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ELIMINATING WASTE AND FRAUD IN MEDICARE: AN EXAMINATION OF PRIOR AUTHORIZATION REQUIREMENTS FOR POWER MOBILITY DEVICES

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BEFORE THE

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ELIMINATING WASTE AND FRAUD IN MEDICARE: AN EXAMINATION OF PRIOR AUTHORIZATION REQUIREMENTS FOR POWER MOBILITY DEVICES

WEDNESDAY, SEPTEMBER 19, 2012

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:38 p.m. in Room SD–562, Dirksen Senate Office Building, Hon. Bob Corker, presiding.

Present: Senators Corker [presiding] and Blumenthal.

OPENING STATEMENT OF SENATOR BOB CORKER

Senator CORKER. I think we'll go ahead and get started, and thank you very much for being here, and all of you who have come to this hearing.

Instead of reading my opening statement, I'll start by saying that some time ago, I don't watch a great deal of television, but I would see ads on television regarding all kinds of mobility devices where people could, it appeared, just call up and the companies would figure out some way for this person to own these mobility devices with little or no money down. It almost gave the impression that they would ensure that you paid nothing.

Obviously that's taxpayer money, and it looked to me to be very flagrantly in the face of anything that would have value for the American taxpayer, and it also seemed to me that people were taking advantage of this and probably jeopardizing people who really do need these mobility devices down the road.

And so our staff began looking into it. We have learned that CMS has an 80 percent fault rate on these. In other words, 80 percent of the people who apply for these mobility devices get turned down, initially anyway. So there's a huge problem here. I think most Americans have seen these advertisements on TV and probably question what the Federal Government is doing. I certainly do. It's actually—well, I'll just leave it at that.

I know that we have a new program now that, through CMS, is going to look at this and try to get that fault rate down from, again, 80 percent to some normal level. So we have a program that is being advertised to the American people. People are applying for it. Lots of people are receiving these mobility devices, but we have an 80 percent case of these devices not meeting standards.

So now we've hired contractors, I understand, to deal with this. These, by the way, are the same contractors we've been working with in the past on this same program.

So the purpose of this hearing is to look into that and to ensure that we as a government are going to do those things that are responsible as it relates to these mobility devices. So I thank you all for being here.

I might add, by the way, this is the same entity that's going to be dealing with all kinds of other responsibilities, especially as we move forward with the new health care bill.

So I think this is something very timely for us to look at. I thank you all for participating. I'm going to go ahead and mention who all the participants are.

Deborah Taylor, obviously, is the Chief Financial Officer and Director of the Office of Financial Management for CMS. We thank you so much for being here.

Later on Panel 2, we'll have Paul J. Hughes, who is a physician and the Medical Director for the National Heritage Insurance Company, Durable Medical Equipment Medicare Administrative Contractor, responsible for Jurisdiction A, which is comprised of the northeastern states from Maine to Washington, D.C.

We also have Stephen T. Peake, Ph.D., who is the Medical Director, and M.D. I might add, Medical Director for the Senior Care Division at Blue Cross Blue Shield of Tennessee.

We have Michael Clark, J.D., the Chief Administrative Officer and General Counsel of the Scooter Store. I think this might have been the entity that I continued to see these advertisements with.

And then Jerome Epplin, M.D., who is a family practitioner at the Litchfield Family Practice Center in Litchfield, Illinois, and also trains students at Southern Illinois University. In 2010 he received the American Geriatric Society Clinician of the Year Award.

Now that I filibustered by introducing everybody on the front end, hoping that some of my colleagues would be here, if you would go ahead and start I would appreciate it, and certainly the meeting is now in order.

STATEMENT OF DEBORAH TAYLOR, CHIEF FINANCIAL OFFICER AND DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT, CENTERS FOR MEDICARE & MEDICAID SERVICES, BALTIMORE, MD

Ms. TAYLOR. Sure. Good afternoon, Ranking Member Corker, and thank you very much for the opportunity to discuss the Centers for Medicare & Medicaid Services' efforts to reduce fraud and improper payments for power mobility devices and to update you on the prior authorization demonstration, which CMS began earlier this month.

Power mobility devices, or PMDs, have historically had high incidents of fraud and improper payments, and the suppliers of PMDs continue to be subject to significant law enforcement activities. Joint investigations by the Department of Justice and the HHS Office of Inspector General and CMS have resulted in numerous suppliers being charged with and convicted of defrauding the Medicare program. Recently, a Louisiana supplier was sentenced to 180 months in prison for participating in a scheme that defrauded Medicare of more than $21 million for billing for power wheelchairs

and other medical equipment that was never provided to beneficiaries.

In addition, the OIG—and you mentioned this—and our comprehensive error rate results have reported that more than 80 percent of claims for motorized wheelchairs did not meet Medicare coverage requirements. Although CMS recognizes that many improper payments are not the result of willful fraud, this error rate is extremely high.

In an effort to prevent dollars from being wasted and protect the Medicare Trust Funds from fraud, CMS began this PMD, Prior Authorization Demo, for orders written on or after September 1, 2012, for Medicare beneficiaries who reside in seven states. This demonstration will employ prior authorization, a commonly-used private sector tool to protect the Medicare Trust Funds. Prior authorization, sometimes known as prior approval or pre-certification, is currently used by other health care programs such as TRICARE, some state Medicaid programs, and private insurance plans for many services, including PMDs.

With prior authorization, CMS will review the medical records before the supplier delivers the PMD. This allows suppliers to know before an item is delivered to a beneficiary whether Medicare will pay for the PMD. The demonstration does not create any new documentation requirements but simply requires the medical information be provided before submitting the bill for payment.

The demonstration can also help us develop improved methods for the investigation and prosecution of fraud that could ultimately protect the Medicare Trust Funds from fraudulent activities. This prior authorization demo will also help ensure that a beneficiary's medical condition warrants the PMD under existing coverage guidelines.

CMS did seek input from many provider and supplier groups on this demonstration when we originally announced it on November 15th, 2011. We received significant feedback from the industry. In response to that feedback, we did delay the demonstration by nine months from the original January 1, 2012, start date.

CMS also made several other changes, such as reducing the resubmission review time from 30 business days to 20 business days, and allowing suppliers to submit the prior authorization request on behalf of the physician.

In addition, CMS conducted and will continue to conduct education and outreach activities, including Webinars, open-door forums, and in-state meetings. CMS will closely monitor the demonstration and will continue to work to ensure that suppliers, physicians and beneficiaries have up-to-date information about the demonstration.

Prior authorization can be an important tool to help CMS reduce fraud and improper payments for PMDs, while continuing to ensure that beneficiaries have access to needed equipment. We believe this demonstration will help protect the Medicare Trust Funds by utilizing many of the same methods already used by private insurance plans to ensure payment accuracy.

I'm happy to answer any questions you have.

Senator CORKER. Thank you. What was the impetus to create this new pilot program that you're now putting in place?

Ms. TAYLOR. Part of the impetus was the fact that we continue to do education and outreach for providers and suppliers of these PMDs. We have conducted lots of pre-payment review to ensure that they understand the policies. However, we continue to still see high error rates, over 80 percent, with this benefit; and as I mentioned, we continue to have fraud committed against the benefit by suppliers throughout the country.

So we felt that this was the next step, that we really wanted to look at something the private sector uses currently to ensure that we're paying for wheelchairs that are really needed.

Senator CORKER. And I know many of the questions that whoever is here will ask will be of the second panel of people who are very directly involved, and I know you're not. I know you're trying to solve the problem. But 80 percent is a huge number. As a matter of fact, how much do we spend on PMDs annually? Do you know what is your estimate? We have one ourselves.

Ms. TAYLOR. Yes. In 2011, we spent a little over $700 million on power wheelchairs.

Senator CORKER. And 80 percent of the claims for those, as it turned out, were inappropriate as it relates to CMS standards?

Ms. TAYLOR. Correct. On our review, documentation or additional information or the fact that the beneficiary did not need the PMD was what we found when we reviewed those claims.

Senator CORKER. I mean, it seems like any American that would see one of these commercials on television, they would realize that something probably really bad is happening here, and you guys have evidence that 80 percent of the claims shouldn't be there in the first place. So what is it that it takes to create huge alarm bells when we have this kind of money being wasted, being utilized in ways that it's not supposed to be utilized?

Ms. TAYLOR. Conversations we've had with beneficiary groups as we've started to roll out this demonstration. We've continued to emphasize to providers, as well as to beneficiaries, that the Medicare program under statute and by law pays for power wheelchairs for use in the home, for beneficiaries who need a wheelchair to get around their home to perform an activity, one or more activities of daily living, such as going to get food, going to the bathroom. And when we explain that to beneficiaries, I would say many of them are surprised that it is for use in the home, and that is by law. It's under statute that that's the use for a PMD.

And so I do think some of the commercials may be confusing for beneficiaries when they see the primary use for a wheelchair outside the home. That's not the primary benefit that we cover under Medicare.

Senator CORKER. And it is my understanding we're using the same contractors that we have used in the past where we've had this 80 percent error rate. We're using the same contractors on this pilot program. Is that correct?

Ms. TAYLOR. Correct. We are using our durable medical equipment Medicare contractors to do these reviews.

Senator CORKER. Have you talked with any of the contractors themselves just on a one-on-one basis and asked them how in the world they could have an 80 percent fault rate in what they were doing?

Ms. TAYLOR. Yes. We actually talk to our contractors probably quarterly to talk about what they're seeing, and more often if needed. I know that we have one of those contractors on the next panel.

But most of it does come down to documentation. We require a seven-element form to be filled out by the physician, as well as a face-to-face examination. Oftentimes, one or two of those items is missing from the medical record. So it's really almost impossible to know what did the physician see or what did they observe when they saw that patient. So when documentation is missing, it's very difficult to determine what was going on in that examination.

Senator CORKER. But isn't an 80 percent rate almost beyond belief, even for the Federal Government?

Ms. TAYLOR. It's extremely high, yes.

Senator CORKER. Have you—have there been any—I mean, that high rate would almost make one consider whether much of this is being done on purpose and whether there are actually other kinds of activities that are malicious in nature, and maybe there ought to be proceedings in other ways. I mean, have you all considered looking into that?

Ms. TAYLOR. From our standpoint, we believe the prior authorization demonstration will be a great tool for us to look at it. Right now, on an annual basis, the products that are covered under this demonstration last year, or in 2010, we had about 200,000 claims billed for these products, and we looked at very few of those claims. We don't have the budget or the resources to review a lot. This will be the first time we will have, in fact, the records and the documentation up-front for about 40 percent of those.

So we think the prior auth demonstration will, in fact, provide us with a lot of information to get exactly what you're saying, what are the things we should be looking for, is there patterns of fraud here that we should be looking for.

Senator CORKER. So, if I understand you correctly, CMS, which spends billions of dollars each year on durable medical equipment, doesn't have the staff or the resources actually to look at these authorizations in advance in most cases. So when people—I mean, sometimes you think you're hearing folks rhetorically talk about the waste and fraud and abuse that takes place in Medicare. What you would say is that just in this one case, 80 percent of the claims are off, and you think it's over $700 million. This is just one minor case of spending within the Medicare allotment, and you're saying that CMS really doesn't have the resources to know whether that's being carried out throughout the system. Is that correct?

Ms. TAYLOR. Correct on some level. I mean, we do look at it. We do look for patterns where a provider or a supplier may look aberrant. So we do focus in on that. But in the grand scheme of the entire Medicare program, we have to focus our efforts on the highest dollar errors first. So that is where we tend to focus our resources. We have enough money to look at less than 1 percent of the claims that are submitted to Medicare each year, and so we really do have to use those resources sparingly, and we really think that this prior auth demonstration will give us the opportunity to really look at this benefit a little closer than we have been able to do in the past.

Senator CORKER. So we look at 1 percent of the claims, and a vast amount of money. So when people talk about hundreds of billions of dollars in waste, fraud and abuse existing in Medicare, just this one example would lead people to believe that that really might well be the case. Is that correct? The number has to be huge if we're finding in this one little $700 million program that 80 percent of the claims are invalid.

Ms. TAYLOR. Well, we do an error rate each year. We do a measurement, a comprehensive error rate measurement on the entire program, and last year it was less than 10 percent. It was 9-something. So on the entire program, we do do a measurement. We cannot determine how much of that is fraud, but we do know that we do have an error rate in the Medicare program of around 10 percent.

Senator CORKER. What would you expect would be an appropriate rate? When you get through doing this program, do you think there's going to be tremendous improvements? Again, we're using the same contractors in the past that have generated an 80 percent fault rate. So we're using the same people. We're just using a little different process. I would have thought some of them, doing so much business with the Federal Government, would have volunteered that this is a problem, and I look forward to asking some of those questions later.

But what is the rate that you expect? That 80 percent rate will be what rate, in your estimation? What do you think would be a good job, if you will, by these contractors after this pilot is in place?

Ms. TAYLOR. We're in the process right now of acquiring an evaluation contractor for this demonstration. We certainly are going to look at the quality of determinations, the quality of information sent in to us by providers. I don't think we have set a threshold of what is an acceptable error rate. Obviously, we would want an error rate to be zero. That's probably very aggressive given where we are now.

But right now, we sort of need to start the program and evaluate it along the way to see what steps or actions we might need to take to tweak it. But we expect to have quarterly meetings with our contractors on what they are seeing inside the prior authorization demo, and we will have an evaluation contractor looking at the entire program to give us information and feedback on it.

Senator CORKER. So we've set up a program to deal with an 80 percent error rate, one that any American with any kind of ability to comprehend can watch on television and understand that there's probably a tremendous amount of abuse taking place in this program. So we have this program that has an 80 percent error rate, and we put in place a prior authorization pilot, but we haven't yet figured out what our goals are as it relates to an error rate, and we're going to hire another contractor who is an evaluation contractor to help us figure out what that ought to be.

Ms. TAYLOR. We are going to need some resources to help us analyze the data. So the prior authorization is one part of this. When you look at fraud, fraud moves. If someone believes we're looking at them, they are likely to move. So the entire benefit will have to be evaluated under this, and at this point I think it's too early for me to predict or to say what our hope is the error rate would be.

We certainly will evaluate that, and that would be certainly one metric of the success of this program.

Senator CORKER. Well, first of all, I thank you. It sounds like to me that you understand there's a problem, and it sounds like you may be under-resourced, and I look forward to digging into that a little bit more. I really appreciate you being here today.

But I think by just outside observers watching this, it would be almost beyond belief to realize that this has been occurring this long and that we really don't, in advance, have some standards.

How would you feel about us, after we know more about this and dig into it a little bit more and have this hearing, how would you feel about us putting into law—I think the American people would fully stand behind this—but putting into law that if a contractor has an error rate above X, they are no longer a part of our program? Would you feel like that would be helpful to help reinforce what it is that you're doing?

Ms. TAYLOR. We currently do have some metrics in our contractors' awards and the contracts that we sign with them that they must have efforts to reduce the error rates. We typically look at it as a whole, but it's certainly something we'd consider and would be happy to talk to the committee about.

Senator CORKER. So with the contractors who are getting ready to testify with us—and you know who is on the panel, you deal with them—who have an 80 percent error rate, they have in their contracts provisions that say that they need to help you figure out ways of lowering the error rate.

Ms. TAYLOR. Correct.

Senator CORKER. And yet we continue to re-up with them even though they have an 80 percent error rate.

Ms. TAYLOR. It is extremely difficult to be able to look at every benefit under a contractor's purview. We do work very closely with our contractors to make sure they have, you know, actions to deal with these and to mitigate them. So we do work very closely with them to make sure that they are on top of it and are taking actions to correct it.

Senator CORKER. Can you understand why I'd be semi-astonished at where we are today?

Ms. TAYLOR. Yes, I can.

Senator CORKER. I think if most Americans realized that we had agencies of government that continued year after year after year to deal with people that had an 80 percent error rate, and we had in their contract solely that they were supposed to help us figure out ways of mitigating that, of lowering that, and that still hadn't happened, and then we were putting in a prior authorization program now that's a pilot using those same contractors and that we didn't have yet a standard by which we felt like they should live to or not be a part of the program, I think people would be just incredibly astonished, and I just want to make sure—I know that I am now—that I'm not missing something here, that maybe there is something else that you would like to say.

Ms. TAYLOR. I think for the contracts, there are many things that our contractors do. Error rate is one piece of the contract. We do expect them to do education and outreach. Unfortunately, that education and outreach is not having the impact we hoped it would.

Prior authorization is a tool that we think can help significantly lower the error rate and also identify and help us identify fraud that could be occurring inside the benefit, and help us figure out additional things that we may need to do to prevent it.

Senator CORKER. One of our panelists later on is part of Blue Cross of Tennessee, and they have a managed care plan, a Medicare Advantage plan that has a negligible improper payment rate, negligible. I guess I don't understand how they could have one that's negligible—I mean, almost zero—and CMS could have an 80 percent error rate, and we're only checking 1 percent of the claims, and again we're using the same people that are creating this problem to try to fix it. I'm just wondering if you could share with me some of the differences that might exist there.

Ms. TAYLOR. I really can't speak to the Tennessee model. But when we look at what other private insurers do to measure error rate, they typically measure it based on the claim as paid. When we do that same analysis, we pay appropriately based on the information that's on the claim, 99 percent of the time correctly. It's when you require or ask the physician or supplier to send in the underlying medical record that we find the error rate shoot up to the 80 percent that we've been talking about.

So when the claim is submitted and the claim is paid based on the face of the claim—we cannot look at the underlying medical records for every claim—we do in fact pay very comparably, if not better than most private insurers. It's really when we pull the claim and request the medical record and look at the underlying record against our policies and our coverage requirements that there is information missing that would cause us to deny that claim for payment. So that's usually where we differ from private insurers.

Senator CORKER. That's a very good explanation, and I thank you for your temperament. Now that Senator Blumenthal is here, I'm going to turn it over to him. Again, thank you for being here.

Senator BLUMENTHAL. Thank you, Senator Corker, and my thanks to you for holding this hearing today and focusing on an issue that I think has not only financial and fiscal implications, but also potential dangers for consumers and the integrity of the entire program, and the public confidence and trust in its integrity. And I want to thank Senator Kohl, as well, for his leadership on this issue.

Without belaboring some of these numbers, the OIG report in 2011 finding that 80 percent of the claims for power mobility devices did not meet Medicare coverage requirements certainly raises urgent concerns, not just strong but also urgent concerns, and this error rate represents close to half a billion dollars in improper payments at a time when we're trying desperately to cut or reduce the increasing costs of health care.

So I appreciate your being here today. I am really interested in what you can do and what you plan to do to address some of the direct-to-consumer ads. As Attorney General, I'm very familiar with the potential for deceptive and misleading ads to consumers, and especially where you have such strong financial leverage and interest, my view is that you have an opportunity and an obligation to

do more to restrict some of those potentially deceptive and misleading ads.

Could you tell us a little bit more what you can do to exercise some leverage and authority?

Ms. TAYLOR. CMS does not have authority to really oversee or to regulate commercial direct-to-consumer advertising by suppliers for power wheelchairs or really for any health care delivery. What we do is we encourage that they not mislead or put anything in their advertisements that is not correct.

We certainly have heard, as we've been out talking to beneficiary groups, that there is confusion on the part of beneficiaries as to what Medicare does pay for under the power mobility benefit, and by statute, by law, we can only pay for power wheelchairs when it is needed for the beneficiary for in their home to perform one or two activities of daily living.

So when advertisements do show the power wheelchair for the primary use of outside the home, it does create confusion for beneficiaries. But we cannot regulate the advertisements that these suppliers put out there.

Senator BLUMENTHAL. When you say you can't regulate them, I know you can't order them off the air. You can't restrain them from making those ads, but you can refuse to pay for power mobility devices that are produced by those companies if they result in inappropriate use or if the purchases result from inappropriate ads.

Ms. TAYLOR. I'm not sure we can do that. If a provider or a physician sees a patient and orders the wheelchair, and it is necessary for the beneficiary even though there is an ad that's not appropriate, I will and need to pay for the wheelchair that a physician signed an order for.

Senator BLUMENTHAL. So in effect, you're saying you don't have the authority that exists under the FDA Act that applies to a pharmaceutical drug manufacturer. If they advertise to a consumer an unapproved use of a drug, they would be held accountable. You can't do that.

Ms. TAYLOR. I don't believe I can, no.

Senator BLUMENTHAL. Well, would you like that authority?

Ms. TAYLOR. I really can't speak to whether I'd like that authority or not.

Senator BLUMENTHAL. Why not?

Ms. TAYLOR. That's really not my place to kind of say that. We'd be happy to work with the committee, but I can't advocate for that.

Senator BLUMENTHAL. Well, I understand your point, and I understand that you can't speak for the agency. Let me put the question a different way. Wouldn't that authority enable you to safeguard the use of taxpayer funds?

Ms. TAYLOR. It certainly would help not confuse beneficiaries about what the benefit is under the Medicare statute.

Senator BLUMENTHAL. Because I think a lot of taxpayers would be perplexed, to say the least, by payments made by the Federal Government for wheelchair devices that result from purchases induced by misleading ads when the government knows they're misleading or deceptive and does nothing, and therefore is in the position of paying for those devices. I know there's a demonstration project, and I know that you're doing everything that you can, or

at least apparently so, to deal with this really very alarming problem.

But I would like you to think about what we can do to enhance your power, your oversight, and your ability to intervene. I don't think it's so much a matter of regulation as simply oversight and stopping deceptive and misleading practices that result in waste and fraud.

Thank you.

Senator CORKER. Thank you, Senator.

Again, I want to thank you for coming up here. I do want to say that, again, I thank you for your temperament. I know you're the person that's been sent up to deal with this.

I think it's this, again, 80 percent error rate. In any other realm of society, heads would be rolling everywhere. I mean, no contractors would be involved that had an 80 percent error rate, people involved within the institution. And I think it's this lack of alarm, lack of concern, lack of people hitting the roof over an 80 percent error rate that probably drives the American people crazy and causes them to lose trust in the U.S. Government, and I would say rightly so.

So this is of great concern to me, to look at this one thing that's so evident to everybody in America who watches even one commercial that these people put out, that abuses are in place, and yet nothing really happens in a very rapid way.

I do want to correct the record, or at least have you respond later. When I asked you about the error rate at Blue Cross Blue Shield and Medicare Advantage, and your response, it's my understanding they obviously are listening, and other people are. I was just handed a note that apparently the standards that are used by both Medicare Advantage and you are the same. So the 80 percent error rate and theirs being almost none, they are equivalent in their mind. So if you would just for the record respond as to what you were saying, because it appears to me there's a misunderstanding as to how we equate those things.

Again, I want to thank you for coming in. But I think it just points to sort of a morass, if you will, when I know you've got to look at the big numbers. I mean, I know that's where you go is after the big problems. But this one jumps out at you so explicitly on a daily basis. When we see the kind of things that people see on television, and yet people see these things going undone, it just causes people again to lose tremendous faith in our government, as they should when they see this, and I do hope that you will all be absolutely on this pilot program, and I hope that you will terminate anybody in this program that has an unreasonable error rate, and I hope Senator Blumenthal and myself and others will figure out a way to pass some legislation that says that if we have contractors who, year after year after year, have claims that are coming in to you that have an 80 percent error rate, they will be banned from doing business with the Federal Government.

Thank you for coming in.

Ms. TAYLOR. Thank you.

Senator BLUMENTHAL. And I would, if I may, Senator, just add my thanks to you for being here. I know it's a difficult—I don't

know what you did to draw the short straw, but you've done very well, and we appreciate you being here.

Ms. TAYLOR. Thank you.

Senator CORKER. Thank you very much.

Ms. TAYLOR. Thanks.

Senator CORKER. So I think the next panel is coming up. Is that right?

Let me just—I'll tell you what. Why don't each of you just introduce yourselves again? I introduced on the front end, filibustering a little bit for time, but why don't each of you before your testimony just state who you are with and what you do. And we thank each of you for coming up here on this issue. Thank you very much and welcome to the U.S. Senate.

Yes, sir. Paul.

STATEMENT OF PAUL HUGHES, MD, MEDICAL DIRECTOR, NATIONAL HERITAGE INSURANCE COMPANY, DURABLE MEDICAL EQUIPMENT MEDICARE ADMINISTRATIVE CONTRACTOR, JURISDICTION A, LEXINGTON, SC

Dr. HUGHES. I am Doctor Paul Hughes, the Medical Director for the Durable Medical Equipment Medicare Administrative Contractor, commonly called a DME MAC, and my geographic area of responsibility is Jurisdiction A. Jurisdiction A is one of the four DME MACs and encompasses the northeastern states from Maine to Washington, D.C. I have been the Medical Director for this region since 1995. I work for NHIC, which contracts with the Centers for Medicare and Medicaid Services, to administer this jurisdiction since 2006. New York is the demonstration state in our region.

My primary responsibilities revolve around the development and implementation of Medicare coverage policy. This role requires that I be involved in many aspects of NHIC's operations, including routine claim processing, appeals, medical review and provider education.

I have been asked to speak briefly about the preparations NHIC has made to implement the Prior Authorization for Power Mobility Devices demonstration project. For convenience, I would like to separate the discussion into two parts, payment policy and operations.

First, payment policy. Reimbursement for power mobility devices is set out in several sources. There are statutory requirements arising out of the Medicare Modernization Act implemented by CMS' Final Rule in 2006. These provisions require an in-person visit and a medical exam in addition to specific requirements for the creation of the prescription, and the provision of these documents to the DME supplier.

CMS' National Coverage Policy creates the foundation for the medical coverage rules. It allows for the coverage of mobility assistive equipment for beneficiaries with mobility deficits that impair their ability to accomplish activities of daily living within the home. This policy guides coverage for all mobility equipment, from canes and crutches to walkers to manual wheelchairs, all the way up to power wheelchairs. To make a decision about which device is appropriate, CMS' national coverage policy requires a systematic evaluation of the beneficiary by their treating physician in order to

determine which item optimally meets the beneficiary's mobility needs.

In addition to this CMS national policy, the DME MACs also have a local coverage policy for Power Mobility Devices. This local policy pulls together both the statutory and national policy requirements, organizes the nearly 60 individual power mobility codes into five groups of similar products, sets out the criteria for each group and explains the documentation requirements and coding guidelines. In other words, the local policy takes coverage and payment information from various sources, adds additional necessary details for proper claim submission and incorporates those into one document.

The major concern I hear raised by suppliers is whether the DME MACs will be able to review the anticipated request volume in a timely manner. Our staff is knowledgeable and experienced in looking at claims for power mobility. These requirements have been in place, unchanged, since 2006 when CMS' regulation took effect. All DME contractors have performed numerous reviews on power mobility devices since that time to identify problems.

In addition to standard power wheelchairs, we have all reviewed many complex rehabilitation power wheelchair requests under the Advanced Determination of Medical Coverage, usually referred to as ADMC. In Jurisdiction A, we review an average of 240 requests per month under this program.

These complex products must meet the same basic coverage criteria as the products covered by the demonstration project in addition to the requirements necessary to determine coverage for the options and accessories needed to address the needs of these patients. This demonstration project does not change any of the applicable coverage rules. Thus, we do not anticipate any issues in this area.

In fact, the project's focus only on coverage criteria for the wheelchair base simplifies the review for our staff. We do not anticipate that our review staff will have any difficulty in reviewing power wheelchairs of any type, including the numerous options and accessories used with them.

Another issue I hear mentioned is that some suppliers and physicians may not be familiar with all of the policy requirements. The contractors have produced numerous educational resources about this policy, ranging from "Dear Physician" letters discussing the coverage criteria and the need for quality documentations, to Question and Answer documents and articles, webinars and in-person seminars, and CERT and medical review error analyses. In addition to the materials provided by the contractors, CMS' Medicare Learning Network has also published a variety of materials addressing power mobility coverage.

Next, I would like to discuss operations. I know that some in the DME supplier community are concerned that the volume of claims may be too large to review in the allotted time of 10 business days. Based upon historical claim volume in Jurisdiction A, we initially expect 25 to 30 new requests per day for the types of power wheelchairs included in the demonstration project. In anticipation of this project, we have increased our nursing staff and assigned our more experienced personnel to handle the anticipated volumes.

Based upon historical power wheelchair audit data, we anticipate that approximately 50 percent of the initial submissions will not be approved. Likewise, based upon appeals data, we expect that about 50 percent of the resubmitted requests will not be approved.

Once the demonstration project is operational and in full swing, we anticipate a total volume of 50 to 60 new and resubmitted requests per day from this project. We have sufficient additional staff to allow flexibility to deal with variations in volume.

In the non-review areas, resources have been adjusted to allow for additional workload in written and telephone inquiries and in the production and mailing of response letters.

Finally, I would like to discuss errors. Regardless the source of the audit, the types of errors are consistent. For example, our most recent Jurisdiction A report, published in July 2012, showed a charge denial rate of 54 percent. The common denial issues were: 33 percent had insufficient documentation. This includes both a failure to meet the statutory requirements to perform the face-to-face exam, as well as incomplete or poorly documented exams. Twenty-three percent had problems with the 7-element order. This is the statutorily required prescription. Problems include missing elements, illegibility, and that the prescription was created before the face-to-face exam was completed. Nineteen percent had problems with the specialty exam and were missing a financial relationship attestation. Fourteen percent had problems with the Detailed Product Description. This is a document produced by the supplier for the physician's signature. It serves as the prescription for all of the separately billable items. Problems included no detailed product description submitted and the items billed did not match the items ordered. Nine percent had problems with the home assessment. Either none was submitted or was not signed and dated. Four percent had problems with proof of delivery. Either none was submitted or the delivery ticket did not match the claim.

Many discussions of errors focus upon issues related to the quality of the physician documentation and the DME supplier's inability to get the physician to improve. While physician documentation is an important factor in audit findings, it is not the only one. Many other errors occur. Often these others are more within the supplier's direct control either because they create the documentation or because there is an opportunity to screen for mistakes and have them corrected before submission. In this most recent review, most errors fell into this latter category.

This pattern of errors is not unique to this particular report. Our review experience demonstrates that errors would drop significantly if attention were directed to some of these non-medical record issues.

In summary, I believe that NHIC is well prepared to perform the work necessary to meet the requirements of this demonstration project. Thank you for the opportunity to share this information.

Senator CORKER. Thank you, sir.

Mr. Peake. Dr. Peake.

STATEMENT OF STEPHEN PEAKE, D.PH., MD, MEDICAL DIRECTOR, SENIOR CARE DIVISION, BLUE CROSS BLUE SHIELD OF TENNESSEE, CHATTANOOGA, TN

Dr. PEAKE. Ranking Member Corker, I appreciate the opportunity to appear before this Special Committee on Aging. My name is Dr. Stephen Peake, and I am the Medical Director of the Senior Care Division of Blue Cross Blue Shield of Tennessee. Currently, our Blue Advantage Product has approximately 30,000 enrollees, with an average age of 71, and we have been offering this product in Tennessee since 2006.

We were established by Congress in January of 2006, and we must conform to guidelines which are outlined in the CMS Manual, Publication 100.16, which allows for increased flexibility in administering beneficiary benefits as long as they do not result in the beneficiary receiving less than traditional Medicare benefits.

One aspect of this is the flexibility to perform utilization management, which allows us as an MA plan to require prior authorization of services.

We feel strongly that properly applied utilization management protects, first and foremost, the beneficiary from unnecessary risks, but also helps to protect the system from fraud, waste and abuse.

CMS has previously mentioned, has commented extensively, both directly and through the Medicare Administrative Contractors, on the documentation requirements for Power Mobility Devices. Yet CMS continues, as previously has been mentioned, to point out that the majority of claims for PMDs do not meet the documentation requirements for coverage.

At Blue Cross Blue Shield of Tennessee, we in the Blue Advantage program require strict adherence to the documentation requirements as outlined in the CMS literature.

For example, coverage is allowed only if the beneficiary has a mobility limitation that limits their ability to perform mobility-related activities of daily living in the home, such as toileting, feeding, dressing, grooming and bathing in customary locations in the home, not elsewhere. The documentation must indicate that the beneficiary's mobility limitation cannot be overcome with an optimally fitted cane, walker, or wheelchair. In other words, do they require a power mobility device?

Also, it is required that the physician perform a face-to-face examination and "shall" document the examination in a detailed narrative note in their chart in the format they use for other entries. This is a requirement that is far too often not met.

In addition, many suppliers have created forms which have not been approved by CMS. The one we most commonly see is the Texas Academy of Family Practice Mobility Evaluation. CMS even commented that this form was not adequate in the excellent September 2010 Provider Update. However, we continue to see suppliers completing this form and having the physicians sign it and physicians utilizing this form as the face-to-face mobility examination described above. In fact, if you go to their website, it clearly indicates it's not a CMS-approved form.

In addition, the supplier must supply a detailed 7-part prescription but is prohibited in the LCD from completing any portion which must be completed by the prescribing physician. Yet again,

we see what appear to be disparities in the handwriting on the form and the prescriber's handwriting.

Lastly, an in-home assessment, which is often omitted, must be completed to make sure there is room for effective maneuverability, as the primary intent in obtaining a power mobility device is to alleviate barriers to the performance of mobility-related activities of daily living in the home, not elsewhere.

In a one-year interval, Blue Cross Blue Shield of Tennessee Blue Advantage received 397 requests, the majority of which were for the more expensive power wheelchairs. Per CMS regulations, if the initial request is denied, the supplier can request a reopening with additional information. Both the prescribing physician and the beneficiary can appeal, and the prescribing physician can request a peer-to-peer discussion. By incorporating utilization management and requiring prior authorization of power mobility devices, 24 percent of the requests were still found not to be medically necessary. In 2010, and now with the updated information of 2011, which is that approximately $700 million was spent, based on our experience, that would be about $168 million in savings if 24 percent. We believe the savings could be significant.

In conclusion, I personally applaud CMS for initiating this demonstration project and would welcome it in the great State of Tennessee. I appreciate the time you have allowed me to share on how we at Blue Cross Blue Shield of Tennessee's Blue Advantage Plan approach our prior authorizations of power mobility devices, and I welcome any questions you may have.

STATEMENT OF MICHAEL CLARK, JD, CHIEF ADMINISTRATIVE OFFICER AND GENERAL COUNSEL, THE SCOOTER STORE, NEW BRAUNFELS, TX

Mr. CLARK. Good afternoon, Senator Corker and Senator Blumenthal, members and staff. My name is Mike Clark. I'm the Chief Administrative Officer of the Scooter Store, a nationwide supplier of durable medical equipment, including power mobility products and services.

I have submitted extensive comments for the record and would like to take this opportunity to summarize those comments for the committee.

PMDs allow people to retain their independence in their home and complete their activities of daily living safely so that they may age with grace and dignity inside their home. PMDs thus not only improve the lives of fellow citizens, but they also save significant health care dollars by preventing other serious injuries such as falls.

In 2003, Congress decided that payment may not be made for a power wheelchair unless a doctor conducted a face-to-face examination of the individual and wrote a prescription for that item. The face-to-face examination properly places the doctor in charge of the patient's care. The Scooter Store fully supports this requirement and applauds Congress for emphasizing the role of the medical professional when assessing power mobility needs.

Congress' good intentions, however, have been stymied by a review process that places arbitrary constraints upon what constitutes the patient's medical record. For example, Medicare will

not consider attestations or letters of medical necessity provided by physicians who saw the patients face to face, explaining why they prescribed the item. The bottom line is there appears to be more of an interest in denying claims for technical documentation deficiencies rather than determining whether the patient actually needs the item.

Private payers handle the process quite differently. For example, under the prior authorization process utilized by Blue Cross Blue Shield of Tennessee, a managed care program, 85 percent of the Scooter Store claims receive approval upon initial submission, with an additional 10 percent approved after reconsideration or appeal, for a total approval rate of 95 percent. In contrast, the Medicare prior authorization program to date has denied virtually all the claims submitted by the Scooter Store, although the TSS believes that prior authorization done right can be useful, we have several concerns about the program as currently structured.

First, we believe that any prior authorization demonstration must be significantly smaller. Simply put, this is a bet the benefit proposal. By placing roughly 50 percent of the nation's Medicare PMD utilization into prior authorization with no defined phase-in, no calibration between the physician who prescribes one to three a year for the most part. Calibration between the physician, supplier and CMS is exactly what's needed. For example, we've had claims denied because the fact statements where the fax machine says the time and date, that there has to be a date and time, that's not being read properly by the reviewers, and claims are being denied for that. It's that type of calibration that will delay the process of people getting equipment for technical reasons, and at 50 percent of the market, could lead to a disaster.

Under the current CMS claims processing system, a beneficiary is provided his or her PMD after a physician performs a face-to-face examination. Medicare contractors then, upon review, deny 80 to 90 percent of those claims upon review. The patient has the equipment in their house. What's not being discussed right here, right now, is that there's a difference between the error rate and then the final denial rate. Upon appeal, those denials are overturned through the waterfall of the appeals process 80 to 85 percent of the time. So the error rate that is being reported is not the ultimate denial rate. It's just the error rate.

Under prior authorization demonstration project, the 80 to 90 percent is now going to move to the front end of the process, not the back end where the people already have the equipment. It now moves to the front end where they don't get the equipment. This involves problems in that there's no legitimate appeal right in this prior authorization project. You can just continue to resubmit these to the same reviewer.

The doctor's medical judgment is essential to ensure our nation's elderly and disabled receive appropriate medical care. Towards that end, a face-to-face examination and clinical template should be available and sufficient for a determination of medical necessity. The doctor should be given the presumption that he was correct since he's the only one to have seen the patient.

The use of a clinical template is absolutely consistent with documentation practices of our nation's health care providers. CMS has

rejected this concept. They haven't approved any type of form to date.

A face-to-face examination template designed to determine and establish medical necessity is necessary to establish objectivity, clarity and consistency in the claims processing system for all doctors, suppliers and reviewers, and to ensure access to quality health care for our nation's elderly. Everybody needs to work off the same playbook.

I'd like to give you a real-life example of the difficulty beneficiaries are facing with this demonstration. We have a female patient who suffered a significant decline in her resting O2 saturation rates. Over a 7-month period of time, 3 liters of oxygen, her O2 sat rates went from 97 percent down to 83 percent at rest during the face-to-face exam. Her PMD claim was recently denied in prior auth because the doctor did not conduct an O2 saturation test on exertion. An exertion test rate at 83 percent O2 on 3 liters would have significantly put her health at risk.

These types of denials, coupled with the restraints on the medical record, clearly placed the reviewer between the doctor and the patient, detracting from the primary task of simply determining whether the patient needs the equipment.

Again, I thank the committee for allowing the Scooter Store this opportunity, and I welcome any questions you may have. Thank you.

Senator CORKER. Thank you, sir.

Dr. Epplin.

STATEMENT OF JEROME EPPLIN, MD, FAAFM, FAMILY PRACTITIONER, LITCHFIELD FAMILY PRACTICE CENTER, LITCHFIELD, IL

Dr. EPPLIN. Good afternoon, Senator Corker and Senator Blumenthal. I would like to express my sincere appreciation on behalf of the American Geriatric Society for the opportunity to provide testimony on the issues surrounding the use of power mobility devices, or PMDs.

I am Dr. Jerome Epplin, a board-certified family physician and geriatrician in Litchfield, Illinois, a small rural town of 7,000. I am also an active member and fellow of the American Geriatrics Society, a non-profit organization of 6,000 geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of all older Americans.

Today I will briefly provide the perspective of a busy family physician and geriatrician with regard to patient evaluation for these devices. Many of the requests that I receive from my patients for power mobility devices are easy to evaluate. Some people obviously need them, and it is quite a pleasure to help provide them for them. Some patients, however, assume that these devices can be used merely as a convenience and not as a necessity. It is obvious to me that they do not need a PMD and would not qualify under the current Medicare guidelines. In most cases, the health of these patients may be compromised if they use an electronic vehicle rather than remaining ambulatory as their physical activity would be decreased. Preserving function and mobility is one of the hallmarks of geriatric care.

In cases when it is less clear, I often use our physical therapist to help me decide if the patient qualifies for a PMD. They have told me that often a representative from a company that sells PMDs will accompany patients for the evaluation. A representative often wants to help fill out the forms or instructs the therapist in how to fill out the forms to better ensure that the patient will obtain the PMD. Understandably, the therapists feel pressured in such instances.

Often, a letter instructing how to favorably fill out the application for a PMD will accompany the application. I see this as an inappropriate attempt to circumvent or influence my objectivity and clinical judgment when evaluating the patient.

A physician with whom I trade calls recently told me of a patient who was denied by him a request for a power operated vehicle. Soon thereafter he received a call from a representative of the company telling him that if he changed some of his responses, the patient could get such a vehicle. The physician refused.

In Illinois, each nursing home is required to fill out a form on each resident every three months as to why the resident should not have a power operated vehicle. In most cases, the residents do not have the mental capabilities to operate such a vehicle safely. Even if the resident has the cognitive ability to operate the vehicle, the other residents walking in the facility may not have the ability to get out of the way safely, thus putting the other ambulatory nursing home residents in harm's way. This could also be a liability issue for the nursing home.

Unquestionably, the patients have been unduly influenced by the ads seen on television or received in the mail. They are told that all the doctor needs to do is sign the form and they will receive the vehicle. When the patient comes to my office, they already have false hope that they will qualify for a vehicle. If they are denied, many become very upset. I have had patients leave my practice because I denied their request for a vehicle.

A more responsible approach would be for the ads to emphasize that many people who think they qualify for a vehicle may not. The ads could list some of the features that will cause a patient to be disqualified from obtaining such a vehicle and to highlight some of the side effects of the vehicles, such as worsening muscle weakness and the potential for pressure ulcers.

As you know, Illinois is one of the seven states where CMS has implemented a prior authorization process for scooters and power wheelchairs for people with fee-for-service Medicare. The purpose of the demonstration is to ensure that a beneficiary's medical condition warrants the medical equipment under existing coverage guidelines.

I am hopeful that the demonstration project will better match patients who need the power operated vehicle versus those who would be better served by other means. However, the information which I have received from CMS about the demonstration project is lengthy and not very clear. The thick packet of materials received by my office was not well marked as to its contents. This increased the chances that many were discarded before being read or even being opened.

I did review the materials and, in my view, the demonstration needs to be better explained to clinicians in a more concise fashion. It would be helpful for clinicians if the application form could somehow be streamlined, as it takes at least 30 minutes to fill out after a lengthy examination. Perhaps a narrative could be accepted as an opinion. As you know, there is already a dire shortage of geriatrics healthcare providers, and the time spent filling out paperwork could be better spent providing care to patients.

For most experienced clinicians, it is not difficult to quickly determine whether or not a patient qualifies for a powered vehicle under Medicare. But when further assessment is needed, clinicians may give additional weight to the history given to us by the patient, and there is a possibility that the patient was coached by a vendor or influenced by the ads as to what to say in order to qualify for a powered vehicle.

Again, it would be helpful if the expectations of patients were not unduly elevated by outside sources, advertisements for one, when seen for their initial examination. This is an important issue as many older patients, often with complex and chronic conditions, benefit greatly from the use of powered vehicles. The challenge for all of us is to seamlessly get those vehicles to the appropriate patient. From a fiscal standpoint, it is also important that Medicare not needlessly pay for vehicles for patients who would be better served by more beneficial and less expensive modalities.

Again, thank you for inviting me to today's important hearing, and I look forward to answering any questions you may have.

Senator CORKER. Thank you, and thank you all for your testimony.

Senator, I'll go ahead and defer to you and let you start, and thank you very much for being here.

Senator BLUMENTHAL. Thank you very much, Senator Corker.

Let me begin, if I may, with you, Mr. Clark. Just so the record is clear, no one has yet mentioned the 2007 settlement. My understanding is that there was a settlement of allegations with respect to over-payment, and there was an agreement that involved a payback schedule. Has that repayment been completed?

Mr. CLARK. The 2007 settlement was the result of lawsuits between the Scooter Store and the government. That resulted in a corporate integrity agreement. I think you may be referring to an agreement with CMS recently, this year, in 2012.

Senator BLUMENTHAL. There are two separate agreements; is that correct?

Mr. CLARK. Well, no. There was a settlement in 2007 after a long——

Senator BLUMENTHAL. Could you provide us with the—I'm sorry.

Mr. CLARK. After a long, protracted, many years of litigation, there was a settlement in 2007 that resulted in a payment, a payment of $4 million, and then there was a corporate integrity agreement that lasted for five years. The corporate integrity agreement just ended in 2012, in May 2012, entered into with the OIG. There is a separate discussion and agreement that was reached in connection with a voluntary over-payment with CMS, a voluntary refund of an over-payment with CMS earlier this year in 2012.

Senator BLUMENTHAL. And that was an amount between $32 million and $63 million? Is that correct?

Mr. CLARK. No. The amount was—the total voluntary repayment amount was $19.5 million, which represents—the number is big, but it represents 4 percent of our Medicare billings for that two-year period of time. It was over a two-year period of time.

Senator BLUMENTHAL. I'm sorry. The initial figure reached by the reviewer was between $32 and $63 million, but the agreement was to repay $19.5 million.

Mr. CLARK. So there was an independent review organization. Pursuant to the corporate integrity agreement, the Scooter Store had an independent review organization that was hired and overseen by the Office of the Inspector General. The IRO, if you will, the independent review organization does a review of at least 250 claims a year, and if the error rate is at or above 5 percent, they may analyze additional cases to come within a certain statistical certainty of an over-payment. In the third year of our CIA, the IRO came out with a 14 percent over-payment pursuant to their audit, much different than the 80 or 90 percent over-payment that's cited by the government in their audits of the claim.

In year 4, the error rate, if you will, the percentage of over-payment was slightly over 7 percent.

And so based upon those two over-payments, the OIG sent the Scooter Store a letter saying that they thought we were in violation of the corporate integrity agreement, which we weren't. We disagreed with the OIG's interpretation of their ability underneath the CIA, and we felt that their only recourse was to have CMS and the Scooter Store review those claims, come to a decision on what was an over-payment or not.

So that's how that event finally happened, CMS and the Scooter Store came together, reviewed those claims. The Scooter Store then voluntarily repaid back $19.5 million, which represented 4 percent of our overall billings, and that was a payment to be perfect in an extrapolated scenario.

Senator BLUMENTHAL. Has that $19.5 million been repaid?

Mr. CLARK. It was—$5 million was paid up front, and the rest is in a payment schedule.

Senator BLUMENTHAL. So the answer is no.

Mr. CLARK. In total, no.

Senator BLUMENTHAL. How much remains outstanding?

Mr. CLARK. Well, $19.5 minus $5 million, and then we made some payments, I think somewhere around $13. And then we have some credits for some appeals. I don't know exactly what remains outstanding.

Senator BLUMENTHAL. Could you—I don't want to consume a lot more time on this issue.

Mr. CLARK. Right.

Senator BLUMENTHAL. But could you commit to provide the internal documentation relating to the corporate integrity agreement, the repayment agreement with respect to $19.5 million, how much has been repaid and what amount remains outstanding?

Mr. CLARK. So I make it clear, you want a copy of the corporate integrity agreement?

Senator BLUMENTHAL. Well, I want to know, on the repayment, how much has been repaid and the documentation that underlies that.

Mr. CLARK. Yes, I can provide that to you.

Senator BLUMENTHAL. Thank you.

Mr. Chairman, if I may, I'd like to ask that—I understand we have some ads that we can play at this time.

Senator CORKER. I understand that, yes, you all asked permission to do that, and that's fine.

Senator BLUMENTHAL. That's great.

[Video presentation.]

Let me ask you, Mr. Clark, the second of those ads is from your company, is it not?

Mr. CLARK. Yes, it is.

Senator BLUMENTHAL. And how recently was that ad aired?

Mr. CLARK. I don't think that one has been aired recently. I'm not completely sure on that.

Senator BLUMENTHAL. Do you have any reservations or qualms about that ad?

Mr. CLARK. No.

Senator BLUMENTHAL. You stand by everything in it?

Mr. CLARK. Yes.

Senator BLUMENTHAL. And how about the first ad? Do you have any problem with that ad?

Mr. CLARK. No, I don't like Hoveround's ads.

Senator BLUMENTHAL. Well, just as a matter of either their accuracy or——

Mr. CLARK. From the content of their ad, I don't see a problem with it.

Senator BLUMENTHAL. Dr. Epplin, could you give us your opinion of those ads?

Dr. EPPLIN. Well, this morning I saw an ad on TV for a drug where at least half of the ad listed the side effects, and I'm not sure I'd even take that drug, nor prescribe it.

There is nothing in these ads to suggest that actually immobility is not a good thing, that walking around is better, and it puts pressure—I feel like it puts pressure on me because people come in saying I can get this for free, why don't you give it to me? I mean, I hear that almost verbatim from people. It puts a lot of pressure on me. It makes me be the bad guy. Unquestionably, there are some people who need them, and I have no qualms with writing for them to get them. But I don't think these ads tell the whole story, that everybody shouldn't necessarily have one if they're able to get around. Many of them want them as a convenience and not as a necessity.

Senator BLUMENTHAL. So if I can put what you just stated perhaps in slightly different terms, the requirement is that the power mobility device is necessary for mobility. In many cases, there may be mobility through the use of other devices that may, in fact, be better for the patient.

Dr. EPPLIN. Very simply, for some of these people, just a regular standard wheelchair will suffice. If they have good strength in their arms, reasonable strength in their arms, they can get by very well with a wheelchair or a walker.

Senator BLUMENTHAL. What about the use of these devices outdoors as opposed to inside?

Dr. EPPLIN. That's sometimes a little bit more difficult, especially if the person wants to go a quarter mile or a half mile. They wouldn't be able to do that if they were walking. Many of them couldn't. The question is, is that a necessity that they do it, and could they be better served by a standard wheelchair? Not everybody can, of course.

Senator BLUMENTHAL. And these types of ads result in what you referred earlier to—I think you said elevated, unduly elevated expectations.

Dr. EPPLIN. Yes.

Senator BLUMENTHAL. Do you know about instances of supplier representatives accompanying patients to their evaluation appointment?

Dr. EPPLIN. Yes.

Senator BLUMENTHAL. And does that happen?

Dr. EPPLIN. Yes.

Senator BLUMENTHAL. Has it happened to you?

Dr. EPPLIN. Yes, and to our physical therapist. I have pretty much stopped filling these forms out myself. I send them to physical therapy because they take—it's an onerous form to fill out. It takes a while to do that.

Senator BLUMENTHAL. We've heard today also about the danger of falls. In your medical opinion, are there situations where a power mobility device may increase the risk of falling?

Dr. EPPLIN. They can in that the potential that the person will not ambulate and thus get weaker can actually increase their risk of falls, or if they don't learn to properly use, for example, a walker and depend on these power mobility devices, it could increase the risk of falls. There are other people where the risk of falls is very high and these PMDs can help. But other times, if you allow yourself, your muscles to atrophy, you're going to increase your risk of falls.

Senator BLUMENTHAL. You referred earlier in your answers here to ads that you saw for pharmaceutical drugs where side effects were advertised because they had to be under the law.

Dr. EPPLIN. Correct.

Senator BLUMENTHAL. The risk of falls for people who become overly dependent on these mobility devices may be a side effect, if I can characterize it as such, that perhaps should be told to consumers before they go ahead and get one of these devices.

Dr. EPPLIN. Correct, and if they sit in them a lot, some people increase their risk of pressure ulcers as well.

Senator BLUMENTHAL. I have other questions, Mr. Chairman, but I know I'm way over my time.

Senator CORKER. Do you want to keep going for a minute?

Senator BLUMENTHAL. If I may continue?

Senator CORKER. That's fine.

Senator BLUMENTHAL. Let me turn to you, Mr. Hughes, if I may. Do you see any issues or problems with these ads?

Dr. HUGHES. Well, I agree. I think they create an expectation that everybody is entitled to the wheelchair and really, at least from a Medicare point of view, doesn't speak to how really very

limiting the actual Medicare coverage criteria is. All of the ads always show folks very active, almost universally outside for the majority of the activities. So I think that it creates demand. I mean, that's what ads are supposed to do. So I suppose from the company's point of view, they're doing what they're supposed to do. But they create tremendous demand and put physicians in practice in a difficult situation.

Senator BLUMENTHAL. You referred in your testimony, and I'm going to quote, "Our review experience demonstrates that errors would drop significantly if attention were directed to some of these non-medical record issues." Are these the kinds of issues that perhaps attention should be devoted to?

Dr. HUGHES. Well, what I was referring to there is often in discussions of errors, particularly discussions led by suppliers, the attention is given to how hard it is to get a physician to write a complete and thorough and detailed examination. You heard in Mr. Clark's testimony he is advocating for various forms and documents to streamline that process.

Medicare's view when we're looking at medical records is that physicians need to document the way we're taught to document in medical school, the way nurses are taught to document, completely, thoroughly, enough so that an independent person can come along and read that record and know what's going on with the patient. That's a high standard, and many, probably most physicians don't consistently document to that level.

The point I was trying to make is in addition to that problem, which in our most recent report was about a third of the errors, there are a whole variety of other errors not related to the physician's records. Some of the records, some of the documents suppliers create, and yet when they are charged with direct responsibility for creating the records, they fail to dot all the I's and cross all the T's and so on.

With respect to the ads, the errors I'm talking about don't have anything to do with the ads, but it points to there are problems at a lot of levels and it's not entirely laid at the feet of the treating physician and the quality of their record-keeping.

Senator BLUMENTHAL. The treating physician in effect may agree to go along with prescribing or directing the use of these power mobility devices because of the demand generated by these ads.

Dr. HUGHES. Oh, yes, or so I've heard from my colleagues who are still in practice.

Senator BLUMENTHAL. Do you agree, Mr. Peake?

Dr. PEAKE. Yes, I do. As a physician——

Senator BLUMENTHAL. I'm sorry, Dr. Peake.

Dr. PEAKE. That's all right. I've been called worse. I'd make the supposition that most of us went into this profession because basically we like to be affirmed by others and we want to help people, and we like that affirmation that comes in. And tremendous pressure is put on the daily practicing physician in my experience to sometimes acquiesce to these demands, and I think these ads do add to that pressure, as the doctor so eloquently stated from Illinois.

Senator BLUMENTHAL. Thank you very much.

I'd like to thank you all for being here today, and I'm very hopeful that your testimony, with the excellent leadership of Senator Corker, may lead us to take some measures that will address some of the concerns that you have very compellingly raised.

Thank you, Senator Corker.

Senator CORKER. Thank you, Senator, for being here and participating.

I appreciate the testimony. I think it gives really four different views of what's happening here, not that they're necessarily all inconsistent. But I'd like to understand just the identity of interest here. You, Dr. Hughes, you are a contractor that is hired by CMS to make sure that claims are valid. Is that correct?

Dr. HUGHES. The Medicare administrative contractor is basically hired to process claims. That's the vast majority of the responsibility. Our Region A is the smallest. We process a million claims a month. So that's the main task. We also handle appeals, provider education, customer inquiries, and we have a medical review department and a medical director. The medical review department is the place where audits are done.

Senator CORKER. So you process claims that are generated to you through the standard CMS process, and are you paid more or less whether they have high error rates or low error rates?

Dr. HUGHES. I'm sorry, Senator. That's sort of above my pay grade. My understanding is that the contracts are bid based on the projected claim volume. The payment rates and such don't affect that, but I defer that to my bosses.

Senator CORKER. So you have a contract to process the claims, but in essence the outcomes of the claims, based on your understanding, have no effect on what your company is paid.

Dr. HUGHES. That's my understanding.

Senator CORKER. So then, Dr. Peake, you all manage—it's a managed plan, and therefore claims that are inappropriate, if they are processed and people have asked for PMDs unnecessarily, then in essence your company loses money unnecessarily on the patients that you serve on a capitated basis or at a set price. Is that correct?

Dr. PEAKE. That is correct.

Senator CORKER. So your incentive is to serve your clients and to maintain them on your rolls, but you also don't want to pay unnecessarily. So that might speak to the huge differences that exist between what Blue Cross is doing in this case and what a contractor—no offense, but really the outcome doesn't affect them in any way. The outcomes you might imagine would be very different. Is that correct?

Dr. PEAKE. Yes. Our first priority, obviously, is the beneficiary. But then we also have a fiduciary responsibility to properly manage the premium dollar so we can make sure our beneficiaries get the greatest benefits they can get for that premium dollar.

Senator CORKER. But at the end of the day, you've got to provide those services at that premium dollar. Otherwise you can't provide services down the road.

Dr. PEAKE. That is correct.

Senator CORKER. Whereas in a standard fee-for-service program, and certainly with contractors that have no financial incentive,

when you have an 80 percent error rate, it really doesn't raise alarms. Is that correct?

Dr. PEAKE. From what I've heard today, that would seem to be correct. Correct.

Senator CORKER. So then, Mr. Clark, obviously your goal is to sell as many scooters as you can, and you all obviously are doing a very good job, and it sounds like you've been overly aggressive in some cases and have had to deal with some payments back to the Federal Government and obviously are here today testifying because of the aggressive nature, at least from our perspective, that your company is taking.

For me, as I listened to the testimony today, there is either a—I want to use this word not in a definitive term, but there's almost a fraud that's being put on the American people because of the way the system is set up. There really aren't checks and balances because, again, people aren't paid to care what this costs in the standard fee-for-service program. In a program where it does matter, they have different criteria and obviously don't have the error rate that exists.

I know you've made the distinction between denial and errors, but it does appear to just a person who doesn't know much about scooters that there's a problem here, and I just want to ask you. I mean, would you not, based on what we've witnessed today and watched, and just the evidence of the error rate and the settlements that you've had with the Federal Government, would you want to dispel me of the notion that maybe the companies that are dealing with these PMDs are being a little bit overly aggressive?

Mr. CLARK. Yes, I'd certainly like to dispel you of that perception. First of all, of the people that call us for power mobility devices, only 13 percent of those end up in a power mobility chair paid for by Medicare. So between us and the doctors, we screen out 87 percent of those people that call.

The idea that we want to sell as many of these as we can is just not correct. We want everyone who needs one to have one. The ads, in my opinion, let people know that this benefit exists. It doesn't say that you get to have one. In fact, Congress set up that the gatekeeper to that is the physician. I don't sell anything to anyone that a doctor doesn't prescribe, and to have the thought that a doctor would prescribe something he doesn't think a patient needs because of an advertisement, or because the patient walks in and says he or she wants one, is troubling from my seat as to what the physician community is doing.

Senator CORKER. Do you have people who go in with, as Dr. Epplin testified to and we've heard in many cases—as a matter of fact, what we hear a lot in the field is that the handwriting appears to be the same on massive numbers of these. In other words, somebody at the Scooter Store or some other entity is filling out many of these forms. There may be one little section that maybe has different handwriting. But do you have people who——

Mr. CLARK. Senator, I can assure you the Scooter Store is not pre-filling any paperwork. We don't fill out any paperwork because there is not an objective, standard system that's been created for this complex benefit—as testified by the good doctor from Illinois, this is a complicated exam with complicated criteria. Most of these

doctors do this one to three times a year. If there was a process set up by CMS or the carriers that allowed everyone to work off the same playbook, I think it would be easier for the doctors to do these exams and provide the information that they need.

So what happens is a lot of paperwork comes back, and when we look at it, it's not that the patient doesn't need it, it's that the doctor didn't document it appropriately. That's what's being said through the whole panel. That's what Ms. Taylor testified for. So we go back to the doctor and say, look, you didn't document this enough; go back and explain it. But we're not filling out the paperwork. We're not writing what the doctor says. If his nurse writes something and he signs it, it doesn't have to be in his handwriting. If he signs and dates it himself, then he's attesting to that.

But again, we screen 87 percent of the people that call us. There's a gatekeeper. We sell the patient nothing. The doctor prescribes everything. We don't fill out paperwork. We don't sit in the doctor's office, Senator.

Senator CORKER. You don't have any people with your company that ever, in order to meet sales quotas or whatever, ever accompany a patient to the physician's office?

Mr. CLARK. I am unaware of where any representative from the Scooter Store goes and sits in an examination with the patient and their doctor. We have doctors—we have hundreds and hundreds of doctors that refer their patients to us to begin the paperwork process for them to get power mobility devices. We have people in the field that have relationships with doctors. I don't—I'm not personally aware of if one of my representatives, because a patient asked them to say would you go to the doctor's office and sit in the lobby. But there's not one of my people sitting in an exam with a patient and their physician. That's between them and their physician.

There is an enormous difference, Senator, between an error rate and a denial rate.

Senator CORKER. I understand that.

Mr. CLARK. We have a very, very low denial rate. Our ads—I mean, when you talk about an over-payment that was voluntarily paid on a 4 percent denial rate so that we could be at perfection——

Senator CORKER. So what would be your denial rate overall with the PMDs for CMS?

Mr. CLARK. So as I go through the waterfall, they deny—just like all the audits, they deny——

Senator CORKER. I understand. But the net net net——

Mr. CLARK. So the net net net to me, through the governmental appeal process, is anywhere between—around 15 percent is what I end up losing because then I decided not to go to Federal court, where I think I would win more at a Federal court——

Senator CORKER. And then you give them a PMD for free? Is that what you're saying?

Mr. CLARK. Right. We're not going to go pick them up at anyone's house.

Senator CORKER. So they've already been placed in their home by the time this all occurs.

Mr. CLARK. Right. So then I go through 18 months of appeal to get 85 percent of them overturned. I spend an enormous amount

of money doing that. Now you're moving to a prior auth standard with, mind you, Senator, no changes to the system, so the error rate stays the same. Again, we're seeing almost a 100 percent error rate right now coming back from prior authorization. The individual with the O2 sat rates is a bad case, and being denied because the reviewer can't understand the medical record or doesn't know how to look at a fax stamp to find out the date that's there.

But, you know, because the over-payments were brought up, again, the IRO—we've had the OIG sitting over the top of us under the corporate integrity agreement for five years. They've never said anything about our ads. They didn't come after us and allege any fraud, any misuse, any abuse, any changes to our very robust compliance program. CMS, who I've dealt with for years, has not done any of that. We've talked to CMS about our ads. Again, we filter a lot in our ads.

Senator CORKER. Do you think that speaks to the—and I need to move on in just a second. But do you think—and I appreciate everything you've said. Do you think that speaks to the culture, though, at CMS, that they haven't responded? I mean, would you think, just if you were sitting on our side of the dais and we had a Medicare program that was going to be totally insolvent in the year 2022——

Mr. CLARK. Exactly.

Senator CORKER [continuing]. And we're all trying to figure out a way to stave off a fiscal crisis in this nation, the world is looking to us, we see these advertisements on television that—on our side of the dais, I mean, would you not understand why that would create a little bit of concern that we have companies like yours that are so aggressively trying to put these PMDs into people's hands and, in some cases according to testimony, in ways that actually hurt the patient? I mean, can you see why we would have a degree of concern over the testimony today, plus the marketing that's taking place around these PMDs?

Mr. CLARK. I could understand with not having an awareness of the screening process, that only 13 percent get that, with not having an awareness of the fact that the vast majority of error rates are overturned and don't become denial rates. I could understand that one would say, wow, these ads generate a lot of utilization.

These ads have been going on for quite some time. Everyone knows utilization has dropped 30 percent in the last two years. We don't have the 2012 utilization, but it will be significantly less than 2011. Utilization is going down.

Ads don't commit fraud; people do. Forms don't commit fraud; people do. Criminals aren't advertising. There are criminals in the system. There are criminals across every benefit by Medicare.

I think the best thing that we could look to is the independent review organizations and their models. When they look at our claims Senator, they go through 190 questions on each claim over 42 areas of the file. They found an error rate between 3 percent and 8 percent.

The managed care plans that are businesses, they don't have these high error rates. Nobody is judging the overturn rate and saying what's wrong with the process up front on the audits? Why isn't the right answer being decided up front? Because you're look-

ing to deny the claim at all costs. You're not looking to see does the patient just need the equipment.

Senator CORKER. What we understood as far as the settlement that took place is it wasn't done voluntarily, that CMS threatened to cancel your ability to deal with them and this product, and therefore you made this settlement. So you're shading it a little differently than we've been told as to what happened. So which happened? I mean, were they threatening?

Mr. CLARK. So the OIG, the OIG threatened us under the CIA. The OIG had, in my opinion, in counsel's opinion—we wrote the OIG back—they had no authority to do that. They had no authority to do that. We sat down with CMS——

Senator CORKER. But you didn't just come forward with a settlement. You were——

Mr. CLARK. CMS never threatened to pull my supplier number or exclude me from the program.

Senator CORKER. The OIG did.

Mr. CLARK. That was OIG underneath their contract. CMS and I sat down, went over the IRO studies, and again that was an error rate. We went over them. We went over a bunch of files. We talked, and the company, if you look at the documents that came out of that back from CMS, they couch it as a voluntary repayment. We didn't have to pay that. We wanted to work with CMS. We wanted to stay in good graces with them, if you will.

Senator CORKER. I would imagine.

Mr. CLARK. We wanted to be a good partner.

Senator CORKER. What percentage of your business——

Mr. CLARK. We wanted to be a good partner, and it was 4 percent of our business.

Senator CORKER. No, but the percent—CMS is 4 percent of your business?

Mr. CLARK. No, no. The overpayment was 4 percent.

Senator CORKER. And what is CMS as a percentage of your business, since you brought it up?

Mr. CLARK. Roughly 75 percent of our business.

Senator CORKER. Yes. Well, I would think the OIG threatening to end a 75 percent relationship would cause you to want to "voluntarily" settle this.

But let me move on. And we——

Mr. CLARK. They just didn't have authority to do that.

Senator CORKER. For what it's worth, I am so glad they did.

Doctor, just to get identities of interest, you sound like an outstanding physician, and you sound like you care greatly about your patients, and I'm sure that you do. When a physician fills out the forms for one of these PMDs, is there any incentive for them to do that financially, or is that——

Dr. EPPLIN. You can charge Medicare for a higher level of service. It's not a significant—for the amount of time that it takes, the answer is no. There's no financial—you do it just because you have to do it.

Senator CORKER. You do it because you have a patient that is coming to see you to do it. Most physicians, according to the testimony, do it two or three times a year. The form is long, and there's

really no financial incentive, you say, for physicians to really want to prescribe these.

Dr. EPPLIN. There's no big financial incentive to do that. I think you would have to look at the specialty of the physician. I would think that people who are geriatricians or see a high percentage of their patients being elderly would have more than 1 to 3 per year. So if someone is seeing the broad spectrum of either internal medicine or family medicine, that may be true. But if you're seeing a lot of geriatric patients, I would guess it's probably more than that, and I do get requests frequently, and it's probably only, as Mr. Clark says, I can probably can screen out 80 to 90 percent of the people just by telling them you don't qualify. So the number that he gives is about what I see in my practice as well.

Senator CORKER. I know this was really to be about the demonstration program. I want to spend just a minute on that. I know we got a little astray based on the testimony, which we greatly appreciate.

But, Dr. Hughes, what, in your opinion—and I know it sounds like some of the forms need to be reworked, and it sounds like it's very difficult.

Dr. EPPLIN. They're very difficult.

Senator CORKER. And I hear all this, and certainly we'll be corresponding with CMS over the testimony that's come. And I know the error rate is different than the denial rate. But what is the appropriate error rate for this program once it gets refined?

Dr. HUGHES. Well, I hesitate to pick a number. Our numbers, as far as recent audits, are down to 50 percent from the OIG study from a couple of years ago. I don't think it will ever be zero, but I certainly would like to see it down to the single digits.

Senator CORKER. And is that based on your experience? I know what you'd like to see. Based on your experience, is getting the error rate down to single digits something that you think is achievable if we put the right processes in place?

Dr. HUGHES. Yes, I do, partly because of what I had in my testimony. A substantial percentage of the errors are technical things, as Mr. Clark points out. But I believe many of those technical errors are able to be remedied by the supplier, and that will then leave a nub of 20 to 30 percent of errors that have to do with the quality of the medical record. That gets to be subjective, but that's a different set of tools that would need to be worked on that, and maybe a form. I don't know what would be best for that.

Senator CORKER. And, Mr. Clark, I know you have concerns about what's happening, a 100 percent error rate now. Is it your view the pilot program is starting too large and should start in a smaller way to be more effective in figuring out the end processes that ought to exist?

Mr. CLARK. Without a doubt. I think the calibration that needs to happen between the reviewer, the contractor, CMS; the physicians who only do these once, many of them will only do them one to three times a year, it's complicated; the supplier, most of the time the supplier helps educate the physician. There's a great deal of calibration that has to happen in order to get the error rate down, and to do it on a 45 percent demonstration project just sets up an environment where you're betting the benefit if you have 80

to 90 percent denial rates up front, where businesses then have to carry that working capital, if you will.

And particularly in this benefit that's gone from heavy allowable reductions in 2007, 27.5 percent price cut, then another 10 percent in 2008, competitive bidding, conversion to a 13-month rental program in 2012, now having a very high error rate for technical reasons or whatever, that's going to take 60 days because it's 43 business days really, if you look at the 10 business days CMS has, the mail, then the 20 business days, if they get that, that type of working capital would drive a lot of companies out of business while the claims then ultimately get paid.

So our suggestion was to roll this thing out in one city in each state, something similar to what was done with the competitive bid program in DME, where they did it in two areas, worked out all the kinks, and then began to grow it, like they're doing now, that would be, in my opinion, the most effective way to do prior authorization. As well, it allows all parties to understand what's expected of one another without the threat of 50 percent of your revenue, or 100 percent of anyone sitting alone in Illinois or Florida, their business being subjected to that.

Senator CORKER. So I know Dr. Peake mentioned that they use the same coverage determination requirements as DME MACs for their prior authorization protocol. So why is it different for you to do prior authorization at a DME MAC than it is for you at Blue Cross?

Mr. CLARK. Blue Cross, most of the Blue Crosses have a prior authorization template. They have a face-to-face examination guide that the physician uses. So we can—we don't do—if we're doing with a managed care, whether it's Blue Cross Blue Shield or a MAP plan, and the volume is smaller, we can take their face-to-face exam, what they're wanting to see the doctor do, and we can calibrate with them. We can educate the doctor on what Blue Cross Blue Shield of Tennessee requires as far as the format they want to see and how they want to see it. And then that leads to a better face-to-face exam, and then the error rates are lower.

It's just been my experience, Senator, that upon review, most of the managed care plans are more so not trying to just deny the claim. They're really trying to see does the patient need it or not, and the error rates are significantly lower than in Medicare.

Senator CORKER. So I think what you're saying is that CMS in this pilot could learn a lot from what's happening with some of the managed care plans that actually have themselves an incentive not just to provide very good care for the people they serve but also to make sure they do it in a way that's appropriate to keeping the company going.

Mr. CLARK. Absolutely. I think they would agree with me that the managed care plan loses a lot of money through an extended appeals process as well, and because they do have a business model and income they've got to deal with, they don't want to go through a lengthy appeal process. So it's best for everyone in every scenario to know exactly what's expected from them, calibrate to what that is, and then you can effectively move forward.

Senator CORKER. Dr. Epplin, have you—thank you. Dr. Epplin, do you deal with both managed care plans like Blue Cross and

also—obviously, you deal with CMS. Is there a difference for you in filling out the forms and doing the things that are necessary to get someone enrolled?

Dr. EPPLIN. Honestly, Senator Corker, in our rural area, we have very few, if any, managed care plans. So I don't deal with them in terms of filling that out.

Senator CORKER. And, Dr. Peake, would you say that testimony from Mr. Clark is on target?

Dr. PEAKE. We don't have any forms, per se, and we have excellent physicians in Tennessee, like Dr. Epplin alluded to, that do this, that do very good face-to-face examinations. But I do support the documentation requirements from CMS in the fact that each patient is individual and I don't think that you can put them into a template. I think you can give them guidelines, and I think the guides are pretty clearly stated.

But as an MA plan, when I deny something, we clearly articulate why we denied it, and if you read our denials and you figure it out and the patient truly does meet it, you'll know what you need to do so that beneficiary can get what they need. I talk to a lot of physicians about this subject, and I would agree with Mr. Clark. After a lot of our discussions, they don't understand that you can't get a power mobility device so mom can go to the park with the family.

Senator CORKER. But you'd have that impression if you saw the marketing materials; is that correct?

Dr. PEAKE. I would have that impression. Unfortunately, and perhaps you have too, I've driven all over the state of Tennessee, and I see many power mobility devices sitting in the front yard, sitting in the backyard, sitting out on the porch because they can't get through the door, and I question how did those get there? I don't know that answer.

Senator CORKER. So the documentation issues that were being addressed earlier, you actually think the forms that Mr. Hughes is using and that CMS is requiring, you think that they're appropriate as they're laid out, or do you think there is some——

Dr. PEAKE. No, I don't think the forms are. The forms can give guidance, but as has been mentioned by my physician colleagues, I personally feel that each patient is an individual and it needs to be documented, as CMS says, in the same format as the rest of the chart. The face-to-face examination does take time, but it's a fairly complex examination, but it's a good physical examination. That's all they're asking to be done.

You're right, you could probably bill it at an 05 or a 15 level. There is a G code that goes with that to give additional compensation. But they're just asking you to paint a picture of a patient that needs a power mobility device, nothing more, nothing less, not trying to put you in the same box with me, me in the same box with him. It's to look at that patient and say do you need this or do you not? I really compliment the doctor from Illinois for bringing up the fact that inactivity can lead to increased obesity, a worsening of diabetes, comorbid conditions. If they need a power mobility device, Blue Cross Blue Shield of Tennessee certainly supports providing that device. But there needs to be a clear picture that that patient needs it because I firmly believe as a physician that if they don't, we're not doing them a favor.

Senator CORKER. Well, I think taxpayers all across our country have seen abuse probably of these, and at the same time I think they realize that they may have a loved one at some point in time that really does need one, and I'm sure many people in the country that are using them really do need them. But it jeopardizes everyone who does have a medical necessity for one of these, and I appreciate all of you being here.

We're closing, and I'm the only one here, and I appreciate all of you coming to testify.

I wonder if any of you would like to take just a moment, a brief moment, sharing with me some misperception or misconception that we might have after hearing the testimony today. Is there anything you'd like to clear up before we leave? I've got a feeling Mr. Clark might, and you're welcome to do that. But do any of you have anything you'd like to say as we leave that might help us as we move ahead looking at this pilot? Dr. Hughes? Dr. Peake? Mr. Clark?

Mr. CLARK. I would say that we are obviously working well together with Blue Cross Blue Shield of Tennessee since we have a 95 percent payment rate with them. So again, I think most of the misperceptions we've talked about. I will not take up any more of your time, Senator.

Senator CORKER. Thank you.

Dr. Epplin.

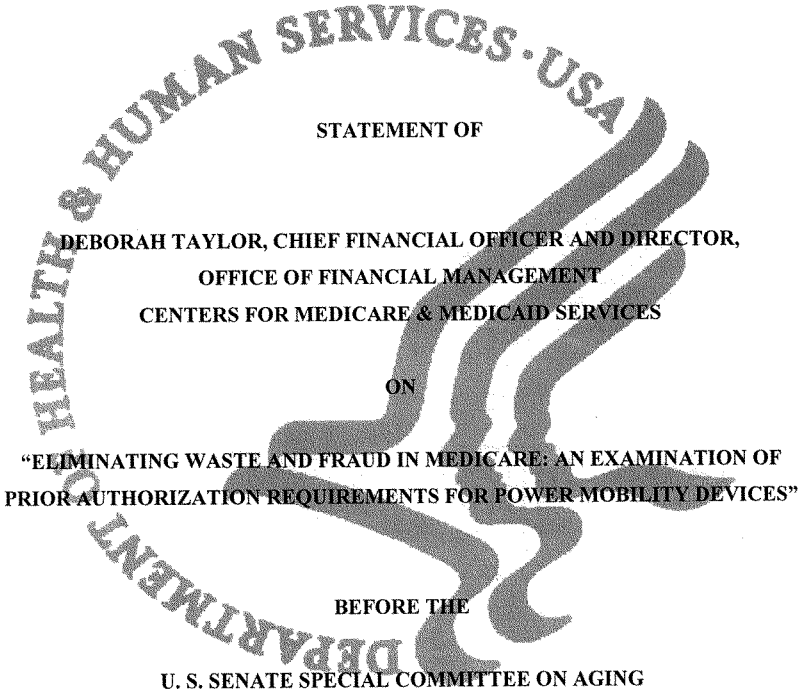
Dr. EPPLIN. No, thank you.

Senator CORKER. Well, thank each of you for coming and testifying. I thank you again, all of you, also for your temperament, and I hope the pilot goes well and hope we get down in the single digits, as you mentioned, Dr. Hughes.

Thank you all, again. I appreciate it.

[Whereupon, at 4:29 p.m., the hearing was adjourned.]

APPENDIX



STATEMENT OF

DEBORAH TAYLOR, CHIEF FINANCIAL OFFICER AND DIRECTOR,
OFFICE OF FINANCIAL MANAGEMENT
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"ELIMINATING WASTE AND FRAUD IN MEDICARE: AN EXAMINATION OF PRIOR AUTHORIZATION REQUIREMENTS FOR POWER MOBILITY DEVICES"

BEFORE THE

U. S. SENATE SPECIAL COMMITTEE ON AGING

SEPTEMBER 19, 2012

U.S. Senate Special Committee on Aging
Prior Authorization of Power Mobility Devices (PMDs) Demonstration
September 19, 2012

Ranking Member Corker, Chairman Kohl, and Members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to reduce fraud and improper payments for power mobility devices (PMDs), which will help ensure the sustainability of the Medicare Trust Funds and protect beneficiaries who depend upon the Medicare program. I appreciate the opportunity to update you on the Prior Authorization of Power Mobility Devices Demonstration, which CMS began earlier this month. PMDs are a group of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) consisting of such devices as power wheelchairs and power operated vehicles (scooters).

Background

DMEPOS, including PMDs, are included under the Medicare Part B benefit. Medicare covers PMDs when a beneficiary has a mobility limitation that significantly impairs his or her ability to participate in one or more mobility-related activities of daily living within the home and the limitation cannot be sufficiently and safely resolved by the use of a cane, walker, or manual wheelchair. These activities of daily living include feeding, dressing, and bathing in customary areas in the home.[1]

A physician/practitioner may prescribe a PMD to be paid by Medicare after they complete the face-to-face encounter process. During this process, the physician/practitioner assesses the beneficiary's medical condition and mobility needs and determines whether a PMD is necessary as part of an overall treatment plan. The ordering physician/practitioner sends a supplier the prescription for a power wheelchair and documentation from the beneficiary's medical record to support the medical necessity of the power wheelchair. Based on the prescription and supporting medical documentation, the supplier recommends a type of PMD for the beneficiary; the type must be approved by the ordering physician/practitioner. The supplier is also responsible for

[1] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PMDFactSheet07_Quark19.pdf

assessing the beneficiary's home environment before or during the delivery of the PMD to verify that the beneficiary can adequately maneuver the item in his or her home.

High Incidences of Fraud and Improper Payments

PMDs have had historically high incidents of fraud and improper payments. PMD suppliers also continue to be subject to significant law enforcement investigation.[2] Based on joint investigations by the Department of Justice (DOJ), CMS, and the HHS Office of Inspector General (OIG), in recent years numerous DMEPOS suppliers have been charged and convicted of defrauding the Medicare program and many have had their Medicare billing privileges revoked as a result of OIG investigations. Examples include the 20 DMEPOS company owners and marketers, most of them in the Los Angeles area, who were charged in 2009 with allegedly billing Medicare for more than $26 million in fraudulent claims for power wheelchairs, orthotics, and hospital beds.[3] More recently, a Louisiana man was sentenced to 180 months in prison for participating in a health care fraud scheme that defrauded Medicare of more than $21 million by billing for power wheelchairs, leg and arm braces, and other durable medical equipment that were never provided to beneficiaries and/or were not medically unnecessary.[4]

In addition, CMS noted in a 2011 Report[5] on improper payments in the Medicare fee-for-service program that over 80 percent of claims for motorized wheelchairs did not meet Medicare coverage requirements. Although CMS recognizes that many improper payments are not the result of willful fraud, this error rate represents over $492 million in estimated improper payments.

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/FR-Notice.pdf
[3] http://oig.hhs.gov/oei/reports/oei-04-09-00260.asp
[4] http://www.justice.gov/opa/pr/2012/August/12-crm-1032.html
[5] http://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/MedicareFFS2011CERTReport.pdf

Prior Authorization for PMD Demonstration

The Affordable Care Act provided CMS with many tools to combat fraud, waste, and abuse in Medicare. In recent years, CMS has implemented powerful new anti-fraud tools provided by Congress, as well as designed and implemented large-scale, innovative improvements to our Medicare program integrity strategy to shift beyond a "pay and chase" approach by focusing new attention on preventing fraud.

To complement these efforts, the Prior Authorization of PMD Demonstration will develop improved methods for preventing fraud and will protect the Medicare Trust Funds from fraudulent actions and the resulting improper payments. This demonstration implements a prior authorization process for PMDs for people with Medicare who reside in seven States (California, Illinois, Michigan, New York, North Carolina, Florida and Texas). The demonstration began on September 1, 2012 for orders written on or after that date. This prior authorization demonstration will also help ensure that a beneficiary's medical condition warrants their medical equipment under existing coverage guidelines. While CMS recognizes there are many honest suppliers, given the widespread law enforcement activity associated with PMD fraud, CMS is taking necessary actions to address these problems.

This demonstration employs an approach drawn from the private sector to protect the Medicare Trust Funds. Prior Authorization, sometimes known as "prior approval" or "pre-certification," is currently being used in other health care programs such as TRICARE, certain State Medicaid programs, and private insurance for many services and items including PMDs. However, unlike some other prior authorization programs, this program does will not automatically deny payment for a PMD if it did not go through prior authorization. With prior authorization, suppliers and beneficiaries will know before an item is delivered to a beneficiary whether Medicare will pay for the PMD. This helps ensure that Medicare pays only for PMDs that meet the longstanding coverage requirements thereby limiting fraud, waste and abuse. Further, suppliers and beneficiaries will know before the item is delivered if they will have to pay for the item. Currently, in many cases, if the item is not covered, Medicare beneficiaries will have to pay for the entire cost of the item because the PMD is delivered to the beneficiary and then Medicare denies the payment because the coverage criteria has not been met.

Prior Authorization Process

Under the demonstration, an ordering physician/practitioner or supplier submits a prior authorization request and all relevant documentation to support Medicare coverage of the PMD to a CMS Durable Medical Equipment Medicare Administrative Contractor (DME MAC). Currently, these requests can be submitted via fax or mail. Beginning later this year, requests can be submitted electronically. After receipt of all relevant documentation, the DME MAC conducts a review, and sends notification of the decision within 10 days to the physician/practitioner, beneficiary and supplier. The DME MAC either affirms (approves) the request or non-affirms (does not approve) the request. To be affirmed, the request for prior authorization must meet all applicable rules, policies, and National Coverage Determination (NCD)/Local Coverage Determination (LCD) requirements for a PMD.

If the review results in a non-affirm, the DME MAC provides a detailed written explanation outlining which specific coverage requirement(s) was/were not met. This notification is sent to the physician/practitioner, supplier and beneficiary. In the event of a non-affirm, a physician/practitioner or supplier may resubmit the prior authorization request an unlimited number of times. The DME MAC will make every effort to review any re-submissions within 20 days.

The demonstration does not create any new documentation requirements, but simply requires the information be submitted earlier in the claims process. CMS has worked to remind people of these longstanding requirements. Instead of reviewing the documentation after the item has been delivered, we now allow the paperwork submission prior to delivery. CMS has and will continue to provide extensive outreach and education to physicians/practitioners, suppliers, and beneficiaries to educate them about the demonstration and the prior authorization process.

All existing appeal rights remain unchanged under the PMD demonstration. If a PMD claim is denied under this demonstration, beneficiaries may appeal the claim denial. Beneficiaries and suppliers cannot appeal a non-affirmative (non-approval) prior authorization request.

However, suppliers have the option of (1) resubmitting the prior authorization request or (2) delivering the PMD, submitting a claim which will be denied, and then submitting an appeal.

There is also an expedited process for practitioners to request a 48 hour review in emergency situations. The DME MAC conducts an expedited review when the physician/practitioner indicates clearly, with supporting rationale, that the 10 business day timeframe for review of the prior authorization request could jeopardize the beneficiary's life or health. The expedited request must be accompanied by the required supporting documentation. Inappropriate expedited requests may be downgraded to standard requests. After conducting an expedited review, the DME MAC communicates a decision for the prior authorization request to the submitter within 48 hours of the complete submission.

Suppliers Who Do Not Submit a Prior Authorization Request

If a supplier submits a PMD claim without first seeking prior authorization, the claim will undergo prepayment review. As part of the review process, the DME MAC sends letters to the supplier requesting all documents to support the claim. Once the supplier has submitted all the necessary documentation, the DME MAC conducts a review of the documentation within 60 days. This is the standard time frame for prepayment review. If the DME MAC determines payment is appropriate, the payment is processed.

Starting December 1, 2012, payments will be reduced by 25 percent for suppliers not submitting a prior authorization request. This reduction is not subject to appeal. The 25 percent payment reduction does not apply to contract suppliers in competitive bidding areas.[6] If a competitive bid contract supplier submits a payable claim that has not been prior authorized for a beneficiary with a permanent residence in a competitive bidding area that is included in the supplier's contract, that contract supplier would receive the applicable single payment amount under its

[6] Note: Section 302 of the Medicare Modernization Act of 2003 (MMA) established requirements for a new Competitive Bidding Program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Under the program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas, and CMS awards contracts to enough suppliers to meet beneficiary demand for the bid items. On January 1, 2011, CMS launched the first phase this program (Round 1 Rebid) in nine major metropolitan areas for nine product categories, including Standard Power Wheelchairs, Scooters, and Related Accessories. The nine metropolitan areas are: Charlotte, Cincinnati, Cleveland, Dallas, Kansas City, Miami, Orlando, Pittsburgh, and Riverside, CA.

contract and would not be subject to the 25 percent reduction. These suppliers must still adhere to all other requirements of the demonstration. (See Table 1). We do not reduce the payment to contract suppliers in competitive bidding areas in order to honor the contracts we signed with those suppliers.

Table 1:

	Prior authorization request is	The DME MAC decision is	The supplier chooses to	The DME MAC will
1	Submitted	Affirmative	Submit a claim	Pay the claim (as long as all other requirements are met).
2	Submitted	Non-Affirmative*	Submit a claim	Deny the claim.

3	Not submitted	N/A	Submit a claim	• Send a documentation request letter.
				• Review the medical record documentation for the claim.
				• If payable:
				  • For non-contract bid winner, pay at 75 percent of fee schedule.
				  • For contract bid winner, pay at single payment amount

*Supplier may choose to resubmit prior authorization request.

CMS Improvements in Response to Industry Feedback

CMS originally announced this demonstration on November 15, 2011 and received significant feedback from industry on the demonstration design. In response, CMS delayed the demonstration from its original January 1, 2012 start date and CMS made several changes to the demonstration to better assist suppliers in implementation. The CMS changes include:

- Removal of the 100 percent Pre-Payment review phase (formerly Phase 1) from the demonstration based on supplier concerns about the financial impact of pre-payment review;
- Reduction of the target review time for resubmissions to 20 business days (from 30 days).
- Authorization of suppliers to perform the administrative function of submitting the prior authorization request on behalf of the physicians/practitioners; and

- Provided physician/practitioners and suppliers an opportunity to comment and make recommendations on how to reduce provider and supplier paperwork burden associated with these demonstrations through a Paperwork Reduction Act (PRA) notice.

Outreach and Education

Prior to the demonstration start date, CMS conducted outreach and education including webinars, in-state meetings and other education sessions for suppliers, physician/practitioners and beneficiaries. In addition, physicians/practitioners and suppliers who have recently furnished or who have recently ordered a PMD for a beneficiary residing in a demonstration State were notified via certified letters about the demonstration prior to the start date of the demonstration. CMS published numerous educational materials to assist suppliers and physicians/practitioners on the policies and documentation requirements for PMDs.[7] CMS also conducted several open door forums on these policies, as well as the process and requirements for the PMD demonstration. We will continue to work to ensure that suppliers, physicians/practitioners, and beneficiaries are educated and have up to date information throughout the demonstration.

Development of the PMD Electronic Clinical Template

CMS recognizes the importance of consistency of documentation within this benefit and is developing an electronic clinical template as part of a physician's/practitioner's electronic health records (EHR). An electronic template that is part of the EHR is a good way to allow physicians/practitioners to have a standard method to document a patient's medical condition. This may help physicians/practitioners more accurately communicate why the PMD is medically necessary for a particular beneficiary. However, use of an electronic clinical template would not be mandatory to receive payment from Medicare, nor would the use of such a template guarantee Medicare payment for the PMD. CMS has developed an initial draft of the suggested electronic clinical template with data elements for a progress note documenting a face-to-face PMD evaluation. Stakeholders have been providing feedback on draft electronic clinical template including through a series of special open door forum calls.

[7] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/PADemo.html?redirect=/CERT/03_PADemo.asp

CMS and the Office of the National Coordinator for Health Information Technology (ONC) intend to collaborate on the development of a strategy to develop a standard for the electronic clinical template for PMD progress notes. Ideally, this standard would be adopted by EHR vendors and, thus, enable physicians/practitioners to access the electronic clinical template as part of their EHR. Our goal would be for the electronic clinical template to be available in all 50 states.

Timing of the PMD Electronic Clinical Template- and the Demonstration

Some have raised the issue of whether the demonstration should be delayed until a PMD electronic clinical template for the clinical information is available. CMS does not believe it is necessary to delay the PMD demonstration until we develop an electronic clinical template. The PMD demonstration has not changed existing medical necessity policies and documentation requirements for furnishing PMD to Medicare beneficiaries. CMS published numerous educational materials to assist suppliers, and physicians/practitioners on the policies and documentation requirements for PMDs. In addition, a draft of the electronic clinical template is available on the CMS website[8] and there is nothing precluding any physician/practitioner from using this template as a tool to assist them in documenting the medical criteria necessary for CMS to approve payment for a PMD.

Conclusion

Prior authorization is an important tool that will help CMS reduce fraud and improper payments for PMDs, while continuing to ensure that beneficiaries have access to needed equipment. We believe this demonstration will help protect the Medicare Trust Funds by utilizing many of the same methods already used by private insurance plans and other programs to ensure payment accuracy.

We appreciate the Committee's interest in combating fraud, waste and abuse in the provision of PMDs. We thank you for your support and your efforts to educate suppliers,

[8] http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/ElectronicClinicalTemplate.html

physicians/practitioners and beneficiaries about the demonstration. I look forward to continuing to work together with the Committee to protect beneficiaries and the Medicare Trust Funds.

17 September 2012

Paul J. Hughes, MD

PWC Prior Authorization Demonstration Project – Opening Statement

I am Doctor Paul Hughes, the Medical Director for the Durable Medical Equipment Medicare Administrative Contractor, commonly called a DME MAC, and my geographic area of responsibility is Jurisdiction A. Jurisdiction A is one of four DME MACs and encompasses the northeastern states from Maine to Washington DC. I have been the Medical Director for this region since 1995. I work for NHIC, which contracts with the Centers for Medicare & Medicaid Services to administer this jurisdiction since 2006. New York is the demonstration state in our region.

My primary responsibilities revolve around the development and implementation of Medicare coverage policy. This role requires that I be involved in many aspects of NHIC's operations including routine claim processing, appeals, medical review and provider education.

I have been asked to speak briefly about the preparations NHIC has made to implement the Prior Authorization for Power Mobility Devices demonstration project. For convenience, I would like to separate the discussion into two parts, payment policy and operations.

First, payment policy. Reimbursement for power mobility devices is set out in several sources. There are statutory requirements arising from the Medicare Modernization Act implemented by CMS' Final Rule in 2006. These provisions require an in-person visit and a medical exam in addition to specific requirements for the creation of the prescription and the provision of these documents to the DME supplier.

CMS' National Coverage Policy creates the foundation for the medical coverage rules. It allows for the coverage of mobility assistive equipment for beneficiaries with mobility deficits that impair their ability to accomplish activities of daily living within the home. This policy guides coverage for all mobility equipment - from canes and crutches to walkers to manual wheelchairs - all the way up to power wheelchairs. To make a decision about which device is appropriate, CMS' national coverage policy requires a systematic evaluation of the beneficiary by their treating physician in order to determine which item optimally meets the beneficiary's mobility needs. In addition to this CMS national policy, the DME MACs also have a local

coverage policy for Power Mobility Devices. This local policy pulls together both the statutory and national policy requirements, organizes the nearly 60 individual power mobility codes into five groups of similar products, sets out criteria for each group and explains the documentation requirements and coding guidelines. In other words, the local policy takes coverage and payment information from various sources, adds additional necessary details for proper claim submission and incorporates those into one document.

The major concern I hear raised by suppliers is whether the DME MACs will be able to review the anticipated request volume in a timely manner. Our staff is knowledgeable and experienced in looking at claims for power mobility. These requirements have been in place, unchanged, since 2006 when CMS' regulation took effect. All DME contractors have performed numerous reviews on power mobility devices since that time to identify problems. In addition to standard power wheelchairs, we have all reviewed many complex rehabilitation power wheelchair requests under Advanced Determination of Medical Coverage, usually referred to as ADMC. In Jurisdiction A, we review an average of 240 requests per month under this program. These complex products must meet the same basic coverage requirements as the products covered by the demonstration project in addition to the requirements necessary to determine coverage for the options and accessories needed to address the needs of these patients. This demonstration project does not change any of the applicable coverage rules thus we do not anticipate issues in this area. In fact, the project's focus only on coverage criteria for the power wheelchair base simplifies the review for our staff. We do not anticipate that our review staff will have any difficulty in reviewing power wheelchairs of any type, including the numerous options and accessories used with them.

Another issue I hear mentioned is that some suppliers and physicians may not be familiar with all of the policy requirements. The contractors have produced numerous education resources about this policy, ranging from "Dear Physician" letters discussing the coverage criteria and the need for quality documentations, to Question & Answer documents and articles, webinars and in-person seminars, and CERT and Medical Review error analysis. In addition to the materials provided by the contractors, CMS' Medicare Learning Network has also published a variety of materials addressing power mobility coverage.

Next, I would like to discuss operations. I know that some in the DME supplier community are concerned that the volume of claims may be too large to review in the allotted time of ten business days. Based upon historical claim volume, we initially expect 25-30 new requests per day for the types of power wheelchairs included in the demonstration. In

anticipation of this project, we have increased our nursing staff and assigned our more experienced personnel to handle the anticipated volume. Based upon historical power wheelchair audit data, we anticipate that approximately 50% of the initial submissions will not be approved. Likewise, based upon appeals data we expect the about 50% of resubmitted requests will not be approved. Once the demonstration is operational, we anticipate a total volume of 50 to 60 new and resubmitted requests per day from this project. We have sufficient additional staff to allow flexibility to deal with variations in volume. In the non-review areas resources have also been adjusted to allow for additional workload in written and telephone inquiries and in the production and mailing of response letters.

Finally, I would like to discuss errors. Regardless the source of the audit, the types of errors identified are consistent. For example, our most recent Jurisdiction A report, published in July 2012, showed a charge denial rate of 54%. The most common denials issues were:

- 33% - Insufficient documentation. This includes both a failure to meet the statutory requirements to perform the face-to-face as well as incomplete or poorly documented examinations.
- 23% - Problems with the 7-element order. This is the statutorily required prescription. Problems include missing elements, illegibility and the prescription was created before the face-to-face was completed.
- 19% - Specialty exam. Missing financial relationship attestation.
- 14% - Detailed Product Description. This is a document produced by the supplier for the physician's signature. It serves as the prescription for all of the separately billable items. Problems included nodetaile product description submitted and the items billed did not match the items ordered.
- 9% - Home assessment. None submitted or not signed and dated
- 4% - Proof of delivery. None submitted or delivery ticket did not match claim.

Many discussions of errors focus upon issues related to the quality of physician documentation and the DME supplier's inability to get the physician to improve. While physician documentation is an important factor in audit findings, it is not the only one. Many other errors occur. Often these others are more within the supplier's direct control either because they create the documentation or because there is an opportunity to screen for mistakes and have them corrected before submission. In this most recent review, most errors fell into this latter category. This pattern of errors is not unique to this particular report. Our review experience demonstrates that errors would drop significantly if attention were directed to some of these non-medical record issues.

In summary, I believe that NHIC is well prepared to perform the work necessary to meet the requirements of this demonstration project.

Thank you for the opportunity to share this information.

U.S. Senate Special Committee on Aging

"An Examination of Prior Authorization Requirements for Power Mobility Devices"

Testimony of Stephen T. Peake D.Ph., M.D.

Medical Director, Senior Care Division

Blue Cross Blue Shield of Tennessee

Chairman, Kohl, Ranking Member Corker, I appreciate the opportunity to appear before the U.S. Senate Special Committee on Aging to discuss prior authorization requirements for Power Mobility Devices. My name is Dr. Stephen Peake and I am the Medical Director for the Senior Care Division of Blue Cross Blue Shield of Tennessee, an independent licensee of the Blue Cross Blue Shield Association. My focus today will be on our Medicare Advantage product which we refer to as Blue Advantage and our strong commitment to utilization management and the use of prior authorizations. In particular I will be focusing on utilization management and the use of the prior authorization process for Power Mobility Devices. I will highlight the successful tools we have implemented through these programs. I will also illustrate some of the problems we have encountered while using these tools. Currently, our Blue Advantage Product has approximately 33, 000 enrollees with an average age of 71 of which approximately 55% are female and 45% are male. Blue Cross Blue Shield of Tennessee has been offering Blue Advantage to the citizens of Tennessee since 2006.

Plans such as Blue Advantage were established by Congress and became a reality on January 1, 2006. The guidelines that we must conform to as a MA plan are outlined in the CMS Manual, Managed Care (Pub. 100.16) which allows for increased flexibility in administering beneficiary benefits as long as they do not result in the beneficiary receiving less than traditional Medicare benefits. One aspect of this flexibility is the ability to perform utilization management, which allows us as a MA plan to require prior authorization of services.

Prior authorization allows us to determine if in fact a requested service is medically necessary and thus reasonable and necessary by reviewing the documentation against the hierarchical requirements set forth by CMS. We feel strongly that properly applied utilization management protects, first and foremost, the beneficiary from unnecessary risks, but also helps to protect the system from fraud, waste and abuse.

I was asked to share our experience with requiring prior authorization on Power Mobility Devices. CMS has commented extensively both directly and through the Medicare Administrative Contractors (MACs) on the documentation requirements for Power Mobility Devices. National Coverage Determination 280.2 Mobility Assistive Equipment (Effective May 5, 2005), Local Coverage Determination 23613 Power Mobility Devices (Revision Effective 08/05/2011) and related Policy Article for Power Mobility Devices (Effective January 2009) and a Provider Update dated September 2010 *POWER WHEELCHAIRS AND POWER OPERATED VEHICLES-DOCUMENTATION REQUIREMENTS* co-signed by all 4 Durable Medical Equipment Medicare Administrative Contractor's Medical Directors. Also the Office of the Inspector General commented about Power Mobility Devices in the August 2009 report *POWER WHEELCHAIRS IN THE MEDICARE PROGRAM: SUPPLIER ACQUISITION COSTS AND SERVICES.*
Yet CMS continues to point out that the majority of claims for power mobility devices do not meet the documentation requirements for coverage.
At Blue Cross Blue Shield of Tennessee we in Blue Advantage require strict adherence to the documentation requirements for a Power Mobility Device as outlined in the above listed documents. For example, coverage is allowed only if the beneficiary has a mobility limitation that limits their ability to perform Mobility Related Activities of Daily Living **in the home,** such as toileting, feeding, dressing, grooming and bathing in customary locations **in the home, not elsewhere**. The documentation must indicate that the beneficiary's mobility limitation cannot be overcome with an optimally fitted cane, walker, or wheelchair: in other words, do they really require a Power Mobility Device?

Also, it is required that physicians perform a face to face examination and the physician "shall" document the examination in a detailed narrative note in their chart in the format they use for other entries, and that the note clearly indicates that a major reason for the visit was a mobility evaluation- a requirement that is far too often not met. In addition, many suppliers have created forms which have not been approved by CMS. The one we see most commonly is the Texas Academy of Family Practice Mobility Evaluation Form, a form Blue Advantage does not recognize for use in the required face to face examination. CMS even commented that this form was not adequate in the September 2010 Provider Update, referenced above. However, we continue to see suppliers completing this form and having the physicians sign it and physicians utilizing this form as the face to face mobility examination described above. In fact, if you go to the Texas Academy of Family Practice's web site www.tafp.org it clearly states this is not a CMS approved form. In addition, the supplier must supply a detailed 7 part prescription but is prohibited from completing any portion which must be completed by the prescribing physician -- yet again we see what appear to be disparities in the hand writing on the form and the prescriber's handwriting. Lastly, an in-home assessment, which is often omitted, must be completed to make sure there is room for effective maneuverability, as the primary intent in obtaining a Power Mobility Device is to alleviate barriers to the performance of Mobility Related Activities of Daily Living **in the home, not elsewhere.**

In a one year interval Blue Cross Blue Shield of Tennessee received 397 request s for power mobility devices, the majority of which were for power wheel chairs. Per CMS regulations, if the initial request is denied, the supplier can request a reopening with additional information. Both the prescribing physician and beneficiary can appeal, and the prescribing physician can request a peer to peer discussion. By incorporating utilization management and requiring prior authorization for Power Mobility Devices, 24% of the requests were found not to be medically necessary. In 2010 CMS published data estimated $606 million was spent on power mobility devices.

If in fact the implementation and utilization of a prior authorization program mirrored Blue Cross Blue Shield of Tennessee's Blue Advantage's experience the potential savings could be significant.

In conclusion I personally applaud CMS for initiating this demonstration project and would welcome it in the Great State of Tennessee. I appreciate the time you have allowed me to share on how we at Blue Cross Blue Shield of Tennessee's Blue Advantage Plan approach prior authorizations of Power Mobility Devices. I welcome any questions you may have.

Testimony of Michael B. Clark
Chief Administrative Officer and General Counsel
The SCOOTER Store, New Braunfels, Texas

Before the US Senate, Special Committee on Aging
On

"Eliminating Waste and Fraud in Medicare: An Examination of Prior Authorization Requirements for Power Mobility Devices"

September 19, 2012 @ 2:00pm

Ranking Member Corker, Members and staff of the Senate Special Committee on Aging, my name is Mike Clark. I am the Chief Administrative Officer and General Counsel for The SCOOTER Store, a nationwide supplier of durable medical equipment (DME), including Power Mobility Devices (PMDs)[1] to the disabled and elderly who rely on this equipment to conduct their activities of daily living in the home. Based in New Braunfels, Texas, The SCOOTER Store started as a small family business in 1991 and now employs roughly 2300 individuals throughout the country.

Our company is committed to regulatory compliance and providing our fellow citizens with the finest quality health care products and services. TSS maintains accreditation from an independent, third party, the Accreditation Commission for Health Care ("ACHC"). ACHC is nationally recognized for helping companies meet customer and regulatory requirements, and continually enhancing their employee skills and efficiencies for promulgating quality management systems and processes against those standards.

I would like to thank the Committee for holding this very important and timely hearing to discuss Prior Authorization for PMDs and the Medicare Demonstration that began on September 1st in seven States that cover nearly half of all Medicare beneficiaries.

Power Mobility Devices Are Essential to Address Heath Care Needs of the Nation's Elderly and Disabled, and Their Use Generates Health Care Savings

PMDs allow people to retain or regain their independence in the home, and complete their activities of daily living safely and with dignity. Innovative technology has made PMDs more usable by allowing the equipment to maneuver in tight spaces. Ultimately, this keeps people in their home and out of nursing homes and hospitals.

PMDs enhance the lives of untold thousands of people who would otherwise be left either bed or chair bound and unable to live their lives in dignity. Without the use of

[1] PMDs include both power wheelchairs (four-wheeled motorized vehicles with steering operated by an electronic device or joystick to control direction and turning) and power-operated vehicles ("POVs")(three or four-wheeled motorized vehicles operated by a tiller) used in the home.

this equipment, seniors would be more likely to incur significant injuries simply trying to get from room to room.

PMDs help prevent people from falling. The Centers for Disease Control and Prevention (CDC) identifies falls as the leading cause of injury and/or death in people 65 or older.[2] We also note that an April 1, 2000 Report written by George F. Fuller and published by the American Academy of Family Physicians, entitled *Falls in the Elderly*, concluded that "falls are the leading cause of injury-related visits to emergency departments in the United States and the primary etiology of accidental deaths in persons over the age of 65 years."[3] At the time, George F. Fuller was the White House physician and deputy director for clinical operations. Studies estimate the direct costs of non-fatal falls in those 65 and older to be at least $19 billion annually.[4]

Power mobility equipment not only improves the lives of our fellow citizens, but it also saves health care dollars by preventing worse injuries.

Medicare Rightfully Requires a Face-to-Face Examination Prior to Payment For a Power Mobility Device

Congress, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the physician/ treating practitioner as the gatekeeper when dealing with power wheelchairs covered by Medicare. Specifically, Congress set forth that payment may not be made for a motorized or power wheelchair unless a physician, a physician assistant, nurse practitioner, or a clinical nurse specialist "has conducted a face-to-face examination of the individual and written a prescription for the item." *The face-to-face examination is the event established by Congress to determine whether a beneficiary is qualified for a power wheelchair.*

In 2004, the Centers for Medicare and Medicaid Services (CMS) convened an Interagency Wheelchair Working Group (IWWG) comprised of physicians, occupational therapists, physical therapists, researchers, and policy specialists from different federal agencies including the Veterans Administration, National Institutes of Health, Food and Drug Administration, and Department of Education. IWWG recommended that CMS replace the wheelchair "bed and chair confined" standard with a new *functional* standard.

On June 3, 2005, CMS modified the Medicare National Coverage Determination Manual, replacing the National Coverage Determinations ("NCDs") for PMDs, power operated wheelchairs (§ 280.1) and power operated vehicles (§ 280.9), with a new

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[2] *Falls Among Older Adults: An Overview*, Centers for Disease Control and Prevention, *available at* http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html (referencing data found in the CDC's Web-based Injury Statistics Query and Reporting System, as accessed on November 30, 2010).
[3] George F. Fuller, Falls in the Elderly, 61 American Family Physician 2159-2168 (2000).
[4] *See e.g.*, JA Stevens, et al., *The costs of fatal and non-fatal falls among older adults*, 12 Injury Prevention, 290-295 (2006).

Mobility Assistive Equipment[5] ("MAE") NCD (§ 280.3). Effective for claims with dates of service on or after May 5, 2005, the MAE NCD establishes that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home.[6] This standard is thus based on the beneficiary's present abilities and condition at the time he or she is evaluated and equipment is prescribed and is not diagnosis dependent. These determinations can only be made during the face-to-face evaluation required by law.

CMS regulation makes clear that a physician or treating practitioner must conduct "a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity."[7] In the preamble to the final PMD rule issued April 5, 2006, entitled "*Medicare Program; Conditions for Payment of Power Mobility Devices (PMD), Including Power Wheelchairs and Power-Operated Vehicles,*" CMS declared that no format is required to document the face-to-face examination[8] and the information recorded at the face-to-face examination will generally be sufficient.[9]

The congressionally mandated face-to-face examination properly places the physician/treating practitioner in charge of patient care. TSS fully supports this requirement and applauds Congress for emphasizing the role of the medical professional when assessing power mobility needs.

Congress and the Centers for Medicare and Medicaid Services Have Instituted Significant Fraud and Abuse Safeguards Governing the Power Mobility Benefit

As a taxpayer, I want to know that money used toward any government program is properly administered and dispensed. TSS applauds efforts to combat fraud and abuse. Toward that end, we have supported efforts by Congress and CMS to increase program integrity requirements in recent years including the following:

- Accreditation for all DME suppliers.
- CMS' issuance of new PMD billing codes.
- Increased supplier standards for PMDs
- Surety Bond requirement for DME suppliers.
- Face-to-Face examination
- Seven element prescription
- Detailed product description

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[5] "Mobility assistive equipment" includes: canes; crutches; walkers; manual wheelchairs; power wheelchairs; and scooters. Medicare National Coverage Determination Manual, § 280.3 (eff. May 5, 2005).
[6] Medicare National Coverage Determination Manual, § 280.3.
[7] 42 C.F.R. § 410.38(c)(2) (emphasis added).
[8] 71 Fed. Reg. 17021, 17028 (2006).
[9] *Id.* at 17023.

- Home Assessment

These measures help ensure that only law abiding companies participate in the Medicare program and that only necessary equipment is reimbursed by the federal government.

TSS offers additional recommendations that we believe would target real fraud and abuse in the industry:

- *Mandated Equipment Serial Number Tracking System.* Rationale: Industry adoption would allow CMS and its contractors to verify that all claims submitted by suppliers represent supplier deliveries of real equipment obtained from authorized manufacturers.

- *Real Time Auditing of High-Volume Physicians* who have prescribed over 50 PMD units in a 12 month period. Rationale: Industry data indicates that most physicians prescribe two (2) or fewer PMDs per year. Use of physician NPI numbers on claims will help identify abnormalities in the Medicare program.

We look forward to working with this Congress and CMS on these initiatives.

Reimbursement Cuts

There have been a number of legislative and regulatory measures that have impacted the power mobility benefit.

- November 15, 2006 - CMS updated PMD codes (65 codes) resulting in a 27% Medicare reimbursement reduction.
- January 1, 2009 – Comprehensive 9.5% reimbursement reduction due to delay in National Competitive Bidding program;
- January 1, 2011 – all standard power wheelchairs became rental items pursuant to the Patient Protection and Affordable Care Act;
- January 1, 2011 – Round 1 of the Durable Medical Equipment Prosthetics Orthotics and Suppliers (DMEPOS) National Competitive Bidding (NCB) program began in nine of the largest Metropolitan Statistical Areas (MSAs) resulting in a 26% average reimbursement reduction;
- Round 2 of NCB scheduled to start in 2013 in 91 additional cities;

All of these measures contribute to a benefit that has been subject to much regulatory and legislative oversight, significantly reducing the ability of those that might want to defraud the Medicare program.

We note that Medicare power wheelchair utilization has dropped significantly. By our estimates, overall national reimbursements of standard power units declined by 20,157 units in the first half of 2011 representing a 23.5% drop from the first half of 2010. Total

allowed reimbursement for the first half of 2011 delivered units fell nearly $200 million from the same period in 2010, a 65.5% reduction in CMS allowed reimbursements.

TSS Compliance Process

In addition to the legislative and regulatory measures impacting the power mobility benefit, TSS has instituted numerous safeguards to ensure that appropriate claims are submitted to Medicare as well as other payers. The following are some important procedures established by our company.

Our company has an extensive Medicare compliance program, headed by a Corporate Compliance Officer and implemented by a Compliance Department comprised of 128 people. Through its compliance efforts, TSS seeks to ensure that its employees follow the procedures and policies that govern its business. TSS previously hired Steve Ortquist, a nationally renowned compliance expert with the Aegis Compliance and Ethics Center, LLP, to review TSS's procedures to be sure they are the most rigorous in the health care industry.

As part of its compliance department, TSS employs 57 full time Clinician (nurses) and Quality Review (QR) personnel who review and assess claims independent from any sales channel.

TSS also performs a Pre-Delivery In-home Assessment by Mobility Managers, who conduct a thorough in-home assessment for purposes of ascertaining potential or real equipment and safety issues. The Mobility Manager has full authority to cancel the potential delivery, should any irresolvable issues be uncovered, or should they discover for any reason that the customer does not qualify.

*As a result of the policies and procedures and extensive screening process instituted by our company, only **13** percent of beneficiaries who contact us for power mobility equipment have their claims submitted to Medicare.* The fact that 87 percent of the persons who seek power mobility products from TSS under their Medicare benefits are disqualified by the company's screening process is powerful evidence of the company's commitment to ensuring that only legitimate claims are submitted to Medicare.

Error Rate Reporting Does Not Tell the Whole Story

Medicare error rates for PMDs are presented to the public but the whole story is often not told. Based on prior history, Medicare contractors deny nearly all PMD audited claims (80-90 percent) only to have a significant amount of these denied claims overturned during a lengthy and costly Medicare appeals process. The contractor error rates never take into account the denied claims overturned at the redetermination, reconsideration and Administrative Law Judge levels of appeal.

A July 2011 Report issued by the Department of Health and Human Services Office of Inspector General Report, entitled Dep't of Health and Human Serv., Office of Inspector Gen., OEI-04-09-00260, *Most Power Wheelchairs in the Medicare Program Did Not*

Meet Medical Necessity Guidelines (Report), analyzed Medicare claims for power wheelchairs submitted in 2007.[10] The Report did not uncover fraud but rather involved the second guessing by an auditor of a medical determination made by treating physicians.

While the Report suggested that 61% of claims reviewed in the first half of 2007 were medically unnecessary or lacked sufficient documentation to determine medical necessity, only 9% of the total claims were deemed to be medically unnecessary. The Report determined that a vast majority of beneficiaries within this "medically unnecessary" group needed a different type of power wheelchair. In many cases, beneficiaries needed a more expensive power wheelchair.[11] Further, the Report did not take into account that a large number of claims originally denied by a Medicare contractor are overturned during the appeals process, a process that often takes over eighteen months to complete.

The Current Prior Authorization Demonstration Program For PMDs Has Numerous Issues That Need To Be Addressed

I now turn to the prior authorization demonstration project underway September 1, 2012. This demonstration project, representing the first time the agency has required prior authorization for DME, would apply to all Medicare power mobility device claims in the states of California, Florida, Illinois, Michigan, New York, North Carolina, and Texas (roughly 50% of Medicare PMD claims nationwide). Prior authorization would require a provider or supplier to submit a claim to a CMS contractor and obtain approval prior to delivery of the equipment to the Medicare beneficiary.

As of the date of this testimony submission, every prior authorization claim we have submitted has been denied. A 100% denial rate. Several denials are related to technical issues unrelated to medical necessity where the Medicare contractor missed a date that was on a fax stamp.

One denial was for medical necessity and is especially troubling. A female patient with a significant progression in the decline of her *resting* O2 saturation rates (over a 7 month period the doctor documented O2 Sat rates at 3 liters declining from 97% to 83% on the date of the Face-to-Face exam) was denied because the doctor did not conduct an O2 saturation rate test at *exertion*. It would appear that this reviewer was merely following some type of check list. Clearly the reviewer did not have the medical background required to know that requiring the patient to take an exertion test when her resting O2 saturation rate is 83% would have placed the her health at significant risk. Since the Medicare contractors have placed arbitrary constraints upon what constitutes the patient's medical record, this patient may have difficulty getting approved for a PMD without yet another trip to the doctor for a second face-to-face exam. Specifically, the Medicare contractors will not consider Attestations or Letters of Medical Necessity

[10] Dep't of Health and Human Serv., Office of Inspector Gen., OEI-04-09-00260, *Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity Guidelines* (July 2011).
[11] *Id.* at 20.

written by the doctor to explain his/her opinion.[12] Moreover, there is not clear guidance as to what entry to a chart note will be accepted if the entry occurs after the face-to-face exam. These types of denials, coupled with the constraints on the medical record, clearly place the reviewer between the doctor and the patient, detracting from the primary task of determining whether the patient needs the equipment.

Although TSS believes a Prior-Authorization process "done right" can be useful, we have several concerns about the program as currently structured:

- *First, we believe that any prior authorization demonstration must be significantly smaller. Simply put, this is a "bet the benefit" proposal. By placing roughly 50% of the nation's Medicare PMD utilization into a prior authorization model with no defined "phase in," CMS has ensured that if ANYTHING goes wrong, the results will be catastrophic. There is absolutely no logical or justifiable reason for the initial demonstration to have a potentially negative impact on hundreds of thousands of Medicare beneficiaries who may need PMDs to perform activities of daily living.*

- *Under the current CMS claims processing system, a beneficiary is provided his or her PMD after the physician performs the face-to-face examination. Medicare contractors routinely conduct audits and initially deny nearly all the claims (80-90 percent). A substantial amount of these denied claims are overturned during a lengthy and costly appeals process. The appeals process occurs after the patient receives the PMD.*

- *Under the prior authorization demonstration project, the 80-90 percent denial rate will move to the front end of the process, meaning that beneficiaries will no longer have access to the PMD while awaiting the decision of the Medicare contractor. With no formal appeals process in place to challenge a Medicare contractor's prior authorization denial, beneficiaries will be denied access to PMD's up front, and legitimate law abiding health care companies will simply go out of business.*

- *Based on our company's experience, the proposed prior authorization demonstration is different than other established prior authorization models developed by managed care companies and state Medicaid systems. Unlike other models, the proposed demonstration project (i) does not have a face-to-face examination template and (ii) de-emphasizes the documentation generated from the face-to-face examination, putting the government between the doctor and the patient.*

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[12] In a guidance document entitled *Power Mobility Device (PMD) Demonstration Operational Guide*, provided on CMS' website, the agency states "physician attestation letters (e.g. Letters of Medical Necessity), are deemed not to be part of a medical record for Medicare payment purposes. Review contractors shall NOT consider this type of documentation when making a coverage/coding determination." *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/PMDDemonstrationOperationalGuide_v11_08282012.pdf.

- *A face-to-face examination template must be part of any prior authorization program. Information recorded by a physician/treating practitioner during the face-to-face examination should be presumed to be valid and sufficient to determine medical necessity.*

The Size of the Prior Authorization Demonstration is Too Large and Should Be Reduced

Traditionally, a CMS demonstration project tests a payment model on a small segment of the Medicare population across a limited geographic area in order to ensure beneficiaries are not adversely impacted on a broad scale. For example, CMS conducted a **two location** durable medical equipment competitive bidding demonstration project, starting in Polk County (Florida) and then proceeding on to San Antonio. After studying the results, Congress initiated the next phase of the bidding program in nine (9) Metropolitan Statistical Areas (MSAs) starting in 2011. After 3 years, the next phase of the bidding program is set for 2013.

Sen. Rockefeller, in a July 2012 letter to Secretary Sebelius also expressed great concern over the unprecedented size of a proposed Coordinated Care Demonstration Project for dual eligible, stating that "this [demonstration] would greatly exceed the size of any previous CMS demonstration changing the way Medicare beneficiaries receive care, even though this demonstration is extremely complex. While it is clearly important to have an adequate sample size in order to evaluate demonstration programs, these changes appear to go far beyond what is necessary or appropriate...".[13]

If a smaller segment were tested initially, then the problems could be vetted and addressed without putting many beneficiaries and suppliers at risk.

A Face-to-Face Examination Template Is Necessary and Proper Weight Must Be Given To Such Template

A face-to-face clinical examination template is necessary to educate the physician/treating practitioner, supplier and beneficiary as to the exact information CMS believes is needed to properly document the face-to-face examination.

The physician/treating practitioner's professional medical judgment is essential to ensure that our nation's elderly and disabled receive appropriate medical care. Toward that end, a face-to-face examination Clinical Template should be designed to be comprehensive and sufficient to determine medical necessity. The prescribing physician/treating practitioner should be given the presumption that his/her medical judgment determined during the face-to-face exam is valid. Only when a reviewer finds clear and convincing evidence to rebut any documented face-to-face examination findings of a physician or treating practitioner should a claim be denied.

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[13] Letter from John D. Rockefeller IV, Senator from West Virginia, to Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services (July 10, 2012).

The use of a Clinical Template is absolutely consistent with the documentation practices of our nation's healthcare professionals. Physicians/treating practitioners routinely use forms/templates to include as part of their medical records. The American Academy of Family Physicians (AAFP), for example, has provided many examples of forms for use by physicians. A website promoting these forms states, in part, that "[i]f you write progress notes by hand, you may find that the forms save you time as well as improve your documentation and coding by helping ensure that you capture the relevant information in an easily retrievable format."[14] Various medical record forms are also available to physicians from professional groups as well as private document/form companies that publish and sell such forms.[15] Similarly, many Medicaid programs currently require forms as the means to satisfy coverage for mobility items.

We note that CMS has developed a "*Suggested Electronic Clinical Template Elements of a Progress Note Documenting a Face-to-Face PMD Evaluation" (Clinical Template).*[16] While we applaud the agency for taking this first step, this clinical template has not been finalized to coincide with the beginning of the prior authorization demonstration project for PMDs.[17] CMS recently informed the Office of Management and Budget of the following:

> *CMS does not believe that a prior authorization request form is necessary for this demonstration.*[18]
>
> *CMS does not believe that a template for documenting the existing face-to-face encounter is necessary to conduct this demonstration.*[19]

We respectfully disagree. A face-to-face examination Clinical Template, designed to determine and establish medical necessity, is necessary to establish clarity and consistency in the claims processing system and to ensure access to quality health care for our nation's elderly and disabled. Moreover, such a template will be important in an environment of electronic health records as more physicians move away from paper toward the health care system of the future.

Beneficiaries Must Be Afforded An Appeal Right

Under the current proposed demonstration, CMS has indicated that the beneficiary may resubmit the claim after receiving an initial prior authorization denial. At that point the reviewer will have at least 20 days to review the resubmitted claim. If denied again, it appears the beneficiary's only remedy is to keep resubmitting the claim to the same

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[14] American Academy of Family Physicians, available at http://www.aafp.org/fpm/2006/0900/p63.html
[15] *See, e.g.*, DocumForms: Innovative Podiatric Forms, available at http://www.dpmforms.com.
[16] *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/Downloads/SuggestedPMDElectronicClinicalTemplate.pdf.
[17] The current CMS version of the proposed electronic clinical template spans seven printed pages with detailed questions requiring collection of a vast amount of information. Surely, improvements could be made to benefit physicians/treating practitioners, suppliers, beneficiaries and the Medicare program.
[18] *CMS-10421 Response to 60-day public comments,* Centers for Medicare and Medicaid Services at 11-12 (May 30, 2012).
[19] *Id.* at 12.

Medicare contractor that has denied them access to care in previous instances. This process places decisions regarding the beneficiaries' access to care solely in the hands of a government contractor with no right of redress at a higher level.

CMS has not developed an appropriate appeals process that will ensure proper safeguards for Medicare beneficiaries. Under the proposed demonstration, a prior authorization denial would leave the beneficiary with no right to appeal to a separate independent body, thus making the initial contractor the ultimate and only arbiter. Beneficiaries and suppliers must retain appeal rights in any system proposed by CMS. This includes appeals to a Qualified Independent Contractor, Administrative Law Judge, Departmental Appeals Board and judicial review should the beneficiary and/or supplier choose to pursue this course.

Prior Authorization Recommendations

The American Medical Association (AMA) offered significant input in a June 2011 document entitled "*Standardization of prior authorization process for medical services white paper*".[20]

In their white paper, the AMA highlighted the enormous burden associated with prior authorization and the resulting "detrimental health consequences for patients."[21] The AMA offered the following recommendations: (1) The development of a standard uniform prior authorization form that can be submitted to and accepted by all payers; (2) Transparency, accessibility and consistent application of prior authorization requirements and restrictions, including a standard definition, are needed; (3) Transparency, accessibility, and consistent application of utilization review criteria and clinical expectations are needed; (4) There should be practical limits on medical record requests, which should in any event be reserved to those cases when there is difficulty determining medical necessity; (5) Consistent response times and processes with respect to prior authorizations or adverse determinations in non-urgent circumstances are needed to achieve administrative simplification; and (6) Industry consensus efforts should be aggressively pursued to automate the prior authorization processes on behalf of patients and physicians to reduce unnecessary costs.[22]

We believe the common sense recommendations of the AMA, as well as the other recommendations offered in this statement, should be fully implemented prior to starting any prior authorization program.

I appreciate the opportunity to provide this information to the Committee, and we look forward to keeping you informed as the prior authorization demonstration progresses.

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[20] American Medical Association (June 2011) *available at* http://www.ama-assn.org/resources/doc/psa/standardization-prior-auth-whitepaper.pdf.
[21] *Id.* at 4.
[22] *Id.* at 10-12.

STATEMENT OF

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ON BEHALF OF THE

AMERICAN GERIATRICS SOCIETY

BEFORE THE SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

SEPTEMBER 19, 2012

INTRODUCTION

Good afternoon Chairman Kohl, Ranking Member Corker and Members of the Committee:

I would like to express my sincere appreciation to Senator Kohl, Senator Corker and the members of the Senate Special Committee on Aging for allowing me the opportunity to provide testimony and your willingness to address the issues surrounding the use of Power Mobility Devices (PMDs). This is an important and often times complex issue, with implications for patient care as well as to our health care system.

My name is Jerome Epplin, M.D. I am a board-certified family physician and geriatrician in Litchfield, Illinois – a small rural town with a population of 7,000. When I started my practice in 1978, I saw patients of all ages, but as my practice grew, I started to focus increasingly on older adults and older people now make up 80% of my practice. I am also an active member and fellow of the American Geriatrics Society (AGS), a non-profit organization of over 6,000 geriatrics healthcare professionals dedicated to improving the health, independence and quality of life of all older Americans.

Today, I will briefly outline my experience as a physician caring for older patients who may or may not benefit from a Power Mobility Device.

OVERVIEW

I offer the perspective of a busy family physician and geriatrician with regard to patient evaluations for Power Mobility Devices. Let me first provide you with some background on the role of a geriatrician. A geriatrician is a medical doctor who is specially trained to meet the unique healthcare needs of older adults. Illnesses, diseases and medications may affect older people differently than younger adults and older patients often have multiple health problems and take multiple medications. Geriatricians prevent, manage and develop care plans that address the special health problems of older Americans, which include evaluating patients for Power Mobility Devices.

For a patient to obtain a PMD, which includes both Power Wheelchairs and Power Operated Vehicles (POVs), a physician must support the clinical need for the device. A significant number of patients ask about acquiring a motorized wheelchair or power scooter. In some cases, the patient or his friends or family believe that he or she would benefit from having a PMD. Over the past several years, I noticed that the majority of requests are prompted by ads seen on television or from mailings received by the patient from companies selling the vehicles. I would estimate that out of every 10 people that come to me, only one to two people really need a PMD. On average I send in one to two applications a month for PMDs on behalf of patients with a clinically justified need.

One of the hallmarks of geriatrics care is our focus on preserving function and a key to that is keeping people moving. In my practice, I assess an individual's need for a PMD with a

focus on how mobile they currently are and whether other assistive devices can help them to safely maintain mobility. I also consider the importance of my patients, when feasible, maintaining muscle mass and flexibility.

After I make my clinical evaluation, I talk through what I've discovered with the patient and advise him or her as to whether or not I can complete an application. These can be difficult conversations but I believe that an important part of caring for people is helping them to understand the risks and benefits of treatment decisions. The loss of function often associated with aging is due in large part to physical inactivity. The old adage "Use it or lose it" is especially pertinent when it comes to muscle mass and flexibility and maintaining maximum functionality for older adults.

Let me give you two examples of patients. The first illustrates the type of patient who would benefit from the use of a PMD. In the second example, use of a PMD would not be appropriate for the patient portrayed and, in fact, could hinder her mobility.

PROFILE #1 – A Patient that Needs a PMD

This patient is an 80 year old woman who recently suffered a stroke, with significant impairment of her right arm and little to no strength in her right leg. She remains cognitively intact and is able to speak and swallow. She has learned to transfer from bed to chair with minimal assist. Prior to her stroke, she was very active with no significant impairments. She was the caretaker of her husband who is mildly demented and has significant osteoarthritis. Evaluation of her house shows that it would be feasible for her to operate a vehicle in her home.

In my opinion, such a patient would benefit from a PMD. She is no longer able to walk on her own and does not have a strong support system at home. Without a vehicle, she would be a nursing home candidate, and possibly her husband may go with her. As a couple, they will be able to maintain their independence. Fiscally, under this scenario, federal and state health programs may save money. Use of a PMD would keep the patient safer in her home by preventing falls, a significant and often preventable cause of hospitalizations among older adults. In addition, the medically appropriate use of the PMD may serve to prevent or delay nursing home placement.

PROFILE #2 – A Patient that Does Not Need a PMD, but Receives One Anyway

I will now give an example of a patient whom I feel does not qualify for such a device. This is an 80 year old woman who recently suffered a stroke with residual moderate strength of her right leg. She has only mild weakness of her right arm. She is able to transfer from bed to chair with minimal assistance. After a course of physical therapy she is able to operate a standard wheelchair when going in a straight path and her husband is able to help her negotiate the turns in their house. In addition she has started using a walker with some success.

I feel this patient is best served with a standard wheelchair and a walker, with more physical therapy. If she became dependent on a Power Mobility Device, her residual muscle strength could worsen and her risk of falls increase. In addition, her risk of pressure ulcers would also increase.

REQUESTS FOR PMDs & POTENTIAL RISKS

Many of the requests that I receive from my patients for Power Operated Vehicles are easy to evaluate. In many cases, it is obvious to me that a patient does not need a PMD and would not qualify under the current Medicare guidelines. Some patients are mistaken in believing that it is an easy process to qualify for such a vehicle under Medicare. These patients assume that these devices can be used merely as a convenience and not as a necessity. After I explain the purposes of a PMD, many of these patients drop their requests, although often reluctantly. In most cases, these patients may be harmed by use of a PMD as their physical activity would be decreased.

Occasionally, I suggest to patients that they investigate the possibility of obtaining such a vehicle. I do so when I feel the patient would medically benefit from and qualify for the device, but either had not considered it, or were too proud to ask for it.

However, I am often uncertain if my patients qualify for a PMD. In these cases, I take a more detailed history from the patients, trying to ascertain if the patients' complaints and conditions warrant a motorized vehicle. On the one hand, getting a PMD sometimes allows the patient easier access around the home and may delay or prevent nursing home placement.

I often use our local physical therapists to help me decide if the patient qualifies for such a vehicle. I feel they have more time than I for a thorough evaluation and often have the ability to give a more objective evaluation. Our local physical therapists have told me that often a representative from a company that sells PMDs will accompany the patient for the evaluation. The representative often wants to help fill out the forms, or at least instruct the therapist on how to fill out the forms to better ensure that the patient will obtain a Power Operated Vehicle. Understandably, the therapists feel pressured in such instances.

Often a letter instructing me how to favorably fill out the application for a Power Operated Vehicle will accompany the application. I see this as an inappropriate attempt to circumvent or influence my objectivity and clinical judgment when evaluating the patient. A physician with whom I trade calls told me of a patient who was denied by him a request for a Power Operated Vehicle. Soon thereafter he received a call from a representative of the company telling him that if he changed some of his responses the patient could get such a vehicle. The physician refused.

At least in Illinois, each nursing home is required to fill out a form on each resident every three months as to why the residents should not have a PMD. In most cases, the residents do not have the mental capabilities to operate such a vehicle safely. Even if the resident has the cognitive ability to operate the vehicle, the other residents walking in the facility may not have the ability to safely get out of the way of the vehicle. Thus, in addition to potentially decreasing the muscle strength of the driver of the vehicle, the other ambulatory nursing home residents may be in harm's way. This could also become a potential liability issue for the nursing home.

IMPACT OF DIRECT TO CONSUMING ADVERTISING

Unquestionably the patients have been unduly influenced by the ads seen on television or received in the mail. They are told that all the doctor needs to do is sign the form and they will receive the vehicle. When seen by me in the office, they already have false hope that they will qualify for a vehicle. If they are denied, many become very upset. I have had patients leave my practice because I denied their request for a vehicle.

Perhaps, a more responsible approach would be for the ads to emphasize that many people who think they qualify for a vehicle may not qualify for one. Also the ads could list some

of the features that will cause a patient to be disqualified from obtaining a vehicle. The ads could also list some of the side effects of the vehicles, such as worsening muscle weakness.

In summary, a Power Operated Vehicle can be very helpful and important for some disabled people to have. However, far more want these vehicles when, in actuality, they would be best served by increasing their physical activity. The ads telling patients that all their doctor needs to do is sign their form and they could qualify for a vehicle are misleading and can lead to disappointed, disgruntled and angry patients.

MEDICARE COVERAGE & CRITERIA FOR ELIGIBILITY

If a doctor submits a written order stating that a patient has a medical need for a PMD, Medicare will pay 80% of the Medicare-approved amount. After the patient has paid their Part B deductible, they will be required to pay 20% of the Medicare-approved amount. For Medicare to cover wheelchairs or scooters, the patient must meet the following conditions as outlined by CMS:[i]

- You have a health condition that causes difficulty moving around in your home.
- You're unable to do activities of daily living (like bathing, dressing, getting in or out of a bed or chair, or using the bathroom) even with the help of a cane, crutch, or walker.
- You're able to safely operate, and get on and off the wheelchair or scooter, or have someone with you who is always available to help you safely use the device.
- The dimensions of your home must be able to support the operation of a PMD.

Furthermore, in order to document the need for a PMD there are a few specific statutory requirements that must be met before the prescription is written:[ii]

1. An in-person visit between the ordering physician and the beneficiary must occur. This visit must document the decision to prescribe a PMD.
2. A medical evaluation must be performed by the ordering physician. The evaluation must clearly document the patient's functional status with attention to conditions affecting the beneficiary's mobility and their ability to perform activities of daily living within the home. This may be done all or in part by the ordering physician. If all or some of the medical examination is completed by another medical professional, the ordering physician must sign off on the report and incorporate it into their records.
3. Items 1 and 2 together are referred to as the face-to-face exam. Only after the face-to-face examination is completed may the prescribing physician write the prescription for a PMD. This prescription has seven required elements and is referred to as the seven-element order which must be entered on the prescription only by the physician.

4. The records of the face-to-face examination and the seven-element order must be forwarded to the PMD supplier within 45 days of the completion of the face-to-face examination
5. CMS' National Coverage Determination requires consideration as to what other items of mobility assistive equipment (MAE), e.g., canes, walkers, manual wheelchair, etc., might be used to resolve the beneficiaries mobility deficits. Information addressing MAE alternatives must be included in the face-to-face medical evaluation.

CMS DEMONSTRATION

As you know, Illinois is one of the seven states where CMS is implementing a Prior Authorization process for scooters and power wheelchairs for people with Fee-For-Service Medicare. The purpose of the demonstration is to ensure that a beneficiary's medical condition warrants the medical equipment under existing coverage guidelines.

I am hopeful that the demonstration project will better match patients who need the power operated vehicle versus those who would be better served by other means.

However, the information which I have received from CMS about the demonstration project is lengthy and not very clear. The thick packet of materials arrived by mail to my office not well marked as to its contents. Some physician offices could have unknowingly discarded the package before being read or even opened.

I did review the materials and, in my view, the demonstration needs to be better explained to clinicians in a more concise fashion. I am hopeful that the demonstration project will deter some vendors in that fraud may be easier to detect. However, abuse and misuse would be harder to find as clinicians will still find the application form long and onerous to fill out. In addition, we still are influenced by the history given to us by the patient, which has the possibility that the patient was coached by a vendor or influenced by the ads as to what to say in order to qualify for a powered device.

RECOMMENDATIONS

It would be helpful for clinicians if the application form could somehow be streamlined. A single application takes at least 30 minutes to fill out after a lengthy examination. For most experienced clinicians, it is not difficult to quickly determine if a patient qualifies for a powered vehicle. It can also be easy to determine if the patient does not qualify for one. It would be

helpful if somehow a narrative would be accepted as an opinion instead of filling out a lengthy form. As you may know, there is already a dire shortage of geriatrics healthcare providers and the time spent filling out paperwork could be better spent providing care to patients. In addition, it would be helpful if the expectations of patients were not unduly elevated by outside sources – advertisements, for one -- when they are seen for their initial examination.

CONCLUSION

This is an important issue as many patients benefit greatly from PMDs. The challenge for all of us is to seamlessly get those vehicles to the appropriate patient. From a fiscal standpoint, it is also important that Medicare not pay needlessly for vehicles for patients who would be better served by more beneficial and less expensive modalities.

Thank you again for inviting me to participate in today's important hearing.

Respectfully,

Jerome Epplin, M.D., FAAFP, AGSF

Family Physician and Geriatrician

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[i] Centers for Medicare and Medicaid Services. *Medicare's Wheelchair and Scooter Benefit.* http://www.medicare.gov/publications/pubs/pdf/11046.pdf

[ii] Centers for Medicare and Medicaid Services. *PMD Documentation Requirements (Nationwide).* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/PMDDocumentationRequirementsNationwide.html

Statement on Power Wheelchairs

Senate Special Committee on Aging

Statement Author: Victor A. Hirth, MD, MHA, FACP, AGSF

Date: September 4, 2012

Submitted by: Victor A. Hirth, MD, MHA, FACP, AGSF

Power wheelchairs are a necessary and important device for older persons with significant mobility impairments. However, as the committee has discovered there is a general misunderstanding of both the costs and utility of these devices when applied to older disabled persons within the context of primary care medical practices, families and health care professionals. This misunderstanding has also been perpetuated by direct to consumer advertising which states, you can get your own electric wheel chair "at no cost to you." In our Senior Practice of 14 geriatric physicians it is not uncommon to receive requests, frequently from sons or daughters of patients, to start an application for a power wheelchair or other times we will receive these requests from a durable medical equipment supplier with no underlying rational or justification.

Given the frequency with which power wheelchair applications either were deemed "medically unnecessary" or lacked "sufficient documentation," based on the OIG power wheelchair report, there clearly needs to be a change in how these requests are approved. For the vast majority of Medicare patients the determination that a patient is both eligible and requires a power wheelchair can be both anticipated and planned for well in advance of the actual need. The recent demo of a "pre-approval" process in several states is a step in the right direction. For those patients in whom the need for a power wheelchair is completely unexpected such as major trauma from a motor vehicle accident or a sudden major stroke then it would be reasonable to also have an expedited process for those in whom not having a powered mobility device would significantly and substantially affect his/her well being and ability to be independent.

Another factor to consider is why has the demand for power wheelchairs increased so significantly in the past few years. Based on actuarial data, the rates of disability (based on Activities of Daily Living) in the US have not changed significantly despite a substantial rise in rates of chronic disease and an aging population. Consequently, one would expect that the actual need for these types of devices would only reflect the growth in numbers of the population rather than other factors. Clearly, this has not been the case. It would be certainly reasonable to study the power wheelchair field to see what factors are contributing to the rise in requests for power wheelchairs. Is it that physicians are not properly evaluating patients for physical functional mobility problems? Are physicians and therapists not adequately treating pain and mobility limitations? Do patients understand the consequences of further limiting or restricting their mobility by use of power devices? . Is there sufficient physical and

occupational therapy capacity to properly evaluate older persons with mobility problems and are they being referred for evaluations when indicated? These questions and others may be identified by further study and then an education program could be targeted to the behaviors or beliefs that are driving this demand. Overall, this is a challenging problem to which reasonable solutions appear to be within reach. These will require an adjustment in the method by which patients are "certified" to need a power device as well as the payment mechanism, but also ensuring that patients have a thorough physical functional evaluation to address deficits that are amendable to improvement through therapy without the need of a powered device.

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