

Alan Rudy:
Good morning. First of all, my name is Alan Rudy, I'm with Red Cliff Medical. It's good to see some of you folks again. The inherent reasonableness in this case idly should be supported all to the elimination of the KL modifier completely so there's no distinction between the mail order and retail. However, short of that, I think there is something else that's reasonableness which does not require the same public comment, the rule change, that will also save Medicare between 15 and 60 percent and that can be achieved through CMS confirming its previous written position that a Medicare supplier may drop ship items at a retail pharmacy with a first supplier, the mail order supplier still being the supplier of record. These comments were from 2004. Essentially, what would happen would be the mail order company becomes the supplier for that patient. The patient can either get the supply through mail order or go to the retail pharmacy and pick them up. In this case the mail order supplier saves on shipping and tracking of the items because the patient will sign for the delivery at the time of the pickup, save the expense of operating call center, computer systems, the process order taking, also it helps the Medicare beneficiaries due to the ease of either picking up or getting through mail order, so they have a choice which is one of the things I noticed on your earlier comments. The retailers that we've spoke to like this concept because at the moment they're losing money on the diabetic supplies, primarily due to the excess paperwork they have to do for these supplies. It increases the walk-in diabetes traffic which the retailers like because of the basket of purchases. It empowers the independent retailers to compete with the big chain pharmacies on their services, which is I believe one of the big issues of the smaller chain retail pharmacist said they're concerned about what can happen with this rule change.

The Medicare beneficiaries save money because they are actually going to pay less, they're going to pay the mail order rate rather than at the retail rate and I'm suggesting even the -- what ultimately becomes the mail order competitive bid rate which should be dramatically less than what the retail rate is at the moment. They can continue with their current mail order supplier who has all the paperwork that seems to be a big issue with the patients collecting all the right documentation so that it can be billed to Medicare. They also increased access to the items so they can either go to mail order or retail. We estimate that this save s the Medicare Trust Fund about one hundred million dollars annually and which is dramatically less than the -- I'm sorry – the reimbursement per item is somewhere between 15 and 60 percent less than what is currently being paid at retail. This also -- the Medicare Trust Fund will have less over-utilization, less waste, and reduced fraud because the patient goes in and actually picks up the supplies so they're less susceptible to perhaps a slick talking person over the telephone suggesting how to get the maximum order even when they have lots of supplies in their closet. Instead, in this case, the patient will go in and ask for supplies at the retail pharmacy. We did express this – we got in front of CMS, in front of some of the folks that are here now and asked for a ruling on this to say, "Can we go ahead and be the supplier at the mail order supplier and have the patient pick up the supplies at the retail pharmacy and bill with the KL modifier at the lower rate?" And the response we got was no for three reasons. One, one supplier may not use the enrolled location of another supplier to furnish items because they cannot ensure the other supplier's location complies with federal requirements intended to safeguard the beneficiary and the Medicare program. However, it is common practice when a -- at least in our business - when a patient is out of town and needs oxygen for example, they'll allow the patient to go pick up the items from

another supplier, so if I've got a patient who's on vacation in Topeka, Kansas, they need a new bottle of oxygen, they can go to the local Topeka, Kansas DME supplier, somebody that we work with, that supplier bills us at a wholesale rate, we then bill Medicare and the reason we, the primary provider for that patient bill Medicare because we have all of their documentation, their AOB, insurance, CMNs, etc. So we're the ones that bill Medicare. Perhaps what's missing here, because there's so much attempt to make sure mail order doesn't bill as retail. There's a definition that says there can only be one retailer biller at a particular location but a retailer can certainly drop ship.

Number two, the second reason was must have a Medicare supplier number at the address. The provider must have a Medicare provider number at the address where the product is dispensed. However, it's common practice to drop ship items to Medicare beneficiaries from approved Medicare Distribution centers, including everything from sleep apnea supplies, wheelchairs, etc. It's very common to drop ship so if it's okay to drop ship, normally, why couldn't we drop ship from a retail location. Retail pharmacies are currently approved Medicare suppliers so I think they would fit that definition. The third reason we got was competitive bidding will eventually lower the price of retail. I'm very happy to see here that you're finally looking at retail with inherent reasonableness to get retail in line with mail order certainly is a dichotomy in the market that is causing a lot of -- lot of concern not only on the supplier's part but on the beneficiary part, however the statement of competitive bidding will eventually lower the price of retail, I want to remind this group that retail has been exempted from competitive bidding including round one in 2003, which took an inherent reasonableness reduction across the board, except for retail. Retail is exemptive from competitive bidding in the round one rebid and round 2 and retail was given a cost of living increase while mail order was not. So for nearly a decade, retail has been exempt from competitive bidding. I'm not sure that the statement "competitive bidding will eventually lower the price of retail" is necessarily accurate. By going in and saying it's okay for a mail order company to drop ship from a retail location, it's the retailer's to say "yes, I'm happy to work with a drop shipper." If the mail order company say, "I'm happy to work with a retailer because of the lower costs, it makes the beneficiary happy because they're paying a lower price. All it requires from this group is to say, "It's okay to drop ship from a retail location." That's all of my comments. Any questions? Thank you.

Linda Howard:
Thank you, Mr. Rudy. Our next speaker is Larry Pliskin. [unintelligible] All right, our next speaker is Linda Langiotti.

Linda Langiotti:
Thank you for pronouncing my name correctly, that's a rarity for me. My name is Linda Langiotti I'm with a quality diabetes care coalition. We are the QDCC. The QDCC was established in 2008 and it's comprised of the largest Medicare Mail Order Diabetic suppliers serving 1.2 million Medicare beneficiaries living with diabetes. We are an advocacy in education organization dedicated to insuring Medicare patients living with diabetes continue to have access to needed diabetes control products. We educate policy makers and the public about the importance of home delivery supplies from Medicare patients with diabetes and support policies to ensure the continuation of a reliable mail order benefit. As previously stated in the presentation, mail order was brought into the competitive bid program and the retail setting was

excluded. By eliminating diabetes test strips through the non-mail order sector, the CMS has eliminated savings to the system. In no other category was a product excluded based on the method of delivery. If you look at walkers, they have the same price regardless of whether they come through the mail order or non-mail order channel. Walkers are available in a retail setting. If you review the competitive bid data, in 2008 in the first bid process, in the 10 CBAs diabetes achieved 43 percent savings in 10 markets. In the rebid of round one, the 2011 savings were 55 percent savings in the nine CBA markets. Prior to competitive bidding, a bifurcated rate between channels did not exist. Using inherent reasonableness to eliminate the grossly excessive payments for the non-mail order is appropriate and supported by our organization. In regard to grossly higher payment amount, we have been on record since 2008 in the opposition of the bifurcated payment approach which has resulted in over payments by the Medicare system for the same diabetic supplies wasting hundreds of millions of dollars and tax payer dollars and beneficiary costs.

To illustrate the point, in round one rebid Orlando, Florida; the retail reimbursement for a 50 blood glucose strips is $36. That is 148 percent greater than the competitive bid rate of $14.50. This means Medicare is paying nearly two and a half times the amount for the exact same product. There is no difference in product here. Similar to payment discrepancies it exists in all of the other competitive bid areas in round one. Since the vast majority of diabetic testing supplies are for resupply, there is no justification for two and a half times over payment for the exact same box of strips. While many will argue the face-to-face counseling and education, Medicare has excluded the actual monitor from competitive bidding. They did so by saying in 2010 that would enable the beneficiary to have access to any provider they want including the provider their physician or healthcare professional recommends. Since the patient must be trained on the meter, this enables the patient to have options at time of set-up and training of the meter. Both mail order and non-mail order must assure training for the patient. There is no distinction in our services there. The claims that non-mail order suppliers have a unique responsibility to the beneficiary are incorrect and do not justify an excessive payment.

Cost structure and acquisition costs. Despite the gross overpayment in the mail order setting the cost structure for both channels are similar and I would argue for mail order potentially higher. In the mail order we are required to get stringent accreditation and licensure in every state. In addition as a mail order program moves to national competitive bid, the mail order is also required to not switch patients and provide 50 percent of the products by volume. These protections are not provided to beneficiaries in the non-mail order class. The QDCC would recommend that in addition to limited in any price differential, for the reimbursement that CMS also consider including the 50 percent and anti-switching rules to the retail setting. Some have suggested the acquisition costs in a non-mail order setting are unique and different for mail. Claims that product mix is a proxy for a higher fee structure are incorrect. When diabetes test strips are covered under a DME or medical benefit, there is one HCPCS code and one price. There is no price differential by brand in the program.

Grossly higher payments based on other purchasers. When determining other payments as grossly excessive, one consideration is if the payment is grossly higher than the payment amount for the items are serviced by purchasers in the same locality. As we've discussed within the nine CBAs the overpayments are clearly excessive but I want to remind everyone in the nine CBA

markets the nationwide differential between mail and a non-mail order setting is 16 percent today. It is -- in addition, it is our experience that commercial plans, when covering test strips through a DME medical benefit which is the majority of the time, pay the same rate whether it is mail order or non-mail order.

Policy implications of the excessive payment for non-mail; the current excessive payments for non-mail diabetic testing supplies have resulted in a statistically significant shift from mail to the retail setting. We have seen aggressive marketing practices on behalf of retailers and manufacturers to increase the volume at the higher reimbursed levels. The payment discrepancy in denying the program significant savings and the loss of savings will increase as beneficiaries are incentive to move to the retail setting. Manufacturers have no incentive to lower their price as long as there is a system that allows a 55 percent greater fee schedule. Medicare predicted in 2011 rule making that beneficiaries would stay in the mail order channel. In fact the reverse is showing to occur. By creating two different markets for the Medicare program beneficiaries are experiencing the erosion of their popular mail order benefit. Mail order providers provide many services to beneficiaries other than convenience and lower cost. We all have diabetes care services hot-lines. We work with our patients to orient them to new meters and coach them through their first tests. We also check in with beneficiaries periodically to provide education materials and to assist them with complying with the prescribed treatment regimen. Scientific evidence demonstrates that patients adherence to prescribed therapy is a critical factor in stabilizing diabetic patients. Patient adherence is significantly higher in mail versus the retail setting. Treating mail order suppliers differently than retail threatens the ability of mail order suppliers to provide these services. We have been made aware of opponents suggesting that the eliminating of the diabetes test strip, its over payments and non-mail, that the beneficiaries would not receive quality products or have access to brand. To suggest that mail is not offering quality products is inaccurate and untrue. It is unlawful to provide a non-FDA approved device or non-FDA approved strips. In fact the Medicare supplier standards require you to provide FDA approved products and violation of that standard results in disenrollment from the program. To suggest that mail order does not provide access to branded products is also inaccurate and misleading. The Medicare improvements -- Medicare Improvements for Patients and Provider Act of 2008 established the 50 percent rule. This means mail order providers must cover at least 50 percent by volume of all types of diabetic strips on the market and this rule goes into effect July 1, 2013. This provides appropriate mechanism to assure brand access to beneficiaries. As stated previously, the QDCC strongly encourages CMS to provide beneficiaries the same protection in the retail setting and evaluate the need for the 50 percent rule in the non-mail channel. The bifurcated fee schedule within Medicare's own reimbursement policies between mail and non-mail creates an invitation for waste, fraud and abuse. The excessive payment for non-mail order is self-inflicted, is a self-inflicted disparity that is easily addressed by reestablishing the same payment for these products regardless of channel. CMS stated in testimony before the Senate Finance Committee on March 2, 2011 that disparities between cost of goods and services and allowed reimbursement often make Medicare a more attractive and lucrative target for those attempting to commit fraud. The OIG and the GAO and other independent analysis have repeatedly highlighted that a fee schedule price is paid by Medicare for many DMEPOS supplies are excessive. These inflated prices in turn increase the potential profits of those intending to defraud the Medicare program. We have provided the agency with

multiple examples of aggressive tactics that are being used to seek the higher reimbursement channel through advertisement.

In conclusion, we applaud the agency for initiating this stakeholder session. We agree with CMS that the agency needs to immediately eliminate the pricing disparity and gross overpayments in the non-mail order setting for diabetes testing supplies. We support the use of IR process as it provides the most efficient, timely and beneficiary friendly solution to addressing excessive payments. It guarantees full access in a non-mail order provider, unlike mail. It eliminates excessive costs and out-of-pocket expense for the program and beneficiaries and it can be implemented in a timely fashion. Operating a separate C-Bid program for this product category is unnecessary, would only exasperate and persist in the problems of having two categories and payment for the exact same supplies. A single price is the right policy, in fact the agency is always operated with a single price for diabetes testing supplies prior to competitive bidding. In just two years time the program has experienced the negative implications of this policy. As we look at the erosion of the mail order benefit, a distorted market place, increased risk for program for waste, fraud and abuse, loss of savings for taxpayers and increased out-of-pocket cost for beneficiaries. We urge timely action in the full removal of a discriminatory payment policy between mail order and non-mail order. Thank you.

Linda Howard:
Thank you very much for your comments. Our next commenter is Mike Iskra.

Mike Iskra:
No Comment

Linda Howard:
William Popomaronis

William Popomaronis:
Good morning. Do I lose two minutes because I missed the bell? Oh, okay. Just wanted to make sure. Good morning everyone, Bill Popomaronis, I'm from the National Community Pharmacists Association, appreciate the opportunity to share some comments with you.

As CMS is considering cutting payments to pharmacies for diabetes testing supplies, NCPA would like to take this opportunity to share our views and concerns for our members. NCPA represents the interests of pharmacy owners, managers and employees of more than 23,000 independent community pharmacies across the United States. NCPA has a strong interest in this issue because independent community pharmacies serve as a critical access point for diabetes supplies, other DME, and especially trying to help persons with diabetes. Community pharmacists are indispensible to helping combat diabetes whether it is the counseling we offer, the medications they dispense, the lifestyle modification classes they provide or a wide variety of testing supplies they carry. Community pharmacists have always played an active role in helping patient cope with diabetes through prescription management, dispensing supplies, such as glucose meters, therapeutic shoes and vital diabetes education services. I want to focus on this point for a second. The pharmacies that I have owned and I have owned 15 and have been in this business for 25 years, we have provided therapeutic shoes, we have provided diabetes education,

medication therapy management. These services were enacted by congress, they are face-to-face services for the most part, best provided in that format. It seems to me not to make good sense to separate and yank out strips by lowering the prices for whatever reason we feel on this day and having pharmacists drop out of the program or having it become tougher for beneficiaries, especially our most fragile seniors, the ones that are used to talking to me over a period of 10 to 15 years, the ones that I've seen their kids grow up, the ones that I've seen that I've taken care of for 20 years going to the nursing homes, going to the assisted living centers that trust me, not the voice on the phone. They trust me and they want to get these items from me. It seems ludicrous that we would talk about yanking this away by making it so difficult for small independent pharmacies to continue to provide the services at the low margins that already exist. Face-to-face counseling for the medication they dispense, independent community pharmacies obviously play an essential role in improving healthcare outcomes and decreasing long-term care costs. However, that dynamic will be harmed if these small business pharmacies are forced to walk away from the pricing structure for diabetes testing supplies that only a large self-warehousing chain pharmacy or mail order suppliers can make work. We're not talking about bent metal here. We're not talking about walkers. Why are we looking at this benefit in a vacuum? Why aren't we looking at the fact that if we can get, as community pharmacists, the patients to adhere and persist and take and test their -- and take their medications properly, take test with diabetes testing supplies, utilize the hemoglobin A1C benefit, take the diabetes education, why are we looking at it in a vacuum?

If part B utilization goes up or somebody using supplies, and drugs go up, the part B benefit goes up, but ultimately we stop that patient that pricks their foot, ends up going into the hospital because of a wound care problem, has one leg amputated, five years later the other leg amputated, that Medicare part A benefit is going to go through the roof. Why are we -- why are we not looking at this as the entire Medicare program? Why is it the Medicare Part B watch and everything else is excluded? I'd like to know if you all have any evidence that shows the impact going forward as to what happens when you pull these part B benefits away, these diabetes supply benefits. And we've only had competitive bidding for a year and I don't think that that's enough time, you know, to recognize this. And I get a little bit of heartburn when I see 87 percent of independent pharmacies and others not able to fill out a CMS 1500 properly. Having that money clawed back when these small pharmacies are doing nothing more than trying to help the person that they've been dealing with for 20 years. They get disenfranchised, they say, "What am I going to do? How can I continue to provide this benefit?" So what happens, the beneficiary suffers. The beneficiary that's been going to me says, talk to somebody they'll help you out, they'll take care of you just like I do.

In addition to all of these requirements, CMS proposing cutting pharmacist payment. If the CMS goal is to drive retail pharmacy out of the program, it is working. But independent pharmacy is a provider that you can least afford to lose. We have five points that we want to share with you.

NCPA believes that inherent reasonable could be used as a substitute for competitive bidding. But we are concerned that CMS is using mail order reference pricing as a test of reasonableness. For retail pharmacies an entirely different market. To say that everything should be in a nice neat package, one HCPCS code is ludicrous. We do not buy at the price that warehousing chains buy at, or at the price that mail order buys at. This isn't a classic trade issue. This is a volume

driven business and there's no way, even with 15 stores that I had I'd be able to buy at that pricing. Independent community pharmacies can not purchase diabetes supplies at the same prices, community pharmacies do not have the volume for diabetes testing supply business to keep their doors open and they must also purchase a wider variety of products. Let's talk about that a second. It's really nice to be able to say I could have a round one bidding, one particular item, even at 50 percent of the market in the round 2 competitive bidding, great. A lot better, but what about the doctors and the endocrinologists and the certified diabetes educator and those that feel that a particular meter or product is going to serve their patient better. Well you know, the decision is now out of their hands, and it's in the hands of those that are not appropriate healthcare professionals, but as a pharmacist because I have relationships with those people, I had to stock these products. So it's not, its apples and oranges, we're not talking about the same thing here. Excuse me. Even with retail community pharmacy there are different costs to purchase diabetes testing supplies for chains and independents. Independents purchase at a higher price, that's a fact folks. Yet, tend to offer a higher level of services for a diabetic patients, as I've said, therapeutic shoes and DSMT. CMS has presented no evidence that the fee schedule is grossly excessive as compared to the cost that we have to purchase at. Look at what we purchase at; decide whether that is an appropriate cost. I don't see any evidence that it' really out of line as it currently stands.

We have data from our pharmacies and private payer reimbursement shows that the current Medicare fee schedule rates are reasonable. If CMS is using mail order rates as the basis for determining retail community pharmacy reasonableness, this discussion is really a waste of our time, respectfully. CMS has taken a narrow view that savings and success for diabetes patients being driving down the costs per unit, I've share that. I think we have to look at this in a whole. This is completely contrary to the integrated care models approved and being promoted by the healthcare system, including Medicare, Medicaid, and the private sector. No where in this discussion is the enormous dollar amount that CMS is wasting on mail ordered diabetes testing supplies that are shipped and never used. NCPA is happy to provide CMS with countless examples of unused diabetes testing supplies that are handed out as part of a drug take back program, offered by independent pharmacies. Indeed we have already shared this with the OIG. One should look no further than one year implementation update to round one published this past April to see the large amounts of waste being generated by mail order supplies. Even CMS's own Jonathan Blum reaffirmed that at the NCPA conference that during round one of competitive bidding, the agency found a decrease in utilization of mail order diabetes testing supplies. A reduction likely due to the fact that mail order providers have been auto shipping and over supplying beneficiaries with these products. In the light of this wasteful mail order spending, Blum suggested that one could infer that community pharmacies could serve patients better than mail order. If small business independent pharmacies are forced to leave the part B program due to drastic cuts in the fee schedule, their patients will be forced to obtain diabetes supplies by other means and suffer significant impact. Do not discount the human touch that independent community pharmacies have with their beneficiaries. I can't believe that somebody that I've been helping that has had to move to an assisted living facility because we're concerned about somebody gaming the system that I can't deliver with my prescriptions as they've moved into the mail order facility, diabetes testing supplies. What are you telling me? That patient that I've helped, you know, all of a sudden we've got to get a healthcare professional from the assisted

living facility to come and get diabetes testing supplies. Why are we doing that? Why are we punishing the Medicare beneficiary by doing this? I don't understand that.

Also of grave concern -- well, I've talked about that. Since only six to eight percent of the average independent pharmacy's annual sales are from DMEPOS, independent community pharmacies sell diabetes testing supplies to provide a service to beneficiaries and not because of a large profit. Even CMS in its preamble to its 2010 proposed rule competitive bidding noted the value of a licensed pharmacist being on hand to offer guidance and consultation to beneficiaries.

And that's it. Okay, I'll, let me just say this to you. Five seconds. My mother died of diabetes, okay. It is a disease that's worse than cancer because it takes a piece of you little by little. These beneficiaries that are coming into my store to see me are fragile, they're frail, they don't trust anybody, they're concerned about people calling them on the phone or knocking on their doors trying to steal from them and take whatever life that they have left. Let them come to someone that they can trust. Let us continue to provide the services at a fair and reasonable price that will help them enjoy their senior years. Thank you.

Male Speaker:
Thanks, Bill.

Linda Howard:
Thank you very much for your comments. Jonathan Napier.

Jonathan Napier:
Good morning. My name is Jonathan Napier and I am pleased to be here today to provide you with comments on behalf of CCS Medical. CCS Medical is a national provider of services and supplies for those living with diabetes, ostomy, urology and wound conditions as well as those in need of medications for chronic conditions. One of our core competencies is the provision of diabetic supplies. CCS Medical offers disease management services provided by certified diabetes educators through hotlines. We work with our patients to help orient them to their new meters and coach them through their first tests. We also check in periodically on our patients and provide educational materials that assist them in complying with the prescribed treatment regime. As a partner and supplier to Medicare beneficiaries, CCS Medical appreciates the opportunity to comment today on CMS's proposed use of inherent authority, which impacts not only our business and industry but also the Medicare beneficiaries our industry serves.

As CMS explained in its notice in the June 26, 2012 Federal Register, the Medicare allowed payment amount for mail order diabetic supplies and retail diabetic supplies very significantly depending on a beneficiary's choice of retail or mail order delivery. This discrepancy is the result of the 55% reduction to the mail order diabetic supply payment amount but not the retail payment amount in nine competitive bidding areas through the competitive bidding program. CCS Medical agrees that the Medicare payment amount for identical diabetic supplies should be the same regardless of whether those supplies are delivered through the mail or through a retail outlet. Therefore, in this unique situation, we support CMS's use of its inherent authority to end the payment disparity for diabetic supplies furnished by mail order suppliers compared with the same supplies, exact same supplies, furnished by retail suppliers.

CMS is authorized by statute to adjust prices for durable medical equipment including blood testing strips for individuals with diabetes before 2016 by using inherent authority. In electing to use inherent authority, the Social Security Act and the CFR set forth the process that CMS must follow in determining whether a payment amount is grossly excessive and in setting a special payment limit. Of course, CMS is meeting the requirements to consult with the representatives of the supplier industry via this meeting. If CMS makes a payment adjustment of more than 15% under its authority to exercise inherent reasonableness then CMS must review the market prices in the years after the year of initial reduction in order to ensure further reductions are appropriate. CMS will meet this requirement through the ongoing competitive bidding program.

CMS must consider the potential impact of payment adjustments on quality, access, beneficiary liability, assignment rates and participation of suppliers if CMS makes a payment adjustment of more than 15%. CMS has demonstrated its consideration of those issues through the Federal Register on June 26. We encourage CMS's continued consideration of those issues throughout the inherent authority process and we provide our comments today for those considerations.

I want to talk about the impact on the beneficiaries. CCS Medical supports the inherent authority process to ensure the Medicare beneficiary has choice and access in their procurement of diabetic supplies. The unreasonable payment amount for retail diabetic supplies requires a larger copayment from the beneficiary and can limit choice. The comparatively high payment amount to retail suppliers requires the beneficiary to pay a higher co-payment for an identical supply the beneficiary could receive through a mail order supplyment [spelled phonetically], supplier with a lower co-payment. Even when the beneficiary has supplemental insurance that covers the co-payment, that discrepancy causes an unreasonably high expense upon that supplemental resource. Therefore, CCS Medical believes CMS should use its inherent reasonableness to protect those beneficiaries and those beneficiary resources from the overpayment because those products are readily available nationally at significantly lower prices.

I want to turn to the excessive payment amount issue. In addition to protecting the interests of the beneficiaries, we believe that the discrepancy between the mail order suppliers and the retail suppliers is grossly excessive. We need CMS to align the amounts between mail order and retail. First, CMS is the primary purchaser of diabetic supplies in the United States. In 2011 alone, Part B allowed charges for diabetic supplies totaled 1.6 billion. In 2010, Medicare paid 1.4 billion for strips, making them the fourth largest Medicare item or service expenditure. According to the industry market data, Medicare and Medicaid purchase over 35% of all diabetic testing supplies. This data suggests that CMS should consider Medicare to be the primary purchaser when they consider the amount that the discrepancy to retail suppliers to be grossly excessive.

Second point I'd want to make under grossly excessive, the payment amounts for diabetic supplies are substantially higher to retail than the payment amounts to mail order. As many people have noted, the competitive bid process resulted in a 55% reduction.
One of the arguments I have heard and that you will hear is that retail suppliers purchase in lower volumes than mail order because it's not their core business. We recognize that it isn't their core business but we don't agree that buying in lower volume actually creates substantially higher acquisition cost and certainly not enough to justify the excessive payment discrepancy for those

identical products. It's well known throughout the industry that retail suppliers do have access to many volume discount programs, group purchasing organizations, pharmacy benefit managers and the major wholesalers. All are active in this space. Those allow retail pharmacies, in fact, to have access to comparable purchasing prices for the supplies comparable to what mail order has.

The third point under the, to demonstrate the grossly excessive payment amount, retail suppliers don't have to compete with mail order suppliers in one competitive market. The retail market is segmented and because of the regulatory factors that protect its payment amount from the broader competition that everyone else has to detail with, in this protection, this artificial payment amount, it truly distorts the supply to the detriment of beneficiaries. Mail order suppliers are forced to operate efficiently and competitively while their retail counterparts have, avoid that competition and receive a much higher payment amount.

Retail suppliers -- I want to talk about face-to-face counseling, which, we've heard some today and you may hear more about. Suppliers often contend that face-to-face counseling justifies the excessive payment discrepancy. CCS Medical doesn't agree that these are grounds for an excessive payment. Phone-based counseling for patients with diabetes, like the service that CCS Medical provides, has been proven in peer-reviewed journal articles to be successful at clinical improvements as well as influencing healthy behavior. Additionally, CCS Medical provides counseling versus, via certified diabetes instructors. CDEs provide several benefits to a beneficiary that a retail pharmacy may not be trained to provide and may not be providing. Counseling for patients is clearly valuable but the provision of face-to-face counseling by retail suppliers cannot account for a 55% payment discrepancy, given the fact that mail order suppliers already provide very effective phone-based counseling.

Another point we need to make when we're talking about the counseling component is that the payment amount is for the actual supply only. If CMS finds value in diabetic counseling services, and we would be happy to meet with you to discuss and demonstrate that value, then CMS should establish a separate payment amount for those services. But at this time, CMS should not entertain an argument that face to face counseling warrants a grossly excessive payment amount to one supplier over another for identical products.

Finally, I'd like to talk briefly about the regulatory burden. With regard to comparing mail order and retail prices for diabetic testing supply, CMS states that several key cost components are identical for both, such as product acquisition costs and administrative costs including claims processing and paperwork costs. We agree that administrative cost components should be identical for retail and mail order suppliers. We think the inherent reasonableness authority process presents an opportunity to review if the costs are, in fact, the same. Many current Medicare reimbursement requirements place heavier burdens on mail order pharmacies than retail pharmacies and consequently make it administratively more complex and therefore costly to meet beneficiary needs via mail order.

For example, DME suppliers can only contact beneficiaries by phone if the supplier has received written permission from the beneficiary or furnished a Medicare-covered item from the beneficiary and are contacting the beneficiary about that item. Another example the regulatory discrepancy is the requirement in CMS's national mail order competition that mail order diabetic

suppliers carry at least 50% of all types of mail order strips. Mail order suppliers must contract with many manufacturers to meet this requirement and it reduces mail order's ability to get those volume discounts from suppliers. On the other hand, retail suppliers can negotiate better rates by supplying fewer manufacturers. Despite the absence of negotiating power restriction, those suppliers receive a comparatively excessive amount for the strips. CMS should collect data on the administrative burdens placed on mail order and retail suppliers through the DME MAC, documentation review, medical necessity reviews and audits. In addition, CMS should take into account the costs incurred in appealing DME MAC determinations to the extent that those determinations are overturned on appeal. CMS should also consider the administrative burdens placed on mail order and retail diabetic suppliers by other contractors such as ZPIC and RACs. We encourage CMS to catalog any differences in its administrative requirements between mail order and retail either at the national level or through one of its contractors. Where there are differences in requirements and burdens, CMS should equalize the requirements and burdens or adjust payment amounts to reflect higher requirements.

In conclusion, the large payment disparity between retail diabetic supply payments and mail order supply payments, amounts necessitate CMS to use its inherent reasonableness authority to protect beneficiaries and correct the imbalance. Several factors support the use of this authority including Medicare's position as the primary purchaser of diabetic supplies, the substantially higher payment amount to retail suppliers and the resulting uncompetitive market. Further more, CMS has the pricing data it needs to determine a reasonable payment amount. CCS Medical encourages CMS to use the inherent reasonableness process in this case to collect more information about suppliers. We believe the value added services provided by a mail order pharmacy must be considered in any payment amount determination. Finally, the assumption of identical administrative cost between mail order and retail suppliers should be validated through audit data collection and review of documentation requirements. Thank you.

Linda Howard:
Thank you, Mr. Napier, for your comments. Our next commenter is Daniel Nam.

Daniel Nam:
Good morning. My name is Daniel Nam. I'm an independent pharmacist, independent pharmacy owner and law student at St. Johns University. So I actually wrote a lengthy comment. It kind of killed my weekend. I wasn't able to see "The Dark Knight" because of this but --

[laughter]

-- it's kind of, I'm not going to read off of it because the law student in me kind of kicked in with the prior comments and I'd like to refute some of the things that were said. Well, first, let me give an abstract of what I was going to say, which is a very important point. As I look around the room, I question whether a lot of people here speak a second language. You know, that's a very, very big barrier when it comes to anything, especially with health. And as an independent pharmacy owner in a very diverse area, I know -- Mr. Kaiser, you said that some patients may prefer face to face but I'm here to tell you that some people require face-to-face counseling. The lack of language proficiency, cultural barriers and other economic barriers are things that the first

two and the prior speaker probably do not have studies on. They probably do not have official positions on. And, you know, this is something that's very, very important to me. Everyday, I see people come in, going to other pharmacies or whatnot, getting other supplies, getting, having to require to get medication from mail order, coming to me for counseling, asking me, "What the heck is this. Why was I sent this?" You know, "I got six scripts, I sent them in. Now I have this box of medications, I don't know what to do." They come to me. I'm the person that does this. And you know what? I'm happy to do it and I've been doing it for absolutely no cost. There's no profit in this. And I apologize for the prior speakers for all their regulatory, administrative burdens but, you know, who's apologizing for me? I'm spending hours a day giving out free advice. I still have loans. In law school, I'm practically going to come out with like $300,000 in debt. I'm not being paid for anything I do that's of service. And this is being translated to DME test strips, currently. I understand as a legal person that inherent reasonableness does have its basis, does have its use and it does have its place in the regulatory scheme. But I urge you to consider these factors that I bring up today. Is a pamphlet translated into Spanish or Chinese or Indian or Korean enough for someone to adhere to these test strip supplies? I don't think so. I don't read these things. Why should, I don't understand why my patients will either.

This is not about cost for me. And as you can see, I'm not bound by some organization or corporation. I can say whatever I want up here. I didn't get reimbursed on my travel costs. I hate ties.

[laughter]

You know?

But I really wanted to be here to make sure that this point is brought across because in the prior competitive bidding processes and in a lot of, or most or all of CMS's policies, this isn't, this is a oversight that is blatant and often times, I wonder if the lack of diversity in the field might result in this, you know.

So back to my rebuttals. I'd like to say that giving face-to-face counseling as, first time I'm hearing this, face-to-face counseling for us is just called counseling. It is realistic and I think that's one of the goals that you had brought up. Increasing adherence, increasing patient care quality through counseling is a realistic goal, is a realistic tool. Second, like I said, determination, determining -- inherent reasonableness isn't just about decreasing costs and cutting costs and cutting savings. It's about restricting access no matter how you see it. You look at your impact study, you're assuming there's going to be an impact on access to healthcare, you're just determining how much. This is not about costs but rather about restricting access. Access to vulnerable populations, not just people who are taking pain meds or, you know, just recreational meds or anything like that. These people rely on test strips. They rely on these tools to maintain their health.

Also, another thing I'd like to point out that inherent reasonableness, as it is, I guess not officially proposed but currently somewhat mushily proposed, is an option and not a requirement and this is a legal fact. You aren't required to look at the situation between mail order and non-mail order. This is something that CMS has determined and I think it's wrong. I've heard

"dichotomy" used a lot. Dichotomy between mail order and non-mail order and I believe that there is. And again, as a law student, I, it kind of, it amused me as to how these arguments were put on its head and proposed in a totally different light. I believe there is a dichotomy. I believe that with mail order, there's increased waste. People come to me with their excess test strips and say, "Do you want these?" I don't need them." I'm like, "No, I can't take those. You have to throw them out. There's nothing I can do about that." Mail order, in my experience, mail order companies auto ship and they auto ship indiscriminately and this creates a lot of waste.
I believe a comment was brought up with walkers and comparing diabetic test strips to walkers. Diabetic test strips are not walkers. And also, I've heard the word "product" used a lot. And I'd like to redefine "product" not as a box of 50s or hundreds or 25s. I'd like to define "product" as a delivery of a service, delivery of health. And this should apply not just for diabetic test strips, for anything we talk about. It's not just shipping mailing, shipping diabetic testing supplies through the mail. It's about delivering that service and delivering this product, this whole product, efficiently and productively.

I'm sorry, I'm trying to decipher my handwriting. I was kind of angry when I wrote it.

So also, another thing is detriments to beneficiaries. This is, this is a really bold-faced argument that people can make saying that decreasing costs or decreasing reimbursement for retail pharmacies will be a detriment, or not doing so will be a detriment to beneficiaries. I ask for any future person to really give an example of how Grandma or Grandpa will be wrongly affected by not having face-to-face counseling, by not being able to walk in with a trusting professional and talk about her or his needs. How, I encourage people to give one example of how that beneficiary will be adversely affected.

Another thing that I, a final thing that I would like to talk about is mail order does offer counseling. I acknowledge that. It's telephone counseling. They do offer pamphlet counseling. And where it comes to people with limited English proficiency and with cultural barriers, try talking to someone like that over the phone. How much can you get across? Can you effectively communicate to this person? One of the important things about minority health is that you need to feel like you belong to the system. Imagine you are someone who can't speak English. Imagine you've developed a relationship with your local pharmacist and all of a sudden, the pharmacist cannot compete. I can't compete. I, if you decrease my cost, my reimbursement, I will have to, I will have to drop out. I am telling you right now. I have reduced my services over the years to -- I can't supply wheelchairs, canes, walkers because of the reimbursement and diabetic testing supplies is the last straw. And if I can't, if I take a loss at every single thing that I, every diabetic testing box that I dispense, I can't, I can't participate anymore. So imagine your pharmacist who you've developed a trust with says, "I can't service you anymore. You have to call this number. You have to mail this. You have to go through the system." This person will, it's the equivalent of pushing away this person from the healthcare system. So again, I urge all of you to hopefully consider this as part of your analysis. Thank you.

Linda Howard:
Thank you, Mr. Nam, for your comments. Our next commenter is Sam Silak.

Sam Silak:

Good morning. Sam Silak with Liberty Medical Supply. Just as a mail order supplier, just have a few rebuttal comments versus a prepared presentation today. So we've heard a lot about MTM processes and education and meter training. You know, or the HCPCS codes that are at call here are not, are resupply. They are not meter trainings that have to be done in a face-to-face. Anybody who supplies a meter has to train a beneficiary on the meter. MTM services are just that. They are a service. So if, respectfully, if the groups that have spoken around services would like reimburse for that then a code needs to be established for that. I'm a pharmacist as well so understand where they're coming from but today in today's society, the HCPCS code in this class of drug is not a service, it is a resupply of blood glucose test strips, lancing devices, etcetera.

You also heard today around oversupply. I'd just like to remind everybody here that to be able to ship in mail order, we have to have consent from the beneficiary to do so at nearly exhausted rates. So I just, they talk about oversupply. It is, we are bound to have permission from the beneficiary to resupply the patient on any of the coverage supplies.

Also, you talk about multilingual requirements in the retail setting. Our accreditation, which we've spoken to through the QDCC, of having to be multilingual in our facilities to be able to be fully accredited by those agencies. So I understand that everyone gets comfortable with their pharmacist but based off of the requirements of a mail order provider, we have the requirement also to be multilingual. Education, as important it is and it is a service, just would like to reemphasize at Liberty, we do offer CDE telephonically to our, to the beneficiaries for diabetes education up and beyond just testing supplies. So with that being said, we have, feel like that we have all these same services available to members via telephony processes versus face to face. Thank you.

Linda Howard:
Thank you, Mr. Silak. Our next commenter is Bob Kusher.

Bob Kusher:
Good morning. Bob Kusher with LogiMedix and we provide diabetic supplies in conjunction with retail pharmacies. Personally, I got involved in the diabetic supply industry in 1988. I had been working in a retail setting. We were providing face-to-face services. At that time, I launched one of the first companies in the country that provided mail order delivery of diabetic supplies on Medicare assignment basis so that's a good bit ago. So I've kind of lived on both sides. I started in retail, I entered the mail order arena, worked there for close to 20 years and now I'm back working with retailers again.
I bring this to light because I will tell you, despite what you may have heard from different viewpoints, there are differences in the service provision. Mail order definitely does have a place. Not everyone needs face to face counseling on every visit or every time they receive supplies. We do have some patients that are limited in mobility and they are better off receiving supplies delivered to their homes. We have other patients that do need frequent face-to-face counseling and a level of support that could be better obtained through retailers. We also have some patients that live in cold climates, warm climates where temperature extremes may be a consideration in the delivery of their supplies and for those reasons, they may prefer to get their product locally as well. So I don't think it's a mutually exclusive arrangement or argument here.

I think both delivery models do have a place. Question is, should they be reimbursed at different rates? And I think from the folks that we've heard so far, obviously people are representing their various viewpoints, voting their pocketbook as it were. I'm sure if the mail order guys were getting reimbursed 37 dollars, they wouldn't consider the 37 dollar retail reimbursement to be inherently unreasonable. At the same time, the pharmacist or the community provider that has these extra level of services and believes, and probably rightfully so, that they are paying higher costs, whether it be brick and mortar costs or wholesale acquisition costs for goods, feels they are justified by being at a higher rate. So try to stay on point with the focus of our meeting today. Should we be looking at inherent reasonableness as a mechanism for adjusting price points here? Is that valid under the rational under which the inherent reasonableness authority has been bestowed upon CMS? And there are several reasons why inherent reasonableness may indeed make sense.

Some of those rational really don't apply here, whether it be for changes in technology or lack of competition in the market place, I don't think those are really relevant here. What may indeed be more relevant is, are there discrepancies that are warranted by acquisition cost, service provision cost, that justify that discrepancy?

I don't think what we're here for today is to determine if the rates between mail order and retail need to be fully and completely homogenized. I didn't see that on the agenda. What I did see is the question as to whether or not the rates paid to retailers for reimbursement of product and their delivery of service is indeed reasonable or is it not.

One thing I would ask is, if the panel does determine that inherent reasonableness is indeed an appropriate mechanism for making such a determination, that they adhere to the guidance in the creation of the inherent reasonableness authority, and look at other purchasers, as a whole, and not necessarily on the single metric of price points that came about from Round One Competitive Bidding.

The terminology for the application of inherent reasonableness talks about viewing other purchasers in the market place. So first, one perspective on it is, if Medicare is looking at payment through their own program, does that indeed meet the criteria of other purchasers? Possibly, possibly not.

Certainly, if you go look at retail as the mechanism for patients paying out of pocket for their own supplies, I think that you would find that the current Medicare reimbursement is at a discount when compared to the 50 plus dollar price point that patients who are uninsured have to pay for their own test strips.

Additionally, if you look at commercial insurance reimbursement, some of that is made through a DME, or medical benefit, and paid under HCPCS coding, and I think in that arena, the Medicare reimbursement that is paid to retailers is deemed fair market value, probably within the 15 percent guidance amount.

Separately, if you're looking at reimbursement paid through commercial carriers through prescription benefit, and we're seeing that more and more over the last decade. You're seeing

that products are paid for on the basis of NDC, or National Drug Code, rather than lumped under singular HCPCS code, and there you see substantial variation by product brand.

With the implementation of competitive bidding in a small sample size market, or markets, what we've seen leaves me to believe that the retailers could ultimately be subjected to adverse selection. There was cited earlier, by one of my colleagues, a shift in patient patronage from mail order to retailers in those markets. Whether they got displaced because their mail order supplier could no longer service them, they called Medicare, Medicare told them they could go to a retailer, or they simply ended up not getting supplies from a mail order because they did not need them. We have seen a market shift, patients returning to retail.

So, that begs the question, why? If the patient could no longer receive their supplies from mail order provider A, and was directed to mail order provider B, a bid winner, who said I don't carry brand X, you have to have brand Y, and they had a continued preference, whether it was indeed a preference or their doctors order, to use brand X, they then were more likely to end up going to a retailer.

So, yes, you could argue that all items are FDA approved, a box of test strips is a box of test strips, but there are substantial cost differences. In a retail pharmacy, if you have access to contracts via your GPO, or certain purchase arrangements through your wholesalers, and you're looking at product from, what we'll call the big four manufacturers, your average acquisition cost of goods for a box of fifty test strips, under contract purchase terms, is $26.69.

Certainly not competitive with what mail order providers are paying, at least for the product that's being provided at a $14.50 to $15.00 price point. So, when you look at, again, under the statements made relative to the invitation to this meeting, there were cited differences in operating costs and recognition that not all costs are the same for mail order versus retail, but there was also a statement made, or a presumption made, that the acquisition of goods is largely similar, if not identical.

And I can tell you that is very far from the truth for the small purchaser that is a retailer or an independent pharmacy. The Round One bid data, I believe if that is used as a metric in this determination, such usage is premature. Round One bidding did not require the adherence to the 50% rule, it did not require adherence to the anti-switching provision, and what we have seen is, that those folks that did win the bids, are predominantly using lower cost goods.

So they're acquiring product, which can be had in the market place now, at single digit dollar price points, in order to survive and profit under a $14.50 or $15.00 price. That is not the case for the retailer that is being responsive to a patient request, or a doctor's prescription, and providing them products from Abbott, Bayer, Roche, or Lifescan.

If it's the intention of CMS to say this is becoming a generic only market place, we're restricting brands, and we're going to pay it based on the lowest available cost, that's one thing. If we are seeking to preserve beneficiary access to the supplies of their choice or their doctor's prescription, retailers have been the conduit for that product, and in all likelihood, will continue to be so.

So, any steps towards treating this as a homogeneous marketplace, not solely on the basis of delivery, or even operating cost, but with disregard for the differential in product being provided and the associated cost pricing would be done in error. I believe we are going to see potentially higher, and maybe substantially higher, price points come about on the next round of competitive bidding, when it is indeed national.

If you look at the first round, many of the companies represented here, the largest mail order suppliers in the country did not participate or did not win first round bids. As we need to go ahead and meet the capacity of a growing nation of diabetic seniors, we are going to need to incorporate some of these large mail order suppliers in that bid process. And as the bid process is currently designed and implemented, that's going to result in a, at least slightly if not substantially, higher price point.

So if we get fixated on a first round result, and a small sample, of a $14.50, $14.80, $15.00 price point, I think we're basing our calculations and expectations on a grossly low amount, that not only fails to incorporate service provider costs and brand differential, but is based on something that may not turn out to be a true metric, July first of next year. Thank you.

Linda Howard:
Thank you, Mr. Kusher. Our next commenter is Bruce Levinson.

Bruce Levinson:
I'm Bruce Levinson with the Center for Regulatory Effectiveness, we're a regulatory watch dog focused on insuring agency compliance with the good government laws that regulate the regulators, and I'd like to start by thanking CMS for holding this meeting.

In addition to being part of your own process, it is a great example of the type of outreach activities that President Obama called for in his landmark memo on open government, which called for agencies to be transparent, participatory, and collaborative.

Now, the agency's Federal Register notice for this meeting said that according to your rules, you have to use valid and reliable data in determining whether a payment amount is grossly excessive or deficient, and CMS emphatically does not have valid and reliable data, and that's not my view, or CRE's, that's the view of over 240 economists from around the country, indeed the world, who wrote a letter signed -- and let's see -- said, this included several Nobel Laureates -- CMS competitive bidding program violates all of the principals, of President Obama's executive order on regulation, especially the principals of transparency and basing regulations on the best available sums.

Indeed, the current program is the antithesis of science and contradicts all that is known about proper market design. Wow, I mean, that's a really extraordinary statement. The antitheses of science, and the first signature on there is a professor from Princeton, and it goes through Harvard, Stanford, Chicago, Oxford, at least a half dozen faculty from the University of Maryland, and around the country, and I think the London School of Economics.

And they went on and provided some detail. Talked about non-binding bids, low ball bids, and said the problems with the CMS auction grow worse upon closer inspection. The complete lack of transparency is inappropriate for a government auction. Moving on from the letter, there was an article recently in the quarterly journal of economics, one of the oldest and most prestigious economic journals in the English language, and that was done by researchers at Cal Tech, and this had to go through all the rigors of peer review, as well as the journal's own standards, and they said, pretty much, the same thing.

The CMS auction fails to generate competitive prices of goods and fails to satisfy demand. The CMS auction performs poorly as a procurement auction. Result five, prices generated in the CMS auction do not approximate the competitive price, they are significantly, and consistently, lower than the competitive price. And, one of their most important statements, the challenge for those who are unconvinced by the evidence that the CMS auction will perform poorly, is to explain why the principles seen operating so clearly in the laboratory environment, will not operate when the auction is deployed in the field.

And the study was financed by the Gordon and Betty Moore Foundation with additional support from the National Science Foundation grant. Now the competitive bidding results from the Round One Rebid not only don't comply with CMS requirements for inherent reasonableness, they also don't comply with the quality standards established by OMB, by HHS, and by CMS implementing the Data Quality Act, an act passed by Congress which set standards for the quality of virtually all data disseminated by Federal agencies.

And that Data Quality Act contains a very unusual phrase, it's actually the only time I've ever seen it in Federal statute, and what the law does, is it gives affected persons the right to "seek and obtain" correction of the data that does not meet those quality standards. And if anyone here would like to learn more about the data quality act, and in particular, in participating in the exercise of your rights to seek and obtain correction of the bidding results prior to that data being used in the inherent reasonableness, please see me, I'll be here throughout the meeting. Thank you very much.

Linda Howard:
Thank you, Mr. Levinson. Our next commenter is Paul Radensky .

Paul Radensky:
Good morning. I'm speaking today on behalf of the Diabetes Access to Care Coalition. The Diabetes Access to Care Coalition comprises patient advocates, suppliers, educators, as well as suppliers of DTS, and we're committed to making sure that beneficiaries have access to high quality diabetes testing supplies through suppliers of their choice, consistent with the goals and objectives of the Medicare program.

This morning, I want to talk about four points related to the inherent reasonableness authority. First, is the scope of CMS's authority under IR. The second are concerns about appropriateness of the use of round one, or even national mail order competitive bidding as a proxy for the pricing in the retail marketplace. Third, is to talk about alternative pricing sources that were

mentioned in the Federal Register notice. And then fourth, to talk about impacts on quality and access.

First, with respect to the inherent reasonableness authority, under the inherent reasonableness authority, CMS is to consider the information that's relevant to the category of items or services. The category of items and services that you're considering, with respect to IR, is non-mail order DTS. That is the relevant category, and what you'll hear throughout my discussion, is it's the data that matter. It isn't simply a question of is there a problem, because there's a disparity between mail order and retail. The question is finding what is the price in that market place, in the non-mail order market place, it's not a question as to whether or not CMS likes, or dislikes, that price, it's not a question as to whether or not there is a back door way to bring competitive bidding into the non-mail order market place.

If you're embarking on inherent reasonableness, you have to follow the inherent reasonableness rules, which are finding the right price in that market place, and that's critical. With respect to the mail order, whether it's mail order generally, or round one, or the national mail order, mail order is a different market place from the non-mail order market place.

As was just mentioned by one of the other speakers, in the Federal Register notice, CMS said that they believe that mail order prices can inform the analysis of non-mail order supplies, because several key cost components are identical for both, such as product acquisition costs. We've heard a lot this morning about the service supplies -- service costs, I'm not going to talk about that.

What I'm going to talk about is, as the speaker two speakers ago mentioned, the product acquisition costs are not the same. That might not be obvious to someone who hasn't looked at this market place, but if you look at the market place, any survey that you will see, and particularly if you're looking at the competitive bidding market place, you will see that the supplies that are offered are in fact different from the mail order -- mail order and non-mail order market places.

First, if you just consider some of the differences in the structure of those two marketplaces, it becomes clear why that inherently is the case. First of all, when you're dealing with retail versus mail order, you have a difference in the number of outlets. You have many, many more outlets in the retail setting than you do in the mail order setting.

When you're looking at the basis for product availability, what consumers get and have offered to them, when you go into a retail facility, what's there is what's going to catch your eye on the shelves. What you've heard about. You know, my doctor told me to get brand X, or my insurance company told me that I have to get brand Y, that's what drives what's on the mail order -- the retail shelves. That's not the case in the mail order setting.

In the mail order setting, it's principally what can I get the best contract on? When you're looking at ability to move market share, or to move volume, even among the largest retailers, they're dependent on the local outlets. Go and look at your -- at the supermarkets in the

communities. You can have the same chain, but in two different neighborhoods, they'll offer totally different offerings.

Where I live, in Florida, I live in a neighborhood that happens to have a lot of Brazilians, and so we have offerings the Brazilian community wants. You go a few neighborhoods away, where there's a very heavy Orthodox Jewish community, that's what they offer, it's the same chain. But the ability for that chain to move supplies is determined by the local outlet, not necessarily by what the headquarters can purchase.

So there are substantial differences. But I'm not asking you to take my word for it, and I'm not asking you to take the word of those who have a financial interest, one way or another, and many of the speakers today would, as you'd expect, that's what they're going to comment on.

What we're suggesting is, you need to look at the retail data, and we're happy to come in and assemble and provide to you the information that we believe can inform what, in fact, the pricing is in the retail market, and that's manufacturer average sales price.

That's not to say that that's the total cost, we're talking about trying to get you a better number on the product acquisition cost. And we'd be happy to arrange a meeting to go over those kinds of data, it's not something that we can easily do in public, considering antitrust guidelines.

In the Federal Register notice, CMS mentioned that there were other pricing information that you all had. We'd love to comment on that if we know what the other pricing information is. We have no way of commenting on that at a public meeting like today, because I don't know what you're talking about. I don't know what other data you were looking at, other than the mail order competitive bid rates. So we would certainly urge CMS to provide what information you have, so we can help explore and understand if they are valid sources of data for the retail, non-mail order marketplace.

In addition, it's important to consider access and quality considerations. Again, a number of commenters have suggested that these are the same supplies, they are not. The American Association of Diabetes Educators did a survey, looking at the nine competitive bidding areas, and called the suppliers to see what was available. Both what was available based upon just what generally is available, and what was available based upon what was on the Medicare website as to what they said would be available.

Of the nine largest brands, according to the OIG survey of mail order supplies that were in effect in 2009 -- purchases in 2009 -- 1.44, 16%, were available in the competitive bidding in Round One. CMS may hope that by adopting Round One pricing in the retail setting, you won't have a change in the supplies, but you will not be able to have retailers offer the supplies because, as was said before, the pricing that was described before is accurate pricing. It is simply not the pricing that you see in the mail order setting or the pricing that you see in the competitive bidding mail order setting. And I'm talking about product acquisition cost. And again, it's because the retail setting cannot move the volume the way the mail order setting can.

Also, with respect to quality, a recent publication study that came, was presented at the American Association of Clinical Endocrinologist Conference showed that looking at compliance with FDA and ISO standards for performance of supplies, showed that four supplies out of seven, that are commonly provided--not commonly provided, at all, in the retail setting, but are offered in the mail order setting, failed to comply with ISO and FDA standards. It's not to say that FDA isn't doing its job, but FDA has limited resources and its incumbent on the suppliers to make sure--I'm sorry, the manufacturers, to make sure that their tests meet the ISO and FDA standards. But they don't always do that. And if you drive to the lowest denominator, that's what you're going to drive toward.

So in conclusion, the DAC is not saying that the disparity in pricing between retail and mail order is--creates no problems for CMS. But what we are saying is that if CMS intends to move forward with inherent reasonableness authority, you must, as you know, and as was stated, you must find that the prices are inherently unreasonable and you have to do that based upon the non-mail order marketplace. Again, this is not a question of wanting to substitute a price that you'd prefer. It's what does that marketplace show? And we're confident that if you do surveys and you look at the data, both because structurally, they are different marketplaces, but because the data, most importantly, will show you that the pricing that is available to retail markets is not the pricing that is available in the mail order setting. And if you lower the rate, especially to anywhere near the Round One competitive bidding rates, you will find that the retail suppliers simply will not be able to offer supplies that they are currently offering. And that will result in an impact on access and quality for Medicare beneficiaries, which no one wants. So again, we'll be happy to collect those data, and happy to meet with you all to share those data with you because again, it's the data that, what IR is about is a data finding exercise and we're happy to meet that challenge. Thank you.

Linda Howard:
Thank you, Mr. Radensky. Our next commenter is Richard Price.

Richard Price:
Good morning, I'm Richard Price here representing the Advanced Medical Technology Association, AdvaMed. I'll be summarizing my full statement that I'll submit for the record later. The first point we'd like to make is that AdvaMed urges CMS to be cautious about using price and payment amount information obtained through the competitive bidding program as a proxy or any kind of guide, to adjust payments for diabetes testing supplies, DTS, purchased through retail pharmacies. It is critical that beneficiaries continue to have access to retail pharmacies where they can obtain both the in-person assistance and the brands of testing supplies that they and their physicians have determined are most appropriate for their needs. In AdvaMed's view, such access both to in-person assistance, beneficiaries might prefer, but also, as we heard from Mr. Nam, may actually require, as well as access to the brands their physicians have suggested to them, and have prescribed for them as being necessary for their particular medical condition, that this access would undoubtedly be compromised if Medicare payments for DTS furnished in the retail pharmacy setting do not adequately cover the costs incurred by retail pharmacies.

We have three major concerns about applying data from the mail order competitive bidding program to retail rates setting. Our first concern: mail order and retail supply channels differ in many ways, thus making the price information obtained from one setting inappropriate as a proxy to adjust payments for the other setting. Our principle observation here is that products available in the two settings, and their pricing, are fundamentally different. We first note that retail pharmacies and mail order suppliers are very different business models. And CMS, you all have acknowledged, in the recent past, that this is the case. The previous speaker, Mr. Radensky, talked about a survey I was going to highlight here, that being the survey of the AADE from August 2011. And two points about this survey, I guess. First of all, AADE found only 1.44 brands of the top nine brands identified by OIG being offered by mail order suppliers from Round One. So, you know, the products being offered by retail pharmacies are very different and those offered by mail order are also very different from retail. And AADE, I'll add, noted that beneficiaries in areas subject to competitive bidding in Round One were being made to switch to a different testing system, or purchase DTS through retail settings where more brands are generally available. So, you know, we have the retail setting making more brands readily available to beneficiaries.

And, you know, when we look at CMS trying to come up with a structure for differentiating the business models for retail versus mail order, we believe, and we're very concerned, that it would be challenging for CMS to accurately determine such operating and other costs incurred by retail pharmacies. So, we're very concerned about what data you'll actually be using to document that.

Our second concern: most pharmacies will be unable to obtain the same pricing as large national purchasers. As Mr. Kusher, a couple speakers ago noted, such as large mail order suppliers, or the very large major chain retailers, because they simply will not be purchasing the same volumes of products. This differential will be especially large as CMS moves to national mail order program, where mail order suppliers will be bidding based on the expectation of having a large national contract with the potential to sell very large numbers of strips per year. Pharmacies without comparable volumes of business cannot be expected to obtain supplies, simply put, at the same price as mail order suppliers. Therefore, the single payment amount utilized for the national mail order competitive bidding program should not be perceived as an appropriate price for DTS in the retail setting, even for comparable products, let alone other costs unique to bricks and mortar operations. If retail pharmacies were also subject to the single reimbursement amount paid for mail order supplies, they too might end up limiting the range of products available and beneficiaries would be left for no options, for obtaining the specific DTS products recommended by their physicians, or those whose functionalities best meet beneficiary needs. This would be especially concerning for beneficiaries whose communities are served by small, independent retail pharmacies.

And finally, our third concern is that with the bid and price setting process CMS has used in the past to establish the single payment amounts used in competitive bidding, we are concerned that this same bidding methodology, which we have commented on numerous occasions as being structurally flawed, that the same bidding process will be used to establish prices in the retail setting. We've asked, and specifically recommended on numerous occasions in the past, that the bidding methodology used by CMS require that all bidders be bound by their bids and that payments should not be determined by the median of winning bids, but rather by the amounts

winning suppliers actually bid. And to date, CMS has made no material change, of course, in these processes that moves beyond Round One to Round Two, let alone a larger national mail order competition. Our concern is that CMS will continue using the same framework for determining single payment amounts for DTS, as it has in the past, that this flawed framework will be applied directly, or indirectly, to DTS in retail settings and that beneficiaries, as a result, will experience the same limited access to brands in the retail setting that AADE documented in 2011. And remember that's having access to 1.44 brands identified by OIG as among the nine largest brands used by beneficiaries.

Now our concerns with the bidding process itself become especially critical when we read in the notice for this meeting that CMS believes that it has information necessary to determine whether it should adjust payment amounts for non-mail order DTS because it has information generated from the local Round One Rebid competitions for mail order DTS, as well as other pricing information. AdvaMed argues that the Round One pricing information should not be considered relevant to the process for determining appropriateness for DTS pricing amounts in retail settings because of the underlying flaws in the bidding process used in the Round One rebid and also because, as we've learned, products available and used by beneficiaries in retail settings are very different from those available through mail order. In addition, bid amounts obtained through competitive bidding process inherently rely on a perceived increase in volume as competition is driven out of the market. This is not the case in a rate setting mechanism, such as inherent reasonableness. Like the previous speaker, Mr. Radensky, we were struck by this term "other pricing information" that's included in the notice for this meeting and we're wondering exactly what that other information is. And we urge CMS to disclose this other pricing information as soon as possible in the interest of transparency.

In conclusion, in a final rule in 2010, CMS stated that the Agency agreed with commenter's that it was necessary to preserve beneficiary choice and access to local storefronts for obtaining their diabetic testing supplies. I believe that's actually a quote from the Rule. It is critical that an alternative payment method for paying for diabetes test strips in retail settings not compromise beneficiary access to this option or to the full range of products their physicians consider to be medically appropriate for their care needs. If CMS decides to proceed with an inherent reasonableness proposal, it will need to describe, in detail, the methods by which it meets the regulatory requirements for using only valid and reliable data to establish payment amounts for these products and the related services provided by bricks and mortar suppliers and living up to its commitment to preserve beneficiaries' access to the DTS they prefer. We expect to have additional comments if and when such a proposal is made and we thank you for this opportunity to present our views now.

Linda Howard:
Thank you, Mr. Price. Excuse me. Our next speaker is Eric Juhl.

Eric Juhl:
Good morning and thank you, again, for holding this public hearing and having the opportunity to provide comments today. My name is Eric Juhl. I'm with the National Association of Chain Drug Stores. Community pharmacies are the face of neighborhood health care. Innovative programs that chain pharmacies deliver, their unsurpassed value improving health and wellness

and reducing health care costs through face-to-face counseling, the pharmacist/patient relationships helps to take medications correctly. This improved medication adherence means a higher quality of life and the prevention of costly treatments. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of the annual prescriptions filled in the United States. To ensure that community pharmacies continue to play a role in providing quality health care services and decreasing medical costs, it is vital that Medicare beneficiaries have continued access to medications and supplies through retail pharmacies. CMS is considering its inherent reasonableness authority to reduce reimbursement amounts for diabetic testing supplies obtained at retail community pharmacies. However, the reduction of reimbursement for these supplies obtained at retail pharmacies will limit beneficiary access, leading to lower quality services, poorer health outcomes, and increased overall medical costs. In 2010, an estimated 25.8 million individuals, or 8.3% of the population had diabetes, causing an estimated 174 billion in direct and indirect costs. An additional 79 million people are estimated to have pre-diabetes, a condition that puts people at increased risk for diabetes. In many cases, chronic diseases, including diabetes, can be prevented or managed with appropriate lifestyle modifications and medications. Medications and needed supplies are especially important to the management of chronic diseases that require long-term or lifelong therapies, such as diabetes. Any disruption in the ability of individuals to receive their diabetes testing supplies could result in increased illness and increased medical costs, both of which will be avoidable if beneficiaries continue to have access to their supplies at the retail level. Additionally, reducing reimbursement for diabetes testing supplies obtained at the retail setting, and therefore, reducing beneficiary access, would fragment patient care by requiring a beneficiary to obtain supplies from one source, i.e. mail order, and medication from another source, such as their local pharmacies.

This increases the possibility for patient confusion, disruption of therapy, and waste, all of which can contribute to overall program costs. Pharmacists are uniquely qualified as medication experts to work with patients needing medical supplies, such as diabetic testing supplies. They play a key role in ensuring patients use their supplies in the most proper and meaningful way. Reducing access to retail pharmacies will limit the number of options available for beneficiaries. This will also prevent beneficiaries from continuing their relationship with pharmacists they have been using for years. Beneficiaries should have continued ability to obtain their medical supplies from pharmacies with which they have a longstanding relationship. In addition to furnishing supplies, one-on-one patient consultation provided by pharmacists are often the first opportunity to identify other chronic illness and changes in patients' conditions. These consultations often result in early detection, referral, and treatment. Ensuring continued participation of the community pharmacy, community retail pharmacies in serving Medicare patients with medical supplies, such as diabetic testing supplies, should therefore, be a priority in the Medicare program.

Many pharmacies will not be able to provide diabetic testing supplies if CMS reduces the reimbursement for such items. All pharmacies, not just small retail pharmacies, currently provide these supplies to all types of beneficiaries, including seniors who have built up a relationship with their pharmacist over the years. Research shows that only 50% of patients adhere properly to their medication, or their prescription drug therapy regimens. Poor

medication adherence costs the national approximately $290 billion, 13 percent of total health care expenditures, and is associated with 47 billion annually for drug-related hospitalizations and an estimated 40 percent of nursing home admissions. Pharmacists provided medication therapy management, included complex service, such as counseling patients on their diabetes medication and their diabetes testing supplies, and providing follow up phone calls, refill reminders, and other consultation type services for a variety of medications for chronic diseases including diabetes. There are already a number of barriers in place acting to reduce medication adherence, including restrictive eligibility requirements for MTM services, lack of patient awareness of MTM-type services, copayments, poor health literacy, and ineffective compliance messaging, resulting in difficulty remembering and managing complex regimens. Reducing reimbursement to diabetic testing supplies obtained at the retail setting, and therefore, limiting access to retail community pharmacies for beneficiaries will lead to poorer adherence for diabetes medication and result in poorer health outcomes and increased overall healthcare costs.

As indicated in the Federal Register notice for this meeting, based on information--that based on information generated from the Round One Rebid, CMS believes it has information necessary to determine whether payment amounts for non-mail order diabetics testing supplies are grossly excessive and should therefore, be adjusted using its inherent reasonableness authority. NACDS would caution CMS that this approach--would caution CMS in this approach as diabetic testing supplies obtained through mail order in the competitive bidding program is not a good comparison for determining pricing for supplies obtained at the retail community pharmacy. First, there is a difference in cost to dispense the supplies in mail order and the retail setting, because mail order suppliers deal in higher volumes of product, they are able to obtain discounts from manufacturers that just aren't available to retail pharmacies. CMS should not assume that the cost to provide diabetes testing supplies are the same in both the retail and the mail order setting. Secondly, the types of products available to beneficiaries through the competitive bidding program are dramatically different than those available in the retail setting. In fact, this is indicated by evidence that beneficiaries in the competitive bidding areas are opting to use mail order--I'm sorry, are opting to use retail pharmacies as their particular diabetes testing supplies are not available through mail order. In these competitive bidding areas, retail community pharmacies have been a necessary safety net for beneficiaries unable to obtain their diabetes testing supplies, which work best in managing their diabetes. Reducing reimbursement for supplies obtained in the retail setting will eliminate this vital safety net.

In conclusion, thank you very much for your consideration of our comments and allowing us to share our views on the important role community pharmacy can play in providing medical supplies, such as diabetes testing supplies, and then need to maintain access to retail pharmacies for Medicare beneficiaries. We welcome the opportunity to work with CMS further on this issue. Thanks.

Linda Howard:
Thank you, Mr. Juhl for your comments. Our next commenter is Laurence Clark.

Laurence Clark:
Hi. Dr. Larry Clark, Medical Director NGS on behalf of my DME colleagues, Dr. Stacey Brennan, and her colleagues. Thank you. I'm here mainly as a neutral observer appreciating the

commentary. I would like to make a couple of comments as an individual and as a continuing practicing internist, that it does help in terms of sharing diabetic supplies, in terms of observation of inability to utilize diabetic monitoring apparatus, and in terms of non-compliance that the human eyes are very valuable. And aside from that, I think everything else has been said. Thank you very much.

Female Speaker:
Thank you, Dr. Clark. Our final commenter this morning is Walt Gorski.

Walt Gorski:
Good morning. It appears I'm the only thing standing between you and lunch, so. It's hard, I think, to sometimes finish up last because a lot of the things that, the points that people want to make have already been made. But I just want to reinforce a couple points and make a couple new observations as I've been sitting here. I'm Walt Gorski, I'm with the American Association for Home Care and I represent a unique set of groups. Whereas there's a lot of community pharmacists and the mail order people, I represent the manufacturers, diabetic providers, both in the retail and mail order setting. So I think I have some unique perspectives to add here at today's meeting.

You know, as I was sitting here listening to all the commenter's, I think, I mean, the key thing to remember for us is that this is more than just a reimbursement issue. This is an extremely complicated area, as you peel back the layers of the onion, and you learn different facets about both retail and mail order. And so I think the common denominator has to be patient care and patient access. And so, as that as the backdrop, I think that the key issue that we're worried about is restricting brands and restricting access. I think that there are good comments made both for the mail order people and the retail people about the differences that they bring when they service a customer. But I thought that the AADE study that showed the types of brands that were available under competitive bidding differs dramatically than what's available outside of competitive bidding. So, I mean, a key issue that I think that I really want to impress on CMS is that not all diabetic testing supplies are the same. A box of test strips is not a box of test strips. I would encourage CMS to work with experts in the diabetes arena, or if you have family members, or you use diabetic supplies yourselves, switching testing supplies for frail elderly population is not easy. And the co-morbidities associated with diabetes is enormous. We can't make the mistake, just because we see a price differential as large--I mean a $15 or $16 in mail order versus $36 or $37 in retail setting, we have to explore what's going on there. I will differ with CMS in their presentation earlier about acquisition costs. They are not, they are not--there are differences in acquisition costs.

So I would urge CMS to explore that aspect as you move forward here. With respect to several concerns that I've had, and issues that I want to raise, I thought Dr. Radensky's comments and Richard Price's comments were really on the mark that the competitive bidding program is so different than the retail setting that, competitive bidding prices quite frankly, are not relevant to this discussion. And I'd love to work with CMS more on that specific issue because I mean, CMS has bifurcated the channels for more than 10 years. You have modifiers that recognize, that differentiate between the two. I think it's incumbent upon CMS to make sure that they determine what's an adequate price structure in one setting and look at it in the retail setting. I,

quite frankly, think of them almost separate, different benefits. With respect to competitive bidding, and I know that we agree to disagree a lot on these issues, but with respect to complaints, I would say that AAHomecare collected a tremendous amount of complaints, more than 600 complaints about the bidding program, and that differs, then, what CMS has done with respect to the bidding program. But a large majority of the complaints were about beneficiaries having, being able to access their commonly preferred, or the commonly prescribed brands. And CMS had an escape valve here. Your answer, your help line answers were to direct people to the retail setting. And so we've heard a lot about the savings associated with bidding, but we've never really peeled back that layer of the onion and looked, and saw why, we said that there was a higher utilization, that people were stock piling supplies, but we never really looked into it, at least from what the public knows, how much did retail go up as utilization in mail order went down. That's something that I think we need to explore because the complaint would indicate that people had a hard time getting the commonly prescribed testing supplies. So, I talked about the safety valve. I thought the testimony at Ways and Means was really interesting because you're in a test area right now; you only have nine areas of bidding underway.

And what our witness--what the AAHomecare witness testified to was revenue shift. People had footprints within the competitive bid area; they were able to supplement their income with revenue that was outside the bidding area. As we move to 91 additional areas and a national mail order program, that's not going to be--we're not going to have that luxury. I would also say, in an argument against using bidding pricing, you use the median of the prices, not the last price in. I mean, this goes to how the economists view the world when they look at the auction programs, but CMS decided to go with the median, so some people are going to be paid less than they actually, than it costs to prescribe.

And then, and with respect to bidding, I think it's important to know, to take a look and say, "look who won." The people who had the most resources to determine what their costs would be, accurately, 24, I think, out of 25 were not the most commonly, common carriers, common companies in the retail diabetic marketplace. That has to be explored. I think it's, I mean, you have to figure out if, did a supplier come in there and say, "well, I know that Eric Zimmerman, he's going to bid 20% below. I need this bid, I'm going to bid 22% below, but I don't know if it relates to my costs." I think that something worthwhile.

Moving on to my next point, differences in costs between retail and mail order. That is something that I'm not going to delve into here. I don't think anything that I could provide here would be of value to you, other than I think that there are differences in cost with respect to volume discounting and staffing discounting. I think that those were two key points that I heard.

An issue that hasn't been covered here is audits. Now, you might say, well, we're the reimbursement guys, we're not worried about coverage and enforcement. Keeping the beneficiary in mind, I thought it was very interesting that we have an NGS, well, I think, it appears that he left. But we charted out the error rates for each of the DME MACs and in the 2002 probe audits, in the diabetic space, NGS had a 99.5% error rate when they did their probes for diabetic supplies. CGS had a 98 % error rate. We took this back, we looked at all the DME MAC probe audits, and we took them back basically to 2010, which is what we could access. The lowest error rate in any of those quarters was Noridian at 73%. You know, we talked about

access and price as an issue of access, but I think it's incumbent to have CMS take a look and say, 98 percent of suppliers out there are failing? That, ultimately, I think that will affect all, both providers, and manufacturers, and beneficiaries, because technically, when an audit finds that there was an improper payment, sure there might have been fraud, but I doubt it. Who wants to prick their finger three or four times a day to, just for the heck of it? But, suppliers should be doing, is they should be telling their patients, "Medicare does not think you are medically--that this service is medically necessary." What would be ideal is if the suppliers just stopped servicing these beneficiaries because that's what you, CMS, listen to. I mean, you take the factual information that we provide to you, but it's when the beneficiary starts to scream, I know that's when CMS acts. And when you have 98% of beneficiaries being told, or suppliers being said that their patients are not medically necessary, for whatever reason, supplier fault, doctor fault. I think we have a real issue there that we need to explore.

And finally, there is the issue of transparency. I think that what struck me in the Federal Register notice was the issues related to other pricing. We'd encourage CMS to share and be as transparent as possible in this process. We too want to make sure that
Medicare pays a fair price for the product, but we want to make sure they do it in the right way. So, look forward to working with CMS. Thank you very much for your time.

Linda Howard:
Thank you Mr. Gorski. And I'm sorry I dropped the bell, but amazingly enough it was at the right time.

[laughter]

We've had another speaker sign up, so we will have comments from Cynthia Pazos.

Cynthia Pazos:
Good morning. Thank you for allowing me to be present today. I'd like to introduce myself. I am a diabetes mail order and pharmacy supplier. In my past 30 years experience in diabetes health care, I was a sales representative for a pharmaceutical company. I'm responsible for all areas of distribution to the patient in a certain state. From my experience as a pharmaceutical representative, I noticed that there was a big need for a specialty company to help service patients with diabetes. When a patient with diabetes goes into the pharmacy, they sometimes don't always get the attention that they need. As we all know, the technology is constantly changing. Improvements are being made. It's almost impossible to be able to keep up with those improvements.

Therefore, these specialty diabetes suppliers that popped up all over the country were extremely important and that really interested me because I was very interested in caring for patients with diabetes. My mother-in-law died of the Type 2 complications. I witnessed that and really made it my mission to be able to help other patients with diabetes. As the diabetes industry, as, unfortunately, as the disease began to grow, so did the Type 1 patients. And we, at this meeting, seem to have overlooked the Type 1 patient with diabetes and those using advanced therapy products, such as insulin pumps, continuous glucose monitoring. These new products have increased patients' diabetes self-management, not only with those products, but with the help of

the suppliers that supply them with those products. As a supplier that started out catering to the Type 2 patient, I can tell you that there is a big difference in catering to the Type 2 patient and supplying them with their products than there is with the Type 1 patient that use an insulin pump. There are not many suppliers in the country that provide these products, and I'm fortunate to be one of those.

I can tell you, for the past 15 years that I have been supplying these products, I have the opportunity to be able to work with a lot of health care professionals. And it's alarming that, how many health care professionals are not familiar with these products. Even to this day, when you have a child that goes into school, the school nurse might not be familiar. When you have a patient that is admitted to the hospital, the hospital is still not familiar with how to deal with this patient. Therefore, I realize it is so important to be able to understand these patients' care. While I can appreciate the differences between pharmacy and non-mail order, because I operate both. And it is most expensive to operate the DME side of the business. It really is. I love it when it can go through the pharmacy, because it's less operations and--on my company. However, most DME supplies for insulin pumps are put through the DME line of business. It is through the durable medical equipment benefit that CMS pays for these products. If a patient on an advanced insulin therapy product does not have the complete package, therefore, the blood glucose testing supplies that go along with the infusion sets and the reservoirs and the cartridges, then how can that patient truly manage their disease? If there is any interruption in this patient's care and their ability to manage that high tech product, there will be an interruption in their care. Therefore, they may have a visit to the emergency room, which drives up those Part A costs. So with your decisions being made at this point, you know, I myself, have, you know, participated in competitive bidding. Will I lose that Type 2 patient? I have a very strong possibility of losing that Type 2 patient. But I really care about the Type 1 patient because as I continue to supply them with their advanced therapy products, will they be able to use that product to the best of their ability? And use that product in the manner in which it was designed to be used? Unfortunately, those products are coupled with certain products. So when we look at product choice, as even a competitive bid winner, I will not have the ability to service them with those products and they will have an interruption in care. Now if that patient goes to the pharmacy, and they do not have their reorder on their test strips, then what will happen when they go back home and they use that insulin pump? And if they don't have the method to be able to find out what their blood glucose level is, how will they able to know how much to bolus that insulin pump? I have all the respects in the world for pharmacists. I understand exactly what they do in the community. I understand everything that they do, the personalization that they bring. Unfortunately, not all health care professionals are familiar with insulin pump therapy. It is a very, very difficult product line to sell. I've had a great--my challenges myself with adapting my Type 2 customer service reps to a Type 1 customer service reps. And we do have differences in our business. We have to, because we service a different type of patient. We communicate with them differently, we adjudicate their claims differently, and we all around have two different types of businesses within my organization. So I just urge CMS, as they are moving along with their decisions with the pricing, that you take into consideration these Type 1 patients that may be using advanced therapy insulin products because they are very, very high tech and they need people who are very educated with those products to be able to help them along and to ensure that they receive their products at the same time that they receive all products that allow them to

use that advanced insulin therapy to control and to monitor their diabetes. Thank you so much, I appreciate the time.

Linda Howard:
Thank you, Ms. Pazos. She is our final commenter this morning. Does anyone on the panel have anything that they would like to say at this point?

Laurence Wilson:
No, I would just like to thank everybody for coming this morning. This was, I think, a very good discussion that we had today. Discussion around different aspects of this issue. At some points on different sides of the issue, and it was very helpful, for I think, those of here at CMS on the panel to examine. I think, as Linda mentioned earlier, the testimony from today will be available in some form.

Linda Howard:
On the website--

Male Speaker:
I'll let Linda describe that again in a little bit of time. We'll be taking that back looking at it, talking about it internally within CMS, and then trying to make a decision about how to go forward after we've had some time to think about things. But again, thank you very much and look forward to seeing you all soon.

Linda Howard:
Thank you Laurence. I just want to remind you that written comments will be accepted until 5:00 pm on July 30. Comments can be sent through email to dmepos@cms.hhs.gov. It is likely that they comment period will be extended until after the audio and transcription files are available on our website. We don't have a definite timing for the transcription yet, that's why I can't give you something any more certain than that. We want to thank everyone whose--everyone on the panel today. And we also want to thank Charles Hirsch, in our sound booth, for so beautifully handling all of our audio-visual needs and thank you very much for your comments. I want to tell you that my father was insulin-injecting diabetic. He had a heart attack at 46 and died. So, all of this is very important and very relevant to so many people that you know, many people in your community, many people that I know. So thank you again, very much, everyone for coming. We appreciate the time that you've taken from your busy schedules to come today and give us your input. The meeting is now adjourned. Thank you.

[end of transcript]