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MEETING THE CHALLENGES OF MEDICARE DRUG BENEFIT IMPLEMENTATION

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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CONTENTS

	Page
Opening Statement of Senator Gordon Smith	1
Opening Statement of Senator Herb Kohl	3
Opening Statement of Senator Elizabeth Dole	4
Opening Statement of Senator Thomas Carper	6
Opening Statement of Senator Bill Nelson	7
Opening Statement of Senator Hillary Clinton	8
Opening Statement of Senator James Talent	10
Opening Statement of Senator Ken Salazar	11
Prepared Statement of Senator Conrad Burns	12
Opening Statement of Senator Conrad Burns	13
Opening Statement of Senator Rick Santorum	13
Prepared Statement of Senator Blanche Lincoln	87

PANEL I

Mark B. McClellan, M.D., administrator, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Washington, DC	15
Linda McMahon, Operations, Social Security Administration, Washington, DC	51

PANEL II

Robert J. Kenny, Medicare Part D beneficiary, Tillamook, OR	89
Michael Donato, Medicare Part D beneficiary, Mansfield, OH	95
Sharon Farr, Center for Individual and Family Services, Mansfield, OH	99

PANEL III

Timothy R. Murphy, secretary, Executive Office of Health and Human Services, Massachusetts Department of Public Health, Boston, MA	107
Susan Sutter, president-elect, Pharmacy Society of Wisconsin, Horicon, WI;	119
Mark B. Ganz, president and chief executive officer, Regence Group, Portland, OR; on behalf of the National Blue Cross and Blue Shield Association	129

APPENDIX

Prepared Statement of Senator Larry Craig	139
Prepared Statement of Senator Susan Collins	139
Prepared Statement of Senator Russell Feingold	140
Prepared Statement of Senator Rick Santorum	141
Article submitted by Senator Santorum	143
Prepared Statement of Senator Mel Martinez	144
Questions from Senator Santorum for Robert Kenny	144
Questions from Senator Santorum for Susan Sutter	144
Testimony submitted by Long-Term Care Pharmacy Allicance	146
Statement submitted by National Association of Chain Drug Stores	150
Statement submitted by American Society of Health System Pharmacists	158
Statement of the American Psychaitric Association	165
Statement submitted by AARP	169
Statement submitted by the American Pharmacists Association	177
Testimony of Jack Vogelsong, Commonwealth of Pennsylvania, Department of Aging	185
Testimony of Kenneth Goodman, chief operating officer, Forest Laboratories	194

MEETING THE CHALLENGES OF MEDICARE DRUG BENEFIT IMPLEMENTATION

THURSDAY, FEBRUARY 2, 2006

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

The committee convened, pursuant to notice, at 10:03 a.m., in room 216, Hart Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith, Talent, Dole, Martinez, Santorum, Burns, Kohl, Wyden, Lincoln, Carper, Nelson, Clinton, and Salazar.

OPENING STATEMENT OF SENATOR GORDON SMITH, CHAIRMAN

The CHAIRMAN. Ladies and gentlemen, if everyone would take their seats, we welcome you all here. We thank you for coming. This is our first hearing in the Aging Committee of the year 2006 and there is hardly a topic we could address that is more timely and more important to the lives of our seniors than the new prescription drug benefit. Obviously, it has gotten a lot of people's attention as it has been implemented. It has not been problem-free, but this is not a hearing just to pile on. It is a hearing to look for solutions, so we appreciate very much our witnesses who have taken the trouble to be here and we want you to feel at home here. I understand some are feeling quite nervous about this. But this is a great national effort to fill a part of the Medicare promise that should have been done long ago.

But again, our goal today is to evaluate CMS's ability to address current problems in a timely manner and to anticipate future problems before they occur. Only when this happens can we regain and earn the confidence that beneficiaries want to have in this valuable program.

It is most unfortunate that many of the problems have involved what are known as dual-eligibles, which are people who are on Medicaid, which is a State responsibility, and now have been shifted to Medicare, which is a Federal responsibility. These are often the poorest and most vulnerable Americans who rely on medications to manage their chronic physical and mental illnesses. We knew there would be challenges associated with their transition from Medicaid into the new Medicare drug benefit, but it seems that perhaps not enough was done to ensure a seamless transition.

Last March, this committee held a hearing where experts offered solutions to the very problems the program has experienced. I felt their recommendations had merit, strongly enough so that Senator

Kohl and I sent a follow-up letter to CMS. While I applaud CMS's efforts to address the current situations and problems that have arisen, I have to question whether any of this would have developed if the recommendations we made had been adopted.

However, again, let us look forward. I hope to have answers to a number of key questions. First, is the accurate enrollment information about dual-eligibles available to plans and pharmacists to ensure beneficiaries can receive their medications at correct prices? Second, have the call center hold times improved so that beneficiaries and pharmacists can get access to accurate information in a timely manner and resolve problems? Third and finally, are low-income beneficiaries still being denied drugs or charged inappropriate deductibles and copayments?

I know that progress is being made to improve communication between all parties, but I am hearing reports that not all plans and pharmacies are aware of the options to address problems. This is certainly the case with what is called the first fill policy, which requires plans to cover the cost of a 30-day emergency supply of medication when a beneficiary needs a drug that is not covered by his or her formulary. While all plans reportedly had first fill policies in place on January 1, many pharmacists and plan representatives were not aware of them, and even if they were, they couldn't get the authorization necessary to dispense the drug.

I want to note and commend my own State that took action and created stop-gap programs to pay the cost of emergency medications. I am committed to ensuring that States are reimbursed for their expenses. Again, Medicare is a Federal, not a State, program.

While the focus of this hearing is on the immediate challenges associated with the implementation of the Medicare drug benefit, there are some programmatic changes that are needed. One such change is the extension of the institutional copayment exemption to dual-eligible beneficiaries who are receiving care in homes and community-based centers. Under current law, dual-eligibles who reside in nursing homes are not required to pay copayments for generic or brand name drugs. However, those living in assisted living facilities or who receive services through adult day care programs or other types of community-based services are required to pay these costs.

Considering that dual-eligible beneficiaries in both nursing home and community-based care settings generally have the same amount of resources available to them. This is simply not right. It put dual-eligibles in States like Oregon, which provide most of their long-term care services in a community setting at a disadvantage and may even create a disincentive for individuals to choose community-based care options in the future. By the way, some of those options are less expensive than nursing homes, but my point is simply that the seniors should have the choice of where they receive their care.

Yesterday, I introduced a bill along with Senator Bingaman that would extend the copayment exemption to dual-eligibles receiving their care in home or community-based settings. I believe this small change to the Medicare drug program will have an enormous impact to ensuring that low-income beneficiaries have continued access to their drugs while protecting their right to receive care in

the setting of their choice. I hope my colleagues will consider this bill. I think it is an improvement.

I look forward to today's discussion and I hope we have a thoughtful and productive dialog. I am proud of the Aging Committee. We are the first to take up this issue and I know it is of real timely urgency for seniors. We have excellent witnesses, including two beneficiaries who will discuss the success and challenges associated with the program's implementation.

With that, I will turn to my colleague, Senator Kohl, for his opening remarks.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. I thank you, Mr. Chairman, and I also welcome our witnesses who will be here today.

Dr. McClellan, I am glad to see you back again to discuss Medicare Part B implementation. As I am sure you know, we have some serious problems on our hands, and as I am sure we would agree, we need to put aside any partisan thoughts to work together to get this program running so that seniors are better off than they were before we passed the drug benefit. I do not believe we are there at this time.

Every day, we hear stories from seniors and individuals with disabilities. Some find themselves switched from Medicaid into a Medicare drug plan that does not cover the drugs that they need. In other States, hundreds of dollars of incorrectly charged copays. Still others wrestle with the choice between the dizzying number of drug plans, all covering different drugs and different costs, and few that Medicare can explain in any detail.

A good number of these problems, I think you would agree, come from a flaw in the original plan, the primary reason that I and others voted against it in 2003. Medicare Part D is not what many seniors thought they were promised, a simple drug benefit delivered through the reliable, popular Medicare program. Instead, private insurers distribute the drug benefit, and I believe it is set up as much for their profit and convenience as it is for that of our seniors.

Nowhere is that more obvious to me than in the provisions of the drug benefit law that prohibits, as you know, the Federal Government from negotiating with drug companies for lower drug prices. Forty-one million Medicare beneficiaries demanding fair prices, I believe could have backed the drug companies down, but the law will not let them even try.

Striking that provision, and I am a cosponsor of legislation to do that, I believe might be the single most powerful action we can take to increase the popularity and the benefit of Medicare Part D among seniors. I would hope that the administration would endorse fixing that provision. I believe it would not only be good policy, but a strong signal that seniors are, indeed, our primary concern.

I would bet that, Dr. McClellan, you are as disappointed as anyone at the troubled roll-out of Medicare Part D. Seniors don't have enough information, as you know, to choose a drug plan and they get inaccurate or inconsistent advice when they call Medicare. Senator Nelson has introduced a bill that would extend the enrollment deadline from May 15 and give every beneficiary a chance to

change their plan at least once at any point in 2006, and that seems to me something that we could and should do.

We also have to take immediate action to help those hit hardest so far, the so-called dual-eligibles, the very poorest and sickest seniors and disabled individuals who were switched to the Medicare drug benefit on January 1. We hear stories of patients denied medicines because their paperwork is delayed or their new plan does not cover what they need. We know the Administration must be as concerned as we are with that result and we look forward to talking about what we can do to turn it around.

But it is not only seniors who are overwhelmed. Pharmacies, as you know, are struggling to navigate the new system. Today, we will hear from Sue Sutter, a pharmacist from Dodge County, WI, about the extreme steps they have taken to make sure that no patient is turned away. Even in the face of being unable to verify payment, many pharmacists have still dispensed medications to their clients and some pharmacies have been forced to the extreme of taking out lines of credit to cover their costs. Many States, including Wisconsin, have had to step in to cover drugs, as you know, to avert a public health emergency.

I believe we can act now to fix these problems. Dual-eligibles must have guaranteed access to the drugs they need and some real help to get into the proper drug plan. The Federal Government must reimburse seniors, pharmacies, and States who have stepped in to fill the holes. We should extend the enrollment deadline for seniors to sign up for the benefit so that they would have enough time to pick the drug plan that best suits their needs, and we should also let seniors change their drug plans this year if the one they choose changes mid-year and no longer provides coverage for their drug. We should also allow, as I said, Medicare to negotiate directly with drug companies for lower prices for seniors and taxpayers if we cannot explain why they should be disallowed from doing that.

Earlier this week, I met with seniors, individuals with disabilities, pharmacists, and advocates in Milwaukee who have been working around the clock to help people get the drugs they need. The administration needs to show that same commitment and must look at what can be done to rectify the problems that exist with Medicare Part D.

Again, I thank you all and I certainly thank our Chairman for holding this important hearing.

The CHAIRMAN. Thank you, Senator Kohl.

As is our tradition, we will go on those who arrived first, so it is Senator Dole, Senator Carper, Senator Nelson, Senator Clinton, and Senator Talent.

OPENING STATEMENT OF SENATOR ELIZABETH DOLE

Senator DOLE. Thank you very much. Thank you, Chairman Smith, for holding this hearing to examine and address the challenges in implementing the new Medicare prescription drug program.

Twenty-four million Americans, including more than 778,000 North Carolinians, are enrolled in Medicare Part D, and today, these folks are receiving more affordable access to life-saving medi-

cation. For a majority of these individuals, the program is working properly and they are receiving their prescriptions at a much lower cost than before. In fact, pharmacies across the Nation are filling one million prescriptions a day to Medicare Part D enrollees.

However, there are some beneficiaries, in many cases the neediest among us, who are having considerable trouble transitioning into the new program. This is simply unacceptable and clearly not what was intended. It is critical that we identify these problems and work together to ensure that this new program serves each and every beneficiary successfully.

I have heard from a number of pharmacists, providers, and beneficiaries in my home State of North Carolina about both the successes and challenges they have encountered in the first month of the new Medicare drug program. While I am delighted to hear that so many Americans who did not have prescription drug coverage before are now benefiting from this program, I am also very concerned about those who are encountering obstacles as they try to fill their prescriptions.

I have heard reports, as I am sure we all have, about beneficiaries who are being charged the wrong copayment, pharmacists and beneficiaries who are not able to get in touch with the plans, and computer systems that are working inadequately. What is worse is that in many cases, it is the dual-eligible individuals, those who qualify for both Medicare and Medicaid benefits, and the low-income subsidy populations, that are having the most trouble.

Because these beneficiaries often have more serious health concerns and depend on their prescription drugs the most, it is even more important that these problems be addressed quickly.

The new Medicare prescription drug plan is the largest change to Medicare since the program's creation 40 years ago, and with any change that scale, that magnitude, it is nearly impossible to avoid startup challenges. But now we have got to identify those individuals who are vulnerable and make certain their needs are met. We have got to make certain that the new drug program is working for all beneficiaries, pharmacists, and providers alike.

We have already seen tremendous progress in solving some of the initial difficulties. Data submissions have been streamlined. Customer services have been enhanced. Pharmacy support has been expanded. I thank Dr. McClellan and CMS for taking steps to quickly improve the systems that were faltering and to assist those experiencing problems. I also thank the many pharmacists, providers, case workers, State and Federal officials, friends and family members who are working together to assist beneficiaries in their community.

I am disappointed by the unconstructive rhetoric and blame game that some are resorting to. We must work together, not point fingers, to solve these problems.

In conclusion, let me just say that in the coming days and weeks, it is vital that all parties involved continue to make a concerted effort to strengthen the new Medicare drug program. Congress must ensure that diligent work is being done to meet the needs of every beneficiary. Millions of Americans are better off, thanks to the benefits provided by this landmark program, and there is no reason why every enrollee should not share the same experience.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Dole.

Senator Carper.

OPENING STATEMENT OF SENATOR THOMAS CARPER

Senator CARPER. Thank you. I want to welcome our witnesses today. Thank you very much for joining us. It is good to see both of you and I express my thanks to you, Mr. Chairman, and to our colleague, Senator Kohl, for pulling us together so that we can begin to exercise our responsibility and our oversight responsibility as this new benefit is implemented.

We all know, it has already been said, the implementation process has been bumpy, rocky. Maybe it was difficult given the magnitude of the kind of program that we are introducing here. I voted for this benefit in the expectation that we would make improvements and as a first step toward ensuring that all seniors and disabled persons have access to prescription drug coverage under Medicare. However, this is only going to work if we continue to improve the program's implementation almost on a daily basis, and I know that is what you are trying to do and that is what we are trying to do in my State of Delaware.

I just say to my colleagues, I think maybe it is going a little bit easier in Delaware. We had our tough moments and still have them, but we have an extraordinary cooperation between State and local folks, working with CMS, working with Social Security, working with folks in the private sector to try to smooth it out as best we can.

I know we have all heard how confusing this program is and about the transition problems that are associated with the new benefit. Some beneficiaries have gone, as we know, without needed medications. Pharmacists have dispensed medications they have not been paid for. Medicare and health plan phone lines have been overwhelmed, such that resolution of these problems are even harder to come by.

In my State of Delaware, we have done, as I said, I think a pretty good job of trying to implement the process and a lot of people have worked very hard to make that possible. I think we have been able to avoid the worst, but for a lot of people, there has been a lot of heartache, as you know. Now we have got to sort through the problems that we see and we have to fix them.

I am going to suggest several steps. The first one would be that the Centers for Medicare and Medicaid services must address as quickly as possible all the many problems that you have heard about and that we have heard about in this past month or so. This includes that States, that pharmacists and beneficiaries are appropriately compensated for costs that they have incurred as a result of transition problems, and CMS should provide Congress with regular updates on the progress of resolving these issues, and this is an opportunity to provide one update in person. We hope that others would follow.

Second, I believe we will need to streamline and simplify the benefit. As it stands now, CMS, I believe, approved too many plans, each one with different rules, different standards for pharmacists, different standards for appeal. Put quite simply, the program as

implemented today is just too confusing. I will remember for a long time a conversation I had with Senator John Breaux and former Secretary Tommy Thompson a year or two before the adoption of the program and talking to them about my mother, about their mothers and how difficult this stuff is going to be for them to understand on a very good day. What we have done is we have put in place a program that is, for a lot of our senior citizens, almost incomprehensible.

Third point, we need to ensure that CMS has the proper structures in place to oversee participating health plans. CMS must ensure the plans are doing what they are supposed to be doing and that any lack of compliance is immediately identified and corrected.

Finally, we need to ensure that the Social Security Administration continues to conduct outreach to low-income populations. Today, I think only about a million people have been found eligible for the subsidy out of an estimated, I think, eight million people who are believed to be eligible beneficiaries.

I just say in conclusion, we can do better with this drug benefit and I hope that today's hearing is a real good step toward fixing some of the problems that we have all experienced and worked to correct.

Thanks, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Carper.

Senator Nelson, how are we doing in Florida?

OPENING STATEMENT OF SENATOR BILL NELSON

Senator NELSON. Well, you can imagine with the significant senior citizen population we have in our State, and Mr. Chairman, I will be very brief and just summarize because you all have a tough job and you need to know what we are hearing and it has been said here.

We are going to have an opportunity to vote on this today, on one of the things that has already been mentioned here. The Chairman has mentioned it. I have filed an amendment on the tax reconciliation bill that will delay for 6 months the deadline of signing up that will help a lot of the folks that I have been talking to who are quite confused with over 43 plans to choose from. They are not only confused, they are frightened because of that deadline coming and if they make a mistake. So that is a part of the amendment, as well, that they would have the opportunity to change that without having to wait a year.

Now, you have also heard the commentary here about the dual-eligibles. I will tell you, your attention is riveted in a town hall meeting when senior citizens are sitting or standing in front of you and literally tears are coming down their face because they had their prescriptions under Medicaid and now the pharmacist is refusing to give it to them as they have been transferred under Medicare.

Then the third thing that I would just quickly mention is that Senator Clinton and I filed a bill last week, and I just heard you say, Mr. Chairman, that you filed one, as well, and this is prescription drug copayments in those that are in assisted living facilities. Now, if you are low-income nursing home, you don't have to pay the copayments. But if you are low-income and you happen to be

in assisted living facilities, and it may be that you are there because you have got a mental problem and the medications are absolutely essential, you see the problem. They are not getting their medication. Senator Clinton and I have filed a bill that would cancel those copayments for low-income individuals.

Good luck as you are implementing this with everything that we are seeing come up to the top.

The CHAIRMAN. Maybe we should combine your bill with the bill Senator Bingaman and I introduced. Senator Clinton.

Senator NELSON. The more the merrier.

OPENING STATEMENT OF SENATOR HILLARY CLINTON

Senator CLINTON. Mr. Chairman, we would certainly welcome that and we will work together, because that is one issue that must be fixed immediately. I have been in pharmacies from Buffalo to Rochester to Syracuse to New York City. I have been to hospitals. I have spoken with many pharmacists, doctors, nurses, seniors, people with disabilities, their family members, their advocates. Because I worried that the bill itself was fatally flawed in its design, I voted against it, but once it passed, I certainly determined that I would try to do everything I could to make sure that New Yorkers understood it, could access it, and make the best of it.

To that end, I issued in our State a brochure that my excellent staff put together. We have sent out tens of thousands of these in English and Spanish. But as the date approached for the January 1 implementation, I became even more concerned and introduced legislation to try to fix some of these problems that I was convinced were going to happen.

The GAO came out with a report that highlighted and really set off the alarms about a number of these problems, and yet despite the concerns of many about what was going to happen, we were unsuccessful in either slowing down the process or making it work better and the results are the ones that I have seen firsthand over the last several weeks in my State, and I have to identify completely with what both Senator Kohl and Senator Nelson have said. I mean, it is an absolute embarrassment, outrage, deep heartbreaking disappointment to be in the presence of people who are so distraught, confused, upset and feeling abandoned.

I know any program is difficult, but I would remind us we implemented the entire Medicare program in 11 months back in 1965, and we didn't have computers. We had a simple program people could understand and an effective effort to make sure it came into being as smoothly as possible.

Now, the first thing, Mr. Chairman, I would suggest is that we get some agreement on the facts here, because we cannot possibly deal with what we as elected representatives are coping with, which is an overwhelming outpouring of constituent requests, unless we know the facts. I think it is important to start with the fact that the administration continues to claim that we have 24 or 25 million beneficiaries. Let us look at those figures.

First, the 6.2 million dual-eligibles already had prescription drug coverage. They were covered by Medicaid. They got their drugs. Most of them got it for free. It was seamless. Their doctors understood how to access it for them. Four-point-five million Medicare

Advantage enrollees had Medicare managed care plans that offered prescription drug coverage. They already were covered. Seven-point-four million retirees already had coverage from their previous employers for their drug needs. Federal retirees, veterans and their families, 3.1 million, already had existing drug coverage. So we have about 3.5 million new enrollees in our country who signed up for the new benefit.

In New York, we only have 110,000 new beneficiaries, and who can blame them? People are taking a wait-and-see attitude. They don't want to be signed up with some plan that may not even have their drug on the formulary. Their doctors are telling them, wait. Don't rush into this, because I don't want to have to be rediagnosing you. You have been fine on the drugs that I have given you for a decade. I don't want to have to write notes and ask for permission to give you the drug that I think you should have. So people are taking a wait-and-see attitude, except for the dual-eligibles, who were automatically enrolled, who had no choice over what the plan they were going into said or what kind of copayments they would be required to make.

So I think that we need to have, as the first order of business, an agreement that we are going to talk about facts, not spin, not rhetoric, not propaganda. We are going to talk about facts because people's lives are at stake, and I take this very seriously.

There are a number of fixes that we have been putting together on both sides of the aisle. One, you heard about. The Chairman, Senator Nelson, and I, we would like to make sure that the dual-eligibles living in group homes, in assisted living facilities, like a young man that I met recently outside of Albany had a bill for the first time ever that he was supposed to pay to get the drugs he needed will not have to face that.

Second, I would like to see the pharmacists in this country reimbursed. They have been on the front lines. They have been the ones who have had to tell customers, "I am sorry, this isn't covered," or, "Mrs. Jones, I know you used to get your drugs for free, but now you are going to have to pay me $42. Oh, you can't pay? Well, I am going to give it to you anyway and we will try to get this worked out." They are the ones who have been on hold to the Medicare hotline or to the plan's hotline, trying to get answers for their customers about what they were entitled to and how much it was going to cost them. So I certainly hope we will reimburse the pharmacists.

With respect to the recent announcement about reimbursing the States, let us make sure that that is not cutoff at February 15 because I don't think a lot of these problems are going to be fixed by February 15, and I don't think any State that has stepped up to the plate, as so many of ours have, should be penalized because the Federal Government designed a fatally flawed plan and is implementing it in a manner less than acceptable.

Now, I also am deeply concerned about the large numbers of beneficiaries with mental illnesses who have had trouble getting their medications. Now, as beneficiaries finish their one-time transition supplies of medications not covered on drug plan formularies, they will have to switch medications or file for an exception to the plan's formulary policies, and I predict this will be the next big

challenge, Dr. McClellan, that will be faced by the Part D program, as millions of beneficiaries try to take advantage of the exceptions and the appeals process, and I hope you have plans in place, and I would request that your agency provide this committee with data on the numbers of beneficiaries who file appeals to plans, the number of successful appeals, and rejections by plans, and information on the timeliness with which plans handle appeals.

Finally, there continue to be widespread reports of drug plans requiring prior authorization for beneficiaries to receive needed medications. Now, some reports have plans requiring forms for each drug, while others are requiring doctors to fill out forms as long as 14 pages for drugs that a beneficiary has been taking for years. Now, your agency's request that plans discontinue this practice does not seem to be working based on the information we have, and I hope that you will require, not request, require that the plans cease this practice and enforce that requirement.

Mr. Chairman, we have legislation with a comprehensive fix that I hope we can get bipartisan support on. I, for one, believe we should scrap this and start over. We are spending hundreds of billions of dollars on an inefficient delivery of a plan that could be done in a much more cost-effective way. We have taken taxpayer dollars by the billions and transferred it to the pharmaceutical companies and the insurance companies as a way to entice, even bribe, them to provide drug coverage to the poorest of the poor and the sickest of the sick. That is not in keeping with either our values or, frankly, what should be expected of high-performance government.

I look forward to getting responses, but I hope that we will start with an agreement that no spin, no rhetoric, let us talk facts and let us get facts before this committee so that we can discharge our responsibilities to the people who are dependent on us.

The CHAIRMAN. Thank you, Senator Clinton.

We will now hear from Senator Talent, Senator Salazar, Senator Burns, and Senator Santorum, and if you could keep them abbreviated, we would appreciate it. Our witnesses, three panels of them, are waiting. Senator Talent.

OPENING STATEMENT OF SENATOR JAMES TALENT

Senator TALENT. I will be brief, Mr. Chairman. I have had a number of town hall meetings around Missouri talking about this new coverage and listening to seniors. It is the third round of town hall meetings I had on prescription drug coverage. I have encountered in my time in public life many, many senior citizens who were in a position where they were choosing between the necessities of life and prescription drugs because they had no coverage because Medicare did not have prescription drug coverage as a base, and that is not the case now. There are thousands of people in the State of Missouri who were paying thousands of dollars out of pocket a few months ago who are not paying that anymore and that is a huge plus for the program.

But we have a lot of issues that we have to deal with, also, and many Senators have mentioned that. I am looking forward to having the chance to ask you about that.

I am concerned—it is funny, because as I was thinking about this and where we were going to have difficulties, I thought the auto-enrollment process would probably go pretty well because we already had those people on the computers and I thought we would just be able to shift them over. We have had 14,000 Missourians for whom the auto-enrollment process failed. I appreciate your assurances that the State is going to get reimbursed. I want to make certain that that happens.

I also have concerns from a pharmacist's point of view about how this is working out. I have heard from a lot of pharmacists in that respect, and also issues in getting information from the plans as people try and make choices about what plan that they are going to pick.

I appreciate the fact that you are here today and I am going to desist from any further statement and just ask that my opening statement be put in the record.

The CHAIRMAN. Without objection.

Senator Salazar.

OPENING STATEMENT OF SENATOR KEN SALAZAR

Senator SALAZAR. Mr. Chairman and Ranking Member Kohl, I very much appreciate the work you do on this committee and I very much look forward to working with you, since this is my first meeting before this committee.

On the subject that we are dealing with here today, I know the horror stories that we have heard all around the country. They are no different at all in my State than some of the stories that have been talked about here this morning already. In Colorado, we have 17 companies that are providing 42 plans to Medicare beneficiaries. The implementation of the program has caused numerous people in my State to come to me and to my other colleagues and to tell us about the concerns that they have with the implementation of the program.

In the first few days of the program, many of the pharmacies did not have the correct information, and I saw and heard from people who were trying to scrounge together money from friends and relatives to try to pay for prescriptions. Some of them were able to do it. Some of them, frankly, had to go without.

I don't want to go over all the concerns that have already been talked about by my colleagues, but there is one particular concern that I do have that I want to reemphasize and that is the payments with respect to pharmacies that have been providing prescription drugs on a promise that they are going to get reimbursed by the government. In my native San Luis Valley, there are perhaps one or two pharmacists in each of the six counties of my valley. These pharmacists are often the center of health care for the community and especially for the elderly. When they see the elderly hurt, the pharmacists themselves hurt. I have heard from these pharmacists who are paying the up-front costs of the CMS requirement that pharmacists must provide a 30-day supply of drugs to dual-eligible beneficiaries and then to be paid back by the plan the beneficiary is enrolled in. Placing the burden on these pharmacies risks the livelihood of these small businesses. I urge CMS to ensure that each of these pharmacists is paid quickly and accurately.

Finally, I look forward to working on a bipartisan basis with the members of this committee and the other members of the Senate and Congress to try to make sure that we can take care of the humongous problems that have been illustrated with respect to the implementation of this program.

The CHAIRMAN. Thank you.

Senator Burns

Senator BURNS. I would ask that my full statement be put in the record.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Burns follows:]

PREPARED STATEMENT OF SENATOR BURNS

Today, as we discuss the implementation of the new Medicare drug benefit, I think it is important to remember that this is an entirely new program—barely a month old. Before it, drug coverage in the Medicare program was very limited. Seniors whose employers did not provide drug coverage could get it only through what was then known as Medicare+Choice, through Medigap policies, or worse, would have to go without coverage at all.

With that in mind, I voted for the new benefit. As of mid-January, over 24 million seniors have been enrolled—53,000 in Montana, with thousands more enrolling every day. Millions of these Americans did not previously have any coverage, and now they do. Of those who have enrolled, the vast majority are finding that the new benefit covers the drugs they need and will save them money.

However, as we are all aware, the implementation has not gone smoothly in all cases. I'm sure that what I am hearing from my constituents in Montana is no different from what my colleagues on this committee are hearing.

I think that every state has had difficulties encountered by low-income dual eligibles. A number of states, as well as a number of pharmacies have stepped in to cover the costs of providing these beneficiaries with needed medications.

Seniors are finding that the program is extremely confusing.

Some calls from pharmacies and seniors are put on hold for hours. Often this long wait results in merely being given the opportunity to leave a message that is often not returned.

Pharmacies, particularly small ones in rural parts of Montana, are extremely concerned that reimbursement is too low. We cannot afford to have these small pharmacies close in states like mine where beneficiaries often must travel great distances to get their drugs.

Finally, I am personally concerned about the limited efforts CMS is making to reach out to rural and remote areas, most specifically on our Indian Reservations.

While many Native Americans were automatically enrolled at the beginning of the year, many were not.

To date, I have heard of no efforts to reach out to Native Americans to explain to them the importance of enrolling and assisting them with this process. In a state the size of Montana, outreach to these remote areas is critical, and I am concerned that CMS doesn't fully understand how much territory we have to cover out there.

We have not had as much success as I would like to see in getting eligible tribal members signed up for Medicare in general, and I worry that the problem is worse on the Part D program.

The result, I fear, is that many on the reservations will miss the deadline.

I am very concerned about all of these problems, and my office has been helping hundreds of Montanans get the help they need from CMS to get enrolled.

However, these problems do not mean that this is a bad program or that Congress must initiate wholesale legislative changes. I am concerned that some have seized upon these difficulties in a cynical attempt to score political points. We must not do this! Those that have already labeled the program a failure are only discouraging seniors, who many need the help, from enrolling or even investigating their options. Far too much is at stake—people's lives are at stake—and I am unwilling to play politics with the lives and health of our seniors.

To begin making drastic changes now risks exacerbating problems that can and currently are being fixed by CMS. Our focus now should be ensuring that all seniors who want to be enrolled get enrolled by May 15th.

OPENING STATEMENT OF SENATOR CONRAD BURNS

Senator BURNS. This doesn't surprise me. This program is a month old and we Americans are in this business that everything has to be instant—tea, coffee, everything that we do—and we are supposed to just go out there and have a new program, put it in place, and all at once, it is perfect.

I would ask my colleagues that just throwing out a bunch of stuff and try and help and get the program in place serves our purpose and then we know what to fix. Right now, we don't know what to fix, but I would tell CMS this. Your first manual that went out on this was a bureaucrat's dream, but it was a nightmare to seniors. You had to have a lawyer and an accountant there with you to work your way through it. About a third of ours are signed up and we have got until May 15, and I think we should dedicate ourselves, both as elected representatives, to help put this program in place because we have people now getting drugs that couldn't get them before.

Yes, there is a lot of confusion out there because sometimes some folks live on confusion. I would just ask, let us all get together and make it work and then we know what to fix. When we are as old as 11 months it took to put Medicare in place, we might see some holes and we might find that this program might be a pretty good program, that it might be working. But like Americans, we want everything instantly. We want it to just pop up and do this when you have got a lot of folks out there that are dual-eligibles. There has already been a commitment made to the pharmacists that they be reimbursed on the dual-eligibles and what they have been holding in limbo. That commitment has already been made, I think, and I think we should bring that to light here.

We continue to get a lot of calls. We continue to work with our resource centers and our offices to answer as many questions as we possibly can. But just to come out here and throw up your hands and say it is not going to do it, that we are going to start changing it now, is not the correct approach to this. We may find that everything falls into place.

I voted for it and I know it is going to be costly, but I will tell you, I have got people in Montana—we have just come back from the National Prayer Breakfast and there Bono came up with a great statement, and it applies to me in Montana in the same. Where we live should not determine whether we live. So we have some special needs in rural areas.

I would certainly advise everybody, let us make it work. Let us find where the holes are. Then let us fix them, or let us make them work on the ground. Thank you very much.

The CHAIRMAN. Thank you.

Senator Santorum.

OPENING STATEMENT OF SENATOR RICK SANTORUM

Senator SANTORUM. Thank you, Mr. Chairman, and I, too, appreciate your willingness to hold this hearing and to get to the bottom of some of the problems and concerns. I think we need to take a step back and say that it is a good thing that we are here.

For almost two decades, we have been trying to get a prescription drug program passed through numerous administrations,

through numerous Congresses, and we were not able to do it. We were not able to find compromise, and with compromise comes a meshing of a whole bunch of different ideas of how to do things best and often you don't get the optimal solution. I think no one who voted on the prescription drug bill that passed a couple of years ago would have said that that was their optimal plan or this was designed perfectly, from the Congress, I might add, but it was the best we could accomplish given a very divided atmosphere here in Washington, DC.

So it is somewhat remarkable to expect that something that is the product of deep division, lots of haggling, lots of changes that occurred throughout the legislative process, is going to result in a perfect system that would be implemented without error. Those who stand here and suggest that somehow or another that the whole thing should be thrown out may have forgotten that it took us 20 years to get the whole thing passed in the first place and that just throwing it out would doom seniors, 24 million of whom are signed up today and receiving benefits, to a situation where they would be getting less care than they are today. So we should not be so flippant in casting out babies with bathwaters when it comes to a program that was hard fought to get accomplished in the first place.

So while I commend the Chairman and suggest that there is much to be done in improving this situation, the idea that we are going to play, once again, politics with prescription drugs instead of trying to get down to the hard work of trying to fix this system and its implementation, I think is below the dignity of this committee.

I am happy that Dr. McClellan is here. As he knows, we have had many conversations in the last few weeks about the situation in Pennsylvania. I have spoken to Secretary Leavitt on more than one occasion and have encouraged him and am still working with him to have him come up to Pennsylvania.

But that does not mean that we need to start all over or throw this program out. We need to continue to look at it, see if we can implement it correctly, solve the problems that exist, make changes if some are necessary here in the Congress that in all likelihood we created in the design of the program, and then go about the process of making sure that seniors get the kind of care that we have told them that we are delivering to them.

I can tell you that in Pennsylvania—I have just gotten numbers from the problems that exist in my State—for excessive cost-sharing claims, we have about 250 people a day that have made claims to the State to help on that regard and the State has paid out about $100,000. For emergency supply claims, there is about 175 to 200 people per day that have cost the State so far about $55,000. For super priority prior authorizations for dual-eligibles, we have had 180 claims that have cost the Commonwealth $15,000.

Now, each one of these is a problem, but I would not suggest that these numbers suggest that we should throw the program out and start all over again when you are talking about tens of thousands, if not hundreds of thousands, of people being served in the Commonwealth.

So I would just suggest, Mr. Chairman, that we get down to business in figuring out what the problems are, how we can fix them, how we can improve them, and what Congress' role in creating the problems and what our role should be in trying to fix them.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Santorum.

We have on our first panel two witnesses. We are grateful, Dr. McClellan and Ms. Linda McMahon, for your presence here. Dr. McClellan is the administrator for CMS and Linda McMahon is deputy commissioner of Operations at the Social Security Administration.

To my colleagues, we will have 5-minute rounds of questions afterwards, so Mark, take it away.

STATEMENT OF MARK B. MCCLELLAN, M.D., ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. MCCLELLAN. Thank you, Mr. Chairman, Senator Kohl, all of the members here who care so passionately about this program. I appreciate the opportunity to give you a status report on the new prescription drug coverage.

Currently, more than 24 million Americans are receiving help through this program. This includes millions who previously had no coverage, millions who now have better coverage than their Medicare Advantage plans, more complete, more comprehensive, and millions now getting real help keeping their retiree coverage in place, coverage that has been going away over the past 20 years. Drug plans are now filling millions of prescriptions each day. Every day, tens of thousands of new beneficiaries are using their new drug coverage to save money, to get peace of mind, and to stay healthy, and because of competition, because of choice, this coverage is costing much less than people expected, with premiums one-third lower for beneficiaries than had been predicted as recently as last summer.

A change this big in this short a period of time is bound to have some problems and I am very concerned about anyone who has experienced problems in getting their medicines at the pharmacy counter the first time they tried to use their coverage. In particular, some problems with data translation between Medicare and the drug plans and States may potentially have affected—potentially—a few hundred thousand of the six million people with Medicare and Medicaid, particularly those who switched plans late in December. At the same time, some pharmacies have had difficulty in using the support systems intended for those beneficiaries.

We make no excuses for these problems. They are important, they are ours to solve, and we are finding and fixing them.

We have outlined some urgent actions that we are taking in a 1-month report that was just released by the Department of Health and Human Services. This includes actions with our information systems, the health plans, pharmacists, and States, all to help all of our beneficiaries use their coverage smoothly.

On our systems, we built and tested each component and we are working with the health plans and the States to continue improv-

ing them. Prior to January 1, to insure that all duals that we knew about were appropriately covered, we exchanged data files with the States to compare our respective lists. The data matched at a rate of more than 99 percent according to an outside review. To verify that our enrollment information matched plan information, we transmitted, again, files with dual-eligible and low-income subsidy individuals to the plans on January 13, 18, and again on January 30. We are working to provide significantly faster responses to information submitted by plans on their new enrollees and the drug plans are working with us to submit data in ways that can be processed successfully and quickly.

With the plans, we have set up specific checks to ensure that they provide adequate formulary coverage of all needed medicines, particularly those for specific disease populations, such as HIV-AIDS and mental illness that have been a particular concern to this committee. We developed specific procedures for timely exceptions and appeals. In using this procedures, a Medicare beneficiary can get coverage for a drug not on a plan's established formulary.

In addition, we required plans to have a transition policy for dual-eligible individuals, as you all noted, to get a one-time supply of their current medications while they determine whether a less expensive, very similar medicine will work for them or if they need to continue their current drugs. I have made it clear to the drug plans that these transition policies must be followed and we will take further enforcement actions, if necessary.

Many plans have extended their transition policy for the large number of beneficiaries who started their coverage in January. To help ensure a smooth transition for these beneficiaries, Medicare is notifying plans that the transitional coverage period in effect now will continue for 60 more days.

To help pharmacists identify what plan a beneficiary is in when a beneficiary shows up without a card or other billing information, we collaborated with pharmacists starting in 2004 to create an electronic eligibility and enrollment checking system that operates as part of the existing pharmacy computer systems. Response times since January 2 have been less than 1 second and the number of queries is decreasing steadily, because that means more individuals have their cards or their billing information when they go to the pharmacy.

I and my staff have visited pharmacies. We have seen firsthand what they have done to help make sure even those beneficiaries who have difficulty are getting the medicines they need, and we have been very impressed with the tremendous work of the nation's pharmacists and we are listening to their ideas for improving the program. That is one reason we just announced some new steps, like supporting efforts by plan and pharmacy groups to implement consistent and clear messaging systems in pharmacy billing, and that is why we are paying close attention to customer service and pharmacy service.

I am pleased that over the last few weeks, many plans have made great strides in implementing effective pharmacy service lines, and to ensure that they all do so, we are increasing our monitoring and reporting on plan help lines as a basis for further enforcement actions, if necessary.

We have also worked closely with the States, beginning in 2004, on automatic enrollment and on the low-income subsidy eligibility application, the calculation of the State phase-down or claw-back contributions, on training to assist beneficiaries, and on exchanging information between Medicare and Medicaid. When pharmacies were having difficulty filling prescriptions for certain dual-eligible beneficiaries, as you all have noted, a number of States turned their Medicaid systems back on to assist those individuals, and we appreciate the help that States have provided to support pharmacists serving these beneficiaries. We have put in place a payment program to reimburse States for the direct and administrative costs that they incurred.

We are seeing that States that work closely with us, like the State of Pennsylvania, on supporting pharmacists and using the new Medicare systems and connecting people to their Medicare coverage have been able to limit billing to the State systems to relatively small amounts, often just a very small fraction of dually eligible individuals, as they connect those people with their coverage. We intend to work closely with all States to use these approaches to complete the transition to Medicare coverage for the remaining dually eligible beneficiaries.

I want to talk for a minute about the millions of beneficiaries who are choosing to enroll in Medicare coverage and get new savings and protection available right now. It takes a little time to process people through the eligibility and enrollment systems. After you enroll, you will generally get an acknowledgement letter in a week or so and then your drug plan I.D. card in 3 to 5 weeks. That acknowledgement letter and the card contain important information that makes it easier for the pharmacist to help you use your coverage the first time. So we are encouraging people who enroll or change a plan to do so in enough time to get that information into the system.

If you enroll before the 15th of the month, you should have the information you need by the beginning of the next month when your coverage starts. In those cases, we have seen over 90 percent of individuals use their coverage for the first time without difficulty. People who sign up later will still get their medicines, but they are more likely to spend extra time working through some details. As we continue to find and fix problems, we are seeing fewer of these cases.

We are going to continue working around the clock to help every Medicare beneficiary who enrolls to use their new coverage and we are seeing that using the coverage means real savings. Now, for the first time, we have independent budget estimates of the costs of the drug coverage that are based on the actual experience with the strong competition to provide coverage. Medicare's drug benefit will have significantly lower premiums and lower costs to Federal taxpayers and States as a result of stronger than expected competition with lower drug costs. Beneficiary premiums are now expected to average $25 a month, down from the $37 projected in last July's budget estimates. Taxpayers will also save. State contributions for a portion of the Medicare drug costs for beneficiaries who are in both Medicare and Medicaid will be 25 percent lower over the next

decade. All of these savings result from lower expected costs per beneficiary.

I want to thank you for the opportunity to discuss this first important month of the Medicare prescription drug benefit. While we are pleased that millions of Medicare prescriptions are being filled every day, we are going to continue working around the clock all over the country with all our partners to ensure every person with Medicare can use their coverage smoothly, and I am happy to answer any questions you all may have.

The CHAIRMAN. Thank you very much, Doctor.

[The prepared statement of Dr. McClellan follows:]

TESTIMONY OF

MARK B. MCCLELLAN, MD, PH.D.

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

HEARING ON

IMPLEMENTATION OF THE

NEW MEDICARE PRESCRIPTION DRUG BENEFIT

FEBRUARY 2, 2006

CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of
Mark B. McClellan, MD, Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Before the Senate Special Committee on Aging
Hearing on Implementation of the New Medicare Prescription Drug Benefit
February 2, 2006

Chairman Smith, Senator Kohl, distinguished members of the Committee, thank you for inviting me to discuss the implementation of the new Medicare prescription drug benefit. While millions of people with Medicare are now using their new drug coverage effectively, I also want to focus on the work we are doing around the clock to make sure every beneficiary gets the full benefit of their drug coverage.

New Medicare Prescription Drug Benefit Delivers Drugs and Savings to Millions

Prescription drugs are a critical component of 21st Century medicine, but until recently the Medicare program had never included an outpatient prescription drug benefit. Now, Medicare's new prescription drug benefit provides seniors and people with disabilities with comprehensive prescription drug coverage, the most significant improvement to senior health care in 40 years. Millions of seniors and people with disabilities are already using this benefit to save money, stay healthy, and gain peace of mind.

Since the new prescription drug benefit began January 1, 2006, enrollment is off to a strong start. As of mid-January, nearly 24 million people with Medicare now have prescription drug coverage and tens of thousands are enrolling every day. Pharmacists across the nation are filling a million prescriptions each day for people with Medicare. Nationwide, pharmacists are processing more than 40,000 Medicare prescriptions an hour during peak hours as hundreds of thousands of people with Medicare are now getting help with their drug costs each day. In the first 10 days, over three million prescriptions were dispensed to Medicare beneficiaries in nursing homes. And pharmacists across the country are reporting to CMS that people who did not have good coverage previously are now no longer struggling with their drug costs. For example, one pharmacist told us how, for the first time, he didn't have to advise one of his patients with Medicaid about which prescription he couldn't fill completely because of the coverage limits.

And many reports from people who are getting their drugs under the new prescription drug benefit are very positive. One man wrote, "My drug bill went from $154.28 per month to $34 for the same drugs. That is a 78% savings! I chose a program that had no deductible so I would not have to wait to spend $250. After paying the monthly fee of $39.50, my savings per month is 52.7%. Tell me I didn't get a good deal..."[1]

Enrollment Status Update

Figure 1 shows the significant increases in enrollment from about 15 million people with drug coverage on December 21, 2005, just a week and a half prior to the onset of the prescription drug benefit to 24 million on January 14, 2006, two weeks after the benefit debuted.

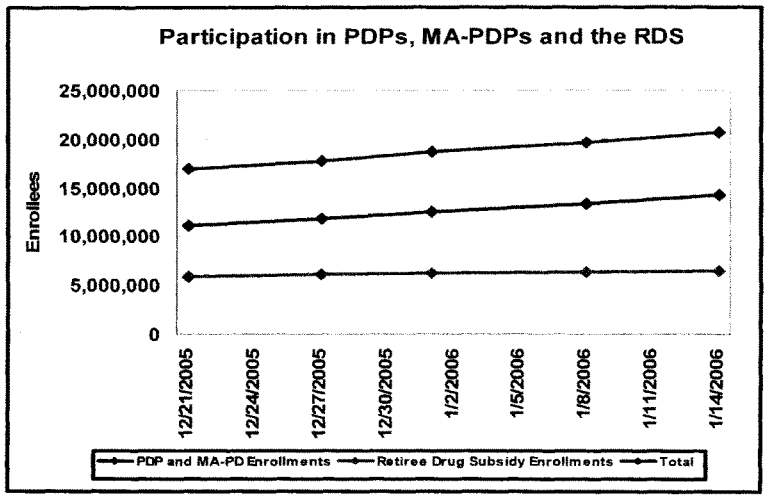

Figure 1: Enrollment in Medicare Prescription Drug Benefit, Medicare Advantage-PDPs, and the Retiree Drug Subsidy.[2, 3, 4]

1 *Wall Street Journal*, January 11, 2006, http://online.wsj.com/article/SB113684922094842048-search.html?KEYWORDS=medicare&COLLECTION=wsjie/6month.
2 MA-PDP enrollments are under-reported as plans update CMS records concerning the movement of beneficiaries from MA to MA-PD plans.
3 Retiree Drug Subsidy enrollment numbers between 12/27/05 and 1/8/06 are estimates.
4 Total enrollment does not include FEHB or TRICARE covered Medicare beneficiaries.

In the last 30 days more than 2.6 million people have signed up for the new stand-alone prescription drug coverage. This number is on top of the 1 million who enrolled in stand-alone plans in the first 30 days of the initial enrollment period. An additional 4.5 million individuals, including 600,000 people who qualify for Medicare and also for full benefits under Medicaid, i.e., full benefit dual eligible individuals, are enrolled in a Medicare Advantage plan. Overall, about 6.2 million full benefit dual eligible individuals, including those enrolled in a Medicare Advantage plan, have transitioned to Medicare prescription drug coverage. In addition, Medicare's retiree drug subsidy will reimburse a portion of drug costs incurred by at least 6.4 million retirees for 2006. Also, an estimated 1 million retirees are in employer- or union-sponsored coverage that incorporates or supplements Medicare's coverage. Another estimated 500,000 retirees are continuing in other employer or union coverage. An additional 3.1 million Medicare eligible retirees are receiving their coverage through TRICARE for Life or a Federal Employee Health Benefit Plan.

CMS Works to Resolve Start-up Challenges

We are fully focused on resolving the difficulties that some beneficiaries have faced in using their coverage initially, particularly a group of people with both Medicare and Medicaid. Adding a benefit as significant as the new Medicare prescription drug program, involves some start-up challenges. CMS recognizes the enormity of this transition and has been working intensively for many months with partners in and out of government, including States, plans, pharmacists, advocates, and other key partners to ensure the transition process is as smooth as possible for people with Medicare and all of our partners. We have improved our data system, particularly helping the dual eligible population, have strengthened our 1-800-MEDICARE call centers, instructed plans on ways to better serve both beneficiaries and pharmacists, and have dedicated greater CMS resources to addressing pharmacists' needs and enrollee concerns.

Despite these efforts, we are very concerned that some people with Medicare have had difficulty in using their drug coverage for the first time. These problems generally do not occur for people who enrolled far enough ahead of using their coverage to get their drug benefit card, and many of these initial problems have been straightforward to resolve. For

example, one woman stated on January 10, 2006 that she did not immediately receive her plan card although her husband received his from the same plan after enrolling at the same time. When she contacted the plan, the problem was quickly resolved. After getting her prescriptions filled, she reported, "I normally spend $538 for a three-month supply of my drugs. But this time it cost only $278. And these weren't even generic drugs."[5] After people use the system once, these initial problems that some beneficiaries have faced with using their coverage generally do not recur.

We have been most concerned about helping beneficiaries who are eligible for Medicare and Medicaid to use their new benefit. While the vast majority of the more than 6 million dual eligible individuals have already begun to use their drug coverage, certain of these dual eligible individuals have had initial difficulties. In particular, a fraction of a potential universe of a few hundred thousand dual eligible beneficiaries who switched plans, particularly near the end of the year, did not have complete information available on their coverage with their new plan in early January. In addition, information transfers among states, CMS, and plans did not occur perfectly for all beneficiaries. This group is an extremely important population and CMS is committed to ensuring they receive their needed prescription drugs. Many steps are now in place to ensure this happens. In addition some states have taken steps to further support the CMS systems.

One major contributing factor to CMS' challenge is that the onset of the benefit affected many millions of people with Medicare simultaneously at the beginning of January, including millions of people who enrolled or switched plans near the end of December. In addition, CMS worked with numerous partners leading up to the start of the drug benefit to educate beneficiaries and their caregivers about the Medicare prescription drug benefit. We, along with the plans, pharmacists, States, and hundreds of other partners, helped people understand how to make decisions about their prescription drug coverage based on cost, coverage and convenience.

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5 *TheStreet.com*, Jan 10, 2006. http://www.thestreet.com/funds/retirement/10260920.html

As a result of our successful outreach efforts, we experienced a substantial surge in enrollment at the end of the year and many dual eligible individuals electing to change plans close to December 31, 2005. As shown in Figure 2, both visitors to the prescription drug plan on-line enrollment center and enrollments rose steadily throughout December and peaked at the end of the month with over 100,000 enrollments on both December 29 and 30, 2005. CMS continues to see tens of thousands of new enrollments daily.

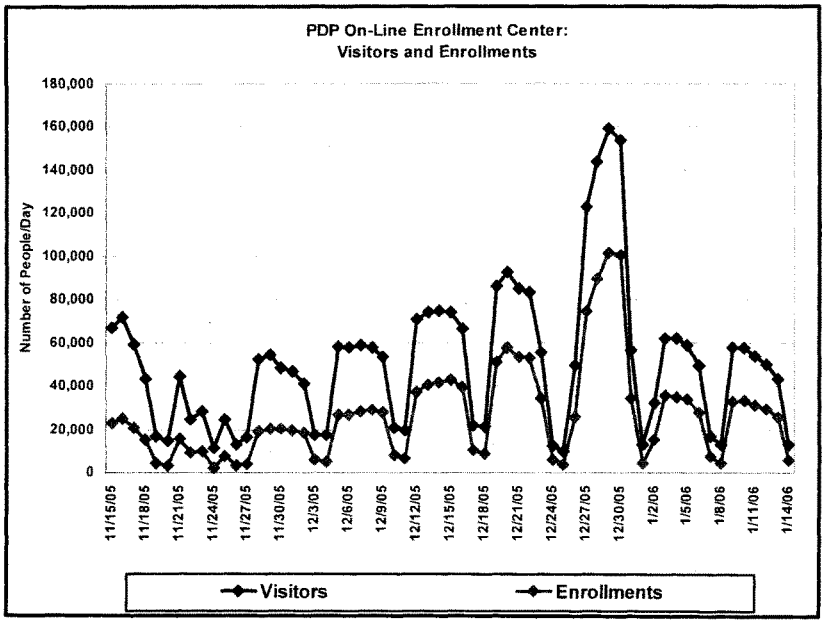

Figure 2: Prescription Drug Plan On-Line Visitors and Enrollments[6]

With the initial implementation of the drug benefit, our start up challenges fall into several key categories including new systems and data transactions issues, customer service, pharmacy support, and State issues. We have worked closely with the plans and our other partners to reconcile specific plan and enrollment information for dual eligible individuals who did not have complete information available with their plan. We are reviewing systems;

6 Cyclical weekly low points are Saturdays and Sundays

continuing pharmacist support, education and outreach; conducting casework around the country; and helping dual eligible individuals and long-term care residents. CMS is committed to making sure that every person with Medicare gets the medications he/she needs. We are seeing improvements on a daily basis as more people with Medicare receive their enrollment confirmations and their personal information is available in the database systems, which allows them to easily fill their prescriptions.

CMS Plans for Implementation of Drug Coverage on January 1, 2006 for Individuals Eligible for Both Medicare and Medicaid

After passage of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in December 2003, CMS began planning for implementation of the Medicare prescription drug benefit. It has been a process involving many steps and partners to get to where we are today. A major focus of this preparation was to provide for the transition of millions of dual eligible individuals who are required to get their prescription drugs through a Medicare drug plan beginning January 1, 2006. Previously, state Medicaid programs provided prescription drug coverage to the dual eligible population.

CMS Worked With States

Since both CMS and the States are responsible for administering benefits for the dual eligible individuals, CMS is committed to working with States on an ongoing and collaborative basis. Both CMS and the States are working to ensure the start up challenges for current dual eligible individuals are addressed. This effort has required an unprecedented level of collaboration between the States and Federal government. This work commenced in August 2004 through the State Issues Workgroup, which included representatives from State Medicaid Agencies, the Social Security Administration, and CMS.

CMS also has worked with States through various workgroups to assure that States report and CMS knows of every dual eligible beneficiary in the country undergoing this transition from Medicaid to Medicare drug coverage. In addition the CMS and State workgroups collaborated to

- develop an efficient and effective low-income application process for individuals who are not dual eligible;
- train, educate, and conduct outreach in a coordinated fashion;
- assure a successful process is in place to auto-enroll every dual eligible beneficiary who does not join a Medicare prescription drug plan on his or her own;
- develop strategies for transitioning dual eligible individuals from Medicaid to Medicare while also assuring coordination of care; and
- assure that the calculation of the phase down State contribution is accurate.

In addition to the ongoing efforts of the State Issues Workgroup, CMS engaged the States in a series of summits, conference calls, and workshops to discuss and address implementation issues associated with the MMA. These gatherings include monthly all-State conference calls; State Pharmacy Assistance Program (SPAP) Workgroup conference calls; and conferences hosted by organizations representing the States including the National Governors Association, National Conference of State Legislatures, and Council of State Governments. In addition, CMS provided States with:

- enrollment information for full-benefit dual eligible individuals including their assigned plans;
- comparative information on the specific Medicare prescription drug plans including formularies and pharmacy networks that are serving each state; and
- targeted educational and outreach materials.

Finally, CMS has worked diligently with States to ensure that they appropriately identify their full benefit dual eligible individuals. CMS validated the information that States reported to minimize reporting errors, mistakes, and omissions that may affect the identification of the States' dual eligible residents. These validation data matches showed match rates of over 99% for all States, according to an independent evaluation completed in the fall of 2005.

CMS Automatically Enrolled Dual Eligible Individuals into Plans

To ensure that there was no lapse in prescription drug coverage for full benefit dual eligible individuals, CMS worked diligently to make sure they were enrolled in a Medicare prescription drug plan before January 1, 2006. In November 2005, any individual who was a dual eligible for even one month, beginning in March 2005, was automatically enrolled in a plan. CMS understood that the dual eligible population is typically the hardest to reach and preparation was necessary. To that end, CMS sent letters in May to all dual eligible individuals to inform them of their upcoming auto-enrollment into a prescription drug plan. Then, in the fall, CMS sent these individuals a letter that informed them of their new plan and the option to choose another plan if they were not satisfied with the auto assignment. In addition to the letters, individuals can call 1-800-MEDICARE to find out the plan in which they have been auto-enrolled.

Also, while other individuals generally have the opportunity to change plans only at the end of the calendar year, dual eligible individuals have the opportunity to change plans at any time. This flexibility ensures continuity of care when Medicaid prescription drug coverage ends, while also allowing them to select a plan that best meets their needs.

CMS also has worked with States to identify and auto-enroll individuals who are about to become full-benefit dual eligible prior to the end of their Medicaid drug coverage to ensure a seamless transition on an on-going basis. This includes those Medicaid individuals who will age into Medicare or who will reach the end of the 24-month Medicare disability waiting period.

CMS Developed New and Enhanced Information Technology Systems for the Prescription Drug Benefit

Information technology (IT) systems played a crucial role in ensuring the prescription drug benefit could be implemented January 1, 2006. Planning for the information technology to support the implementation of the Medicare prescription drug benefit began in 2004 with CMS identifying the key functions affected by the new law and beginning development of a large-scale, integrated computer system. CMS ensured that more than one dozen critical

systems development efforts were implemented in time to meet MMA-legislated deadlines. In conjunction with its business partners, CMS developed innovative solutions and leveraged existing business and systems relationships, such as using the existing pharmacy transaction processing network, to assist with the coordination of the various prescription drug benefit plans covering people with Medicare.

Staff created and modified a variety of complex, integrated systems that currently interact with the private and public sectors to implement the new benefits. These IT systems support the key critical business processes that CMS uses to manage the Medicare Advantage and prescription drug benefit programs. The integrated system provides CMS with the ability, among other things, to enroll people with Medicare into prescription drug plans, make payments to plans, and ensure that beneficiaries receive their drug coverage. The integrated information technology system also allows CMS to pay the Retiree Drug Subsidy to approved plan sponsors and track True-Out-of-Pocket Expenses (TrOOP) for people with Medicare. In addition, the updated systems ensure the correct premium amount is either paid directly to the plan or provided to the Social Security Administration to withhold from a beneficiary's Social Security check. Through contracts with telecommunications clearinghouses that currently service the majority of retail pharmacies, the pharmacies will be able to perform real-time eligibility determinations and will be able to route claims to primary, and if applicable, secondary plans for proper adjudication to accurately coordinate benefits. The new and modified systems also were designed to ensure only authorized individuals have access to Medicare information.

CMS worked closely with industry experts to implement nine system modules. Implementation included application development and integration efforts, system engineering activities, and validation and testing. In order to meet the deadlines, CMS worked creatively and collaboratively to compress what would ordinarily be an 18 to 24-month systems development process. CMS ensured that the necessary computer and network capacity and capabilities were in place as the CMS IT applications came online.

These enhancements included

- providing capabilities for more than 400 new CMS business partners to connect to CMS systems over the Internet,
- providing advanced technology for secure file transfers, and
- implementing a new user id/password management system.

CMS implemented backup and parallel support systems to minimize any vulnerabilities, and also oversaw the implementation of a secure, Internet-based computing environment in the CMS data center. If these systems had not come online on schedule, CMS would not be able to enroll beneficiaries or pay the health plans that are administering the new benefit. CMS set new standards for documenting requirements, program management, managing change, testing systems, and documenting and ensuring that system development life cycle reviews were undertaken.

Extensive Plan Formulary Requirements Provide Access to Needed Prescription Drugs
CMS developed a set of checks and oversight activities to ensure that prescription drug plans offer a comprehensive benefit that reflects best practices in the pharmacy industry, as well as current treatment standards. Plan formularies must recognize the special needs of particular types of people with Medicare, such as individuals with mental health issues, individuals with HIV/AIDS, individuals living in nursing homes, people with disabilities, and others who are stabilized on certain drug regimens. CMS has reviewed plan formularies and benefit structures to verify that they are in compliance with the following critical requirements. A plan's formulary must cover multiple drugs in each class with a minimum statutory requirement of at least two drugs in each approved category and class (unless only one drug is available for a particular category or class). Furthermore, CMS requires that each plan's formulary include all or substantially all drugs in each of the following key categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and antiretrovirals for treating HIV/AIDS.

In addition, each Medicare prescription drug plan's formulary was developed and reviewed by the plan's pharmacy and therapeutics committee. Each formulary must be consistent with

widely used industry best practices. Furthermore, CMS compared the prescription drug plans' use of benefit management tools to the way these tools are used in existing drug plans to ensure they are being applied in a clinically appropriate fashion. Prescription drug plan formularies typically include upwards of 80 percent of the 100 most commonly used drugs.

CMS has developed exceptions procedures designed to ensure that enrollees receive prompt decisions regarding whether medications are medically necessary. For example, if the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the non-formulary drug or would have adverse effects for the enrollee, or both. The plan would have to review the physician's determination and must make its decision as expeditiously as the enrollee's health condition requires after it receives the request, but no later than 24 hours for an expedited coverage determination or 72 hours for a standard coverage determination.

CMS Required Plans to Have a Transition Process for Dual Eligible Individuals

CMS required each Medicare prescription drug plan to establish an appropriate transition plan for all new enrollees with Medicaid. All of the transition plans now include a minimum 30-day one-time fill of any prescription drug excluded from the plan's formulary in order to accommodate situations in which a non-formulary prescription has previously been filled at a participating pharmacy. Each transition plan identifies the plan sponsor's method of educating both people with Medicare and providers to ensure a safe and complete accommodation of an individual's medical needs with the plan's formulary. Additionally, CMS recommends that transition plans address unanticipated enrollee transitions when individuals need to change treatment settings due to a change in their level of care.

CMS Worked With Plans to Ensure a Smooth Transition in Long Term Care Facilities

CMS is committed to ensuring that people with Medicare in long-term care (LTC) facilities continue to receive the medications and pharmacy services they need under the new Medicare prescription drug coverage without interruption.

There are 1.6 million people with Medicare who are residents in 15,800 nursing homes throughout the nation. The majority of nursing home residents are dual eligible individuals. Almost half of all nursing home residents have some or all of their stays covered under Medicare Part A. Individuals in LTC facilities represent a unique and vulnerable population because they have cognitive and/or functional impairments. This population typically has multiple co-morbidities, the highest utilization of drugs, with an average of nine medications per day, and the highest spending for prescription drugs compared to other people with Medicare.

In March 2005, CMS issued guidance for the implementation of CMS requirements regarding pharmacies that provide products and services to individuals in LTC facilities. This guidance addressed pharmacy performance and service criteria, convenient access standards, formulary considerations, and other beneficiary protections that prescription drug plans should consider as they develop their prescription drug benefit offerings for people with Medicare in LTC facilities.

Auto-enrollment of Individuals in LTC

Cognitively impaired individuals represent a particularly difficult group to educate about their enrollment options. Much of this population, specifically dual eligible individuals, was auto-enrolled into the new prescription drug benefit. CMS encouraged nursing homes to determine into which plans their residents were auto-enrolled prior to January 1, 2006. As part of this initiative, CMS established dedicated call lines and overnight mail options to allow nursing homes to fax and mail beneficiary information to CMS customer service representatives (CSRs). This strategy enabled CMS to help nursing homes identify the plans for more than 500,000 residents. Pharmacists used the electronic eligibility and enrollment verification (E1) system to identify the remainder. By notifying plans that their enrollees reside in nursing homes, CMS is ensuring nursing home residents have access to Medicare drug coverage for no premiums and no copays.

Performance and Service Criteria for Pharmacies Providing LTC Service

To address the unique and diverse needs of people with Medicare in LTC, CMS developed minimum performance and service criteria for pharmacies providing LTC service, based on widely used best practices in the market today and with input from external stakeholders. These criteria address:

- Comprehensive inventory and inventory capacity
- Pharmacy operations and prescription orders
- Special packaging of medicines
- IV medications
- Compounding and alternative forms of drug composition
- Pharmacist on-call service
- Delivery service
- Emergency boxes
- Emergency log books
- Miscellaneous reports, forms and prescription ordering supplies

For example, network LTC pharmacies (NLTCPs) must have the capacity to provide specific drugs in unit of use packaging, bingo cards, cassettes, unit dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to or arrangements with a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting. Additionally, NLTCPs must provide on-call, 24 hour a day, 7 day a week service with a qualified pharmacist available for handling calls after hours and must have medication dispensing capability available for emergencies, holidays and after hours of normal operations.

Prescription Drug Plan Formularies for LTC residents

In the long term care setting, the Medicare prescription drug plan formularies are in general more robust than State preferred drug lists or commercial formularies. Plans must accommodate within a single formulary structure the needs of long term care residents by providing coverage for all medically necessary medications at all levels of care. Coverage of

all medically necessary medications may include, but is not limited to, alternative dosage forms such as liquids that can be administered through feeding tubes, intravenous medications, or intramuscular injections.

CMS recommended nursing homes include a 90 to 180 day transition period. The vast majority of plans are providing 90 day transition periods with many offering the option of extending to180 days. However, the LTC emergency first fill policy is unique to this setting and continues throughout the entire year for any off-formulary prescription written. In addition, plans are required to cover drugs as written during the 7 to 14 days allowed for initial exceptions and appeals process.

CMS Provides Education Regarding LTC Pharmacy Requirements

Prior to the implementation of the Medicare prescription drug benefit, CMS conducted extensive outreach and education to ensure LTC facilities, pharmacies and other stakeholders were informed about requirements for delivering services under the benefit. CMS established a working group consisting of representatives from the American Health Care Association, American Association of Homes and Services for the Aging, American Medical Directors Association, the Alliance for Quality Nursing Home Care, Long Term Care Pharmacy Alliance, National Center for Assisted Living, Assisted Living Federation of America, National Association of State Mental Health Program Directors, and the National Association of State Directors of Developmental Disabilities Services that assisted CMS over an eight month period in 2005.

CMS also provided and continues to provide instruction through trade association newsletters, fiscal intermediary newsletters and conferences. In addition, CMS developed electronic messages that are shown to facilities each time they enter data on the Minimum Data Set (MDS) - part of the federally mandated process that provides a comprehensive clinical assessment of all residents in Medicare and Medicaid certified nursing homes. Education included, for example, a three pronged approach for ensuring that nursing home residents who spend down the Medicare simultaneously apply for Medicaid and the low income subsidy and enroll in a PDP to maximize their prescription drug benefits. This

outreach also included numerous Open Door Forums, in which all stakeholders were invited to participate so CMS could share the outcomes of critical policy and procedural decisions and to solicit feedback on areas of concern.

CMS Educated and Coordinated Outreach Efforts for Pharmacies

Partnerships: CMS worked extensively with pharmacy industry leaders to educate and motivate the pharmacist community about the new Medicare prescription drug benefit. Specifically, we partnered with chain and independent pharmacies in an education and outreach program for the low-income subsidy, which reached over 30,000 stores. CMS participated in 24 town hall events hosted by the National Community Pharmacists Association (NCPA). These events provided a prescription drug benefit overview to independent pharmacists and a question and answer session following each event. In total, over 6,500 pharmacists participated in this program.

Direct Communications: CMS made extensive efforts to directly reach pharmacists in preparation for January 1, 2006. CMS created the Medicare Rx Update as a periodic update to pharmacists to ensure they are well informed about the details of the Medicare prescription drug benefit implementation. CMS distributed the Rx Updates through the internet to directly reach practicing pharmacists with highlights and clarifications about implementation issues. Since its inception in May 2005, CMS has sent 25 Rx Updates to the pharmacy community addressing topics including the pharmacists' role with the low income subsidy, marketing guidelines, the prescription drug plan compare tool, and the true-out-of-pocket (TrOOP) facilitator. With thousands of subscribers and because State and national organizations distribute the Update as well, these bulletins have gone a long way toward educating the pharmacy community about the procedures related to the new benefit.

CMS also created and maintains a website (http://www.cms.hhs.gov/Pharmacy/) specifically for pharmacists. In addition to the Medicare Rx Updates, the pharmacist website contains informative prescription drug benefit guidance, links to training materials, information for special practice pharmacies, and more.

CMS' pharmacist outreach team, which includes our regional pharmacists, has conducted the most targeted personal outreach. CMS' central office pharmacy team, which includes 21 pharmacists, as well as the pharmacists and staff from CMS' 10 regional offices, have traveled the country educating pharmacists in all practice settings about the new benefit. The pharmacists have presented at hundreds of events and gatherings reaching tens of thousands of pharmacists.

Furthermore, CMS created a forum known as the Pharmacy Information Exchange, a periodic open phone town hall style meeting. Hundreds of pharmacists attended calls hosted by CMS' pharmacists. These calls have enabled CMS to present on hot topics, answer many questions and identify new issues from the community. Finally, CMS has developed two pharmacist-specific continuing education programs that were distributed through the on-line arm of Drug Topics, the magazine dedicated to the profession of pharmacy, and through Kansas University, respectively.

Plans to Address Pharmacy Operational Issues: Finally, as January 1, 2006 approached, CMS finalized a comprehensive plan for further pharmacist training, including materials targeted to explain technical details of the TrOOP facilitation process, Medicare Part B versus Part D coverage, out-of-network policies for Hurricane Katrina evacuees, the point-of-sale facilitated enrollment process for dual eligible individuals, and more. CMS is working directly with a wide range of pharmacy organizations, identifying operational questions for pharmacists and developing dynamic action plans on how to anticipate problems and, to the extent that we can, address them in advance. In preparation for the first days of the benefit, CMS engaged the pharmacy community in a virtual "war room" so that the Agency could work directly with the industry to provide direct assistance for any issues that arose in the early days of implementation.

CMS Worked With Physicians

An important part of CMS' outreach and education effort included the physician community. Throughout 2005, CMS medical officers spoke to 24 physician specialty groups about the new Medicare prescription drug benefit, transition policies and formulary exceptions and appeals. CMS has held weekly telephone question and answer calls for physicians, other

prescribers, and their office staff in anticipation of the new drug benefit. The first call had 1,300 callers and is averaging about 500 callers a week now. CMS has had a similar call for mental health providers and a call focused specifically on distinguishing between coverage for Part B and Part D prescription drugs. In addition, CMS participates in the AMA workgroup, which has been meeting since November to discuss physician issues and suggest improvements and refinements.

Point-of-Sale System Facilitates Enrollment

CMS is making its best effort to identify and auto-enroll dual eligible individuals prior to the effective date of their Medicare Part D prescription drug coverage eligibility. However, it is possible that some individuals may go to pharmacies before they have been auto-enrolled in a prescription drug plan. For this reason, in anticipation of the shift from the Medicaid to the Medicare program of dual eligible individuals' drug benefits, CMS has developed a process for a point-of-sale interaction to ensure these individuals experience no gap in coverage. CMS contracted with WellPoint, a national prescription drug plan to provide prescriptions and enrollment at the pharmacy point-of-sale (POS). The relationship with WellPoint is specifically designed to ensure that pharmacists can fill prescriptions and bill WellPoint for full benefit dual eligible individuals who had not been previously enrolled in a new Medicare prescription drug plan.

Beneficiaries, who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a prescription drug plan, can leave the pharmacy with a filled prescription and the claim for their medication submitted to a single account for payment. A CMS contractor will immediately follow up to validate eligibility and facilitate enrollment of the full-benefit dual eligible individual into a prescription drug plan. As of early January, over 10,000 dual eligible individuals have received their prescriptions through the Wellpoint point-of-sale system. Many of the individuals who received prescriptions through Wellpoint are members of others plans.

CMS has provided information on the WellPoint system to pharmacy associations, plans, and individual pharmacies. This information describes how the process of POS-facilitated

enrollment starts at the pharmacy with the pharmacist verifying dual eligibility and billing a special Wellpoint account in order to ensure that the individual with Medicare receives the prescription.

CMS Takes Action to Ensure Timely Receipt of Prescription Drugs after Start of Benefit

Despite the best efforts of everyone involved in the new program, there is a group that potentially included a few hundred thousand dually eligible individuals who had difficulty when they initially used their drug coverage. These individuals were described previously. In addition, CMS has taken steps to address other issues that have arisen with the implementation of the drug benefit.

CMS Works to Ensures Emergency Fills for Dual Eligible Individuals

CMS is working to ensure that dual eligible individuals who need emergency fills of their prescriptions receive them in a timely fashion. If any dual eligible individual needs prescriptions immediately, and other mechanisms have not worked, CMS can help them get the medicines they need. Many pharmacies are filling prescriptions for dual eligible individuals that present at the pharmacy counter when enrollment and billing information cannot be confirmed. If the individual is in an urgent situation, he or she should call 1-800-MEDICARE (1-800-633-4227) or the pharmacist can call the pharmacy helpline and tell the CMS customer service representative that a person with Medicare has an urgent situation. As described below, CMS casework staff will be alerted and help the person obtain his/her medication.

CMS Educates People with Medicare About the Timing of Selecting a Plan

CMS has informed people with Medicare about the need to allow some time between the date of enrollment and when they first attempt to fill a prescription. This provides CMS and the plans with enough time to see to it that the data systems are accurately updated in order to properly handle the filling of a prescription. Such is generally the case anytime someone enrolls in a new health insurance plan or makes changes to it, and we want people with Medicare to be aware of this situation.

Generally, if an individual newly enrolls in a plan, or switches to a different plan by the 15th of the month, their information should be available at the pharmacy by the beginning of the next month. So we have begun encouraging people with Medicare to enroll at least a few weeks before they expect to need to use their drug coverage, and to be prepared to wait several weeks to be fully entered into the system.

We are developing model language for plans to use to inform their enrollees of these facts, and will also provide those who enroll through our 1-800-MEDICARE call centers and our internet-based Plan Finder tool with a similar notice. Enrollees will also be informed that while waiting for the data systems to be appropriately modified, they may, if need be, use the acknowledgement letter sent to them by the plan when they go to the pharmacy to fill their prescriptions.

CMS Supports Ongoing Success of IT Systems

To continually improve the IT systems and CMS services to the beneficiaries, plans, and pharmacies, CMS continues to work closely with the plans via system-level conference calls that occur three times a week, in addition to the twice-daily production calls that synchronize the complex operations of all systems. Also, the Agency pulled together critical resources to:

- evaluate the performance of systems,
- identify issues with the plans and pharmacies, and
- develop and implement corrective actions.

Based on these evaluations, CMS has identified, in priority order, key performance and operations issues. The resolution and implementation of the solutions is underway.
CMS has taken steps to ensure plans have the means to cross-check CMS data with plan data for improved accuracy and completeness to ensure that dual eligible individuals can be appropriately identified when they present at the pharmacy counter. On January 12, 2006 and again on January 18, 2006, CMS sent files to each plan with information about its dual eligible enrollees along with instructions on how to process these files. As these data are processed by plans, this process is substantially reducing the workload of the pharmacists and

assisting the vast majority of dual eligible individuals in getting their drugs. Providing this information enables pharmacists to identify plans in which dual eligible individuals are enrolled and ensure that correct and appropriate co-payments are charged to the individual with Medicare. Furthermore, on January 30, 2006, CMS sent an additional file of low income subsidy eligible individuals, this time using an enrollment effective date of February 1, 2006. This file should provide an additional source of information for many of the plan changes that have taken place in the past couple of weeks and help plans prepare for enrollments that are effective beginning in February.

CMS also has been working with specific plans to resolve their unique issues surrounding sending and receiving data files from CMS. As a result of these efforts, dual eligible beneficiaries who had been having difficulty with correct co-payments and eligibility are now getting their prescriptions filled correctly.

To ensure CMS' performance evaluation system and corrective actions are effective, CMS contracted with Electronic Data Systems (EDS) as an independent reviewer to help resolve specific data translation issues with the plans, States, and pharmacies.

CMS Improves 1-800 MEDICARE Call Center to Reduce Wait Times

CMS' 1-800 MEDICARE Call Center has customer service representatives (CSRs) available to answer Medicare questions 24 hours a day, seven days a week. As shown in Figure 3, call volume to 1-800-MEDICARE peaked around 400,000 calls when enrollment began on November 15, 2005 and again in early to mid-January.

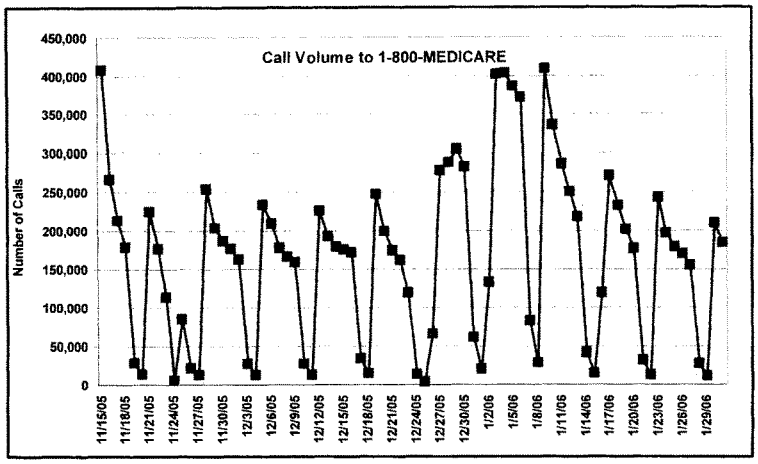

Figure 3: Call Volume to 1-800-Medicare

On average, callers have experienced wait times of less than two minutes from mid-November to mid-January, with longer waits sometimes occurring during peak call periods.

CMS has increased the number of CSRs from 3,000 in June of 2004 to as many as 7,800 to handle beneficiary calls. We have also acquired additional infrastructure including telephone lines, workstations, and seats at call center sites. We have upgraded our CSR scripts by reducing redundant information, indexing scripts for quick access, and including probing questions to help the CSRs better identify the caller's concerns.

CMS has implemented a major enhancement through the use of Smart Scripts, which provide the CSRs with an easily followed path of responses to the most frequently asked questions. Smart Scripts are a new type of script that have hyperlinks built into the body of the text that when activated will take the CSR directly to related information about that subject. In addition, we have CSRs participate in the content workgroups for the actual development of scripts and job aides. CMS also has implemented a CSR feedback system and streamlined our approval process for updating the scripts in a timely manner to respond to the changing needs of our customers or to incorporate policy updates.

CMS hired and trained additional staff to exclusively use the Prescription Drug Plan Finder (PDP) tool to handle only PDP calls. All CSRs receive one week of classroom training followed by two or three additional days of practice calls, simulation, quality monitoring and follow-up coaching to ensure peak performance. CSR certification with a written examination and test calls is required prior to taking live calls. Calls are being handled on an in-bound basis and steps CMS has taken to strengthen the call centers' capabilities and reduce wait times have made it possible to address beneficiaries' concerns as they arise.

Customer satisfaction surveys indicate that the bulk of callers who interact with our CSRs, 84 percent, are satisfied with their experience. They are particularly pleased with how courteous and patient the CSRs are (rated at 97 and 95 percent, respectively). These responses came not only from people with Medicare, but also friends or relatives calling on their behalf, who made up 48 percent of callers during December, 2005.

CMS' Medicare website, www.medicare.gov, has also been a source of useful information for people with Medicare. Since the first of the year, our frequently asked questions have been accessed more than 530,000 times. CMS has also responded to over 5,300 e-mails received through the site, with 93 percent of them being resolved satisfactorily in the first response.

CMS Works with Plans to Improve Their Customer Service

In addition to this significant strengthening of our 1-800-MEDICARE capabilities, we have issued guidance to the plans, instructing them to increase the numbers of CSRs in their own call centers and improve their abilities to immediately resolve enrollee concerns. Plans have responded and reported significant increases in the number of CSRs in their call centers.

We have also informed plans that they must comply with their transition policies so that enrollees who require a specific medications are able to obtain coverage for a one-time supply of those drugs, while they work with their physician and plan to select a new drug in the same therapeutic class, or appeal for coverage of their existing prescription. Further,

plans have been required to inform their CSRs about their transition policies and empower them to permit a pharmacy to dispense these drugs.

CMS Takes Steps to Identify Areas of Concern

To address the need to capture and track complaints, CMS developed the Complaints Tracking Module (CTM). The CTM is a central repository for complaints that come in to CMS' Central Office, and ten Regional offices and the Medicare Rx Integrity Contractors through 1-800-MEDICARE or CMS directly. The CTM is designed to capture complaints from beneficiaries, providers, or plans about prescription drug plans, pharmacies, subcontractors, and providers. Because it is a web-enabled system, CTM can be accessed from off-site locations. This allows for regional and off-site staff to quickly enter information into the system. Since complaints may need to be escalated or referred across components, referral capabilities exist for this type of transfer. This provides for an efficient exchange of information, which allows for a quicker resolution and accountability, as each complaint is assigned to only one individual at a time.

CMS began development of the CTM in the Fall of 2005 and refined the system in response to input from various stakeholders. The design of CTM format and content were driven from previous experience with the Drug Card, intra-agency components, and insights from the Pharmacy Benefit Management (PBM) Industry. CMS launched the CTM into production on October 3, 2005. Since this time, the CTM has been fully tested to accept large numbers of daily transactions simultaneously from many users across the Agency. CMS began tracking complaints in January and although this process is still in the early stages, we have seen a general decline in complaints.

CMS Provides Caseworkers for One-on-One Counseling

While millions of prescriptions are being filled for people with Medicare, CMS is very concerned about those individuals who are encountering difficulties at the pharmacy counter. This is certainly distressing for those individuals and their caregivers.

CMS has established a system to help resolve urgent issues on a case-by-case basis. CMS has hundreds of trained caseworkers who are working as rapidly as possible with individuals with Medicare and plans to resolve urgent issues to help ensure that people with Medicare get their prescriptions filled. CMS urges people with Medicare or their family members who are having difficulties to call 1-800-MEDICARE, and if necessary, their case will be forwarded to our caseworkers. Urgent cases have high priority for rapid solution.

While the number of individual cases is small in comparison to the millions of prescriptions and individuals who are successfully receiving their prescriptions, CMS is committed to ensuring that every individual receives their needed medicines, are properly identified, and are charged the appropriate co-pays in the future.

CMS Provides Dedicated Support to Pharmacists

CMS has provided a number of ways for pharmacists to obtain help in filling prescriptions for plan enrollees. If the enrollee does not have a card, pharmacists can use our eligibility system (the E1 system) to obtain information needed to fill the prescription. Pharmacists can also call plans directly, on lines dedicated for pharmacists. They can contact Medicare's own CSRs if need be, and CMS also has specially trained case workers in our regional offices who can intervene in special cases to make sure that enrollees get the medications they need.

CMS has significantly increased the capacity of the toll-free pharmacy support phone lines to help resolve issues pharmacists encounter in dispensing medications to those newly enrolled in the Medicare prescription drug plans. CMS has increased its call handling capacity at the pharmacist help line 30 fold and the line is now available 24 hours a day. We have increased the CSR staffing to support this initiative from 150 CSRs to about 4,500. The increased capacity has reduced the wait time to less than a minute for pharmacists who want to use this mode of communication for eligibility and enrollment determination.

CMS Responds to Early Technical Problems with the Eligibility and Enrollment Query System for Pharmacists

During the first week of the Medicare prescription drug program, CMS experienced some delays in response time with the new computer tool provided to pharmacists for real time enrollment and eligibility look-up. Working with our contractor, CMS has improved response time to less than one second with no delays. CMS continues to load data into this system from information obtained on individuals' recent enrollment or plan switching activity, which will help pharmacists obtain complete enrollment and billing information on more individuals when they use the E1 system at the pharmacy counter. As shown in Figure 4, CMS is seeing an overall decline in the number of times pharmacists must utilize the E1 system from a high of 1.47 million to about a half million in recent days. This reflects a more efficient and effective use of the system after CMS issued a tip sheet in early January on how best to use the system. In addition, more individuals have received appropriate plan identification information, so the need for the E1 system has declined.

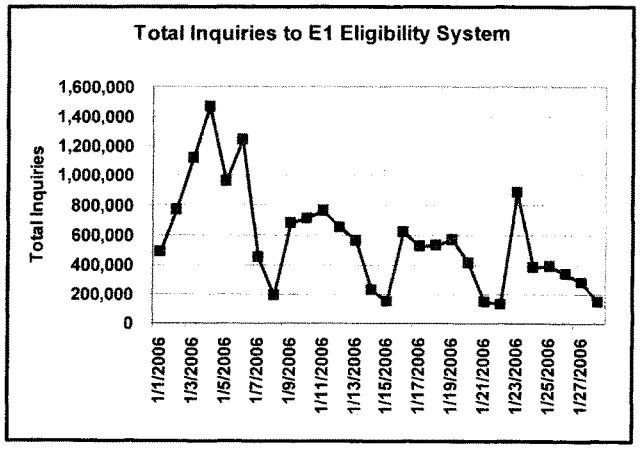

Figure 4: Total Inquiries to E1 Eligibility System

In addition, pharmacists are reporting that they are experiencing improvements in their ability to query and obtain information from the E1 eligibility transaction system. One pharmacist noted on January 11, 2006, "I wanted to take the opportunity to tell you that our

434 pharmacies have found the (E1) system very helpful and we have seen the system's 'integrity' improve significantly from January 2, 2006 to today."[7]

CMS Addresses Issues Between Plans and Pharmacies

In addition, CMS and the Medicare health plans are working to address a number of issues that will improve the efficiency of the process at the pharmacy counter and assure that all people with Medicare get the medications they need. Among the steps CMS has facilitated are: a) increasing the capacity of plan help lines; b) providing direct plan-to-pharmacist technical support; and c) streamlining the data submission and reporting procedures from plans to CMS. Additionally, on January 6, 2006, CMS sent a second letter to plans on enforcement of their own transition plans by educating their customer service representatives (CSRs) and ensuring that their data systems have the appropriate information to implement their transition plans. CMS sent two additional letters to the plans on January 13, 2006 providing further clarification on formulary transition policies and expedited processes on cost sharing for dual eligible individuals. Specifically, CMS required plans to make override information readily available to pharmacists, which will allow the correct co-payment to be charged. Should the plans' pharmacist assistance line be inaccessible, CMS can provide assistance through Medicare's 1-866 designated pharmacist help-line. CMS also specified that steps have been taken to ensure that pharmacists can override inappropriate claim denials. For example, plans must have expedited procedures for pharmacists to obtain authorization to override any improper claim denial, in accordance with their transition policy, in case a beneficiary's prescribed medications are not on the plan's formulary. In all of these areas, health plans had already responded by taking these and other steps to assist beneficiaries. The CMS actions help ensure that all plans provide effective service.

CMS also has regular one-on-one calls with the plans to identify issues and solutions. CMS is in constant communication with the plans pertaining to issues as they arise, and the Agency has developed a collaborative process whereby CMS organizes calls with plans and their pharmacists to resolve problems as quickly as possible.

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7 Winn-Dixie Pharmacist email January 11, 2006

CMS Continues Extensive Outreach to Pharmacists

Since implementation of the benefit, CMS has continued its extensive outreach to pharmacists. We have continued discussions with pharmacy organizations both centrally and regionally, as well as our direct contact with both independent and chain pharmacies. Additionally, CMS hosted a technical support teleconference for pharmacists across the country January 5, 2006 and also hosted a national open door forum for pharmacists January 10, 2006 to answer questions. The first was to directly address the point of sale enrollment process. The second call addressed many implementation issues and included a lengthy question and answer session. We have also sent four Medicare Rx Update communications since December 30, 2005. CMS has identified frequently asked questions regarding the point of sale facilitated enrollment system, plan transition policies, plan contact information, "What If" scenarios for pharmacists, tips for using the E1 system and much more. Specific examples of outreach that CMS has performed in relation to January 1, 2006 issues include:

- Daily calls with pharmacists and pharmacy executives all over the country. These calls help identify trends and workable solutions to numerous issues associated with implementation as well as facilitating outreach to thousands of pharmacists.
- Over 1,000 emails and calls in direct response to specific issues presented to the pharmacist since January 1.

In addition, CMS is holding weekly conferences with pharmacy associations that help CMS distribute information and educate pharmacists to ensure they have the most complete and up-to-date information possible. Also, CMS is communicating on a daily basis with both chain and independent pharmacies. Pharmacists in CMS' ten regional offices are working directly with local pharmacies, pharmacists, and pharmacy associations to identify troubling trends and specific problems. CMS is working closely with the National Association of Chain Drug Stores (NACDS), the National Community Pharmacist Association (NCPA), the American Pharmacists Association (APhA), the National Council of State Pharmacy Association Executives (NCSPAE), the American Society for the Automation of Pharmacy (ASAP) and other groups to help communicate with and educate their membership.

CMS Continues Outreach with Physicians

On January 1 CMS placed an announcement on the welcome page to our Physicians Regulatory Issues Team (PRIT) website with advice for providers and an invitation for them to call or email CMS with issues or concerns about the Medicare prescription drug benefit. We have received and responded to almost 200 emails from providers.

In addition, CMS sent a letter to physicians outlining specific sources of help and information including the following.

- A web-based formulary finder linked to all plan formularies.
- Information about Epocrates, an electronic handheld and web-based drug and formulary reference for physicians, that is providing plan formulary information including both tier and step therapy information and is updated constantly.
- An exceptions and appeals contact list for each prescription drug plan so physicians can help a patient by filing a prior authorization for a medication or appeal a medication's tier.
- Information about coverage determinations, exceptions, appeals, and expedited requests.
- A universal, faxable form created by a coalition of medical societies and advocacy groups for pharmacists and physicians to use in the event a patient's prescription is not on a formulary or on a higher tier. This optional form provides a straightforward way for the pharmacist to communicate with a physician's office.
- A chart to determine if the drug a physician prescribed is a Part B or Part D drug.
- Information about the CMS web-based email and weekly conference calls where physicians can get direct help with their concerns.

CMS Continues Collaboration with States

To ensure ongoing coordination with the States after the prescription drug benefit began, CMS is hosting conference calls with the State Medicaid Directors about Medicare prescription drug plan implementation challenges and solutions several times each week. Additionally, calls continue with States and plans, pharmacists, and CMS staff. CMS

regional offices are making regular calls to the State Medicaid Directors and their staff with updates and to address specific problems.

CMS Establishes Reimbursement Plan for States that Cover the Cost of Dual Eligible Individuals

CMS is working with the States to ensure all dual eligible individuals are able to leave the pharmacy with the drugs they need. In addition, pharmacies need to continue to work with the plans to sort out start-up issues as quickly as possible. However, some States are reporting that dual eligible individuals have been charged the wrong cost sharing amounts when they have gone to the pharmacy and some have left the pharmacy without their drugs.

Certain States have taken steps to help their dual eligible individuals by using their State system of reimbursement to pharmacies. These States are now paying for dual eligible beneficiaries' prescriptions that should be paid for by the prescription drug plans, and, if States have stepped in they will be reimbursed.

On January 25 we announced a demonstration project to reimburse States for their expenses related to the Medicare prescription drug program. CMS will work to ensure that prescription drug plans to reimburse States for the dual eligible individuals up to the amount they would otherwise have paid for the duals' drug costs. Through this demonstration project, the federal government will reimburse States for any differential between the plan reimbursement and the state payment, as well as for certain administrative costs for paying the State claims and facilitating the correct enrollment of dual eligible individuals into a prescription drug plan. States will work with CMS to help obtain accurate beneficiary information on drug spending. They will also use payment approaches that support pharmacists' efforts to primarily bill the Medicare prescription drug plans and ensure the use of the Medicare point-of-sale billing before relying on State payment such that states serve as a payer of last resort. States that follow these recommendations have had only limited claims made against their Medicaid systems. The demonstration requires States to make significant progress toward turning off their State reimbursement systems and return to the

Medicare prescription drug system by February 15, 2006 with the Secretary having discretion to extend the demonstration for a limited period thereafter if necessary.

With input through a State workgroup, CMS developed a template to apply for this demonstration for use by those States that re-instituted some coverage through their Medicaid system for dual eligible individuals. The template is expected to be available shortly and will be posted on the CMS Website.

In addition to providing reimbursement to the States, the demonstration will include timely data sharing and claims identification features. States that participate should provide timely summary information on claims incurred, including summary amount and beneficiary identification information, to facilitate reconciliation and beneficiary transition to prescription drug plans. States should also work with CMS to provide valid data on any set of beneficiaries who may not have been included properly in the State's previous dual eligible files. Also, States should separate claims for the transition period from claims the States would have otherwise paid through a separate State program. In some States, the State has elected to pay all cost sharing, for example, on behalf of some individuals who would otherwise have paid a copayment.

Under the demonstration, plans, and then Medicare, would reimburse State paid claims previously incurred and up to and through the anticipated end date of this demonstration of February 15, 2006. CMS will continue to work closely with the States, as we have been, to resolve temporary transition issues and make sure people with Medicare can get the new prescription drug coverage if they want it.

CMS Continues to Work Hard to Ensure the Most Important New Benefit in 40 Years Delivers Drugs to People with Medicare

Mr. Chairman, thank you for this opportunity to discuss the new Medicare prescription drug benefit and the transition process and protections for people with Medicare. Transition is never without challenges. CMS is taking many steps with systems, plans, pharmacists, States, and other partners to quickly resolve the implementation challenges that have arisen

in the first weeks of this beneficial new program, and we appreciate your collaborative efforts to address them. As the New York Times noted in 1966 when Medicare debuted, "This great new experiment must be given ample time to get over its growing pains."[8] CMS is confident that we too will overcome our "growing pains" as we continue to address the challenges set before us implementing the new Medicare prescription drug benefit. I would be happy to answer your questions.

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8 *New York Times*, "Medicare's Beginning," pg. 34, July 1, 1966

The CHAIRMAN. Linda McMahon.

STATEMENT OF LINDA S. MCMAHON, DEPUTY COMMISSIONER FOR OPERATIONS, SOCIAL SECURITY ADMINISTRATION, WASHINGTON, DC

Ms. MCMAHON. Thank you, Mr. Chairman, Members of the Committee. On behalf of Commissioner Barnhart, I want to thank you for inviting me to discuss Social Security's efforts to implement the new Medicare Part D Low-Income Subsidy Program.

As you know, I am Linda McMahon, deputy commissioner for Operations at the Social Security Administration, and I have been with the agency for 15 years. As you know, SSA was given the responsibility by Congress to take extra help applications and to make eligibility determinations for individuals who were not automatically eligible for the subsidy. We are also responsible for deducting Part D premiums from Social Security benefits when Medicare beneficiaries tell the Prescription Drug Program (PDP) provider that they want that payment option.

SSA was given these Medicare Modernization Act (MMA) responsibilities because of our network of nearly 1,300 offices and 35,000 field employees across the country and because of our prior role in administering some parts of the Medicare program. Upon passage of MMA, we immediately recognized that development of a simplified application for the extra help was essential for successful implementation of that part of the program. Working with CMS, we conducted extensive testing of the extra help application form. In fact, the paper application changed significantly over time and went through many drafts before it was finalized.

Our Office of Systems staff also contributed to the design of the application to make sure that the information on the form could be electronically scanned into our computers. That made it easier for applicants and people who assist them to apply and it minimized the number of employees that we need to process those forms.

Then we worked to develop alternatives to the traditional paper-based application, and in July of last year, we unveiled the Internet version of the application. That allows people to apply online for help with costs associated with the Medicare prescription drug plan. The online application has been a tremendous success and more than 2,000 Internet applications are being filed daily.

Telephone inquiries were also part of our efforts to make the extra help application process as simple as possible. We provided extensive training to our teleservice representatives so that they could answer subsidy-related questions. We developed an automated application-taking system, allowing the teleservice representatives to refer callers directly to specialized claims taking employees who could then take the applications by phone.

Finally, we developed a computer matching process with the Internal Revenue Service to validate certain income information provided by applicants. Using this computer match allowed SSA to build a process that would not require applicants to submit proof of resources and income as long as their statements on the application were in substantial agreement with the computer records.

Now, to ensure that this simplified process that I have just described was put to use, we have worked hard to inform Medicare

beneficiaries about the extra help available for prescription drugs. For example, during the past year, Social Security has held more than 66,000 Medicare outreach events throughout the country, and we have hosted a number of application-taking sessions in Social Security offices. We continue to work with States and other organizations to identify people with limited income and resources who may be eligible for the extra help.

Although the new prescription drug plan did not begin until January 2006, SSA began mailing subsidy applications to potentially eligible individuals in May 2005, and this initial effort allowed us to begin making eligibility determinations for extra help as early as July 2005.

Now, as has been pointed out, as important as the initial mailing of the applications was, follow-up contacts with those individuals who did not return the application has been and continues to be just as important to us. As an example of our ongoing efforts to help enroll as many eligible individuals as possible, we are contacting Medicare beneficiaries who have requested Part D withholding from Social Security benefits and who were mailed a subsidy application but didn't return it. We will be contacting them by phone or by mail and we want to see if we can assist them in applying for the extra help. We will also continue to use our routine agency mailings, such as COLA notices, to inform the public about the subsidy.

So, what has resulted from all this effort? Well, as of January 27, almost 4.4 million people have applied for the extra help. We processed almost 4.1 million, or 93 percent of those cases. Almost 700,000 cases did not require a decision by SSA because the person was already deemed eligible or they had filed a duplicate application. But of the 3.7 million applicants who do require a decision, we have now made determinations for over 3.4 million of them and found nearly 1.4 million of those individuals eligible. That is a 40 percent eligibility rate.

In conclusion, I want to express Commissioner Barnhart's appreciation and my personal thanks to Congress for providing SSA with the resources that we needed to begin this challenging process. Your assistance in fiscal years 2004 and 2005 made it possible for us to hire more than 2,500 employees to work on implementation of MMA provisions. It also allowed extensive training for thousands of on-duty employees and made possible the design of critical new computer systems. Your support has truly been crucial.

We look forward to working with the Committee as we progress with implementation of the extra help program, and we appreciate this opportunity to tell our story and will be happy to answer questions.

The CHAIRMAN. Thank you very much, both of you, for, again, your presence here and your testimony.

[The prepared statement of Ms. McMahon follows:]

Medicare Drug Benefit Implementation

Statement of

Linda S. McMahon
Deputy Commissioner for Operations
Social Security Administration

Before the

Senate Special Committee on Aging

February 2, 2006

Mr. Chairman and Members of the Committee:

On behalf of Commissioner Barnhart I want to thank you for inviting me to discuss Social Security's efforts to implement the new Medicare prescription drug coverage limited-Income Subsidy Program. I am Linda McMahon, Deputy Commissioner for Operations at the Social Security Administration (SSA). While I have been in my current position since November 2001, I have been with SSA for the past fifteen years.

SSA has already done a great deal to assist limited-income Medicare beneficiaries in receiving extra help with their prescription drugs through the new Medicare prescription drug coverage, and we will continue this mission with a firm commitment to the public we serve. As Commissioner Barnhart has said, "Together, we can make sure no one has to make the difficult choice of spending their limited income on prescription drugs or other basic needs."

Background

To begin, it may be helpful to describe Social Security's role and responsibilities regarding the new Medicare prescription drug coverage. This will provide the context to further describe SSA's activities in getting limited-income people the extra help intended by Congress.

As you know, the Medicare Modernization Act, or MMA, enacted in December 2003, established the new Medicare prescription drug benefit. The new Medicare prescription drug coverage was designed to allow all people with Medicare an opportunity to voluntarily enroll in prescription drug coverage. MMA also provided an extra level of assistance for people with Medicare who have limited incomes and resources in helping to pay for the monthly premiums and cost-sharing that are required by the new Medicare prescription drug coverage. This assistance is the limited-income subsidy, or "extra help," as it is frequently called.

The responsibility for enrolling individuals for the prescription drug coverage is a joint effort between the Department of Health and Human Services (HHS) and private insurance companies, which establish Prescription Drug Plans (PDPs) for that purpose. Individuals who were already eligible for Medicare and full Medicaid benefits were automatically enrolled by the Department of Health and Human Services in the subsidy, and did not need to apply. They were also auto-enrolled in a plan in November 2005.

SSA was given the responsibility by Congress to take extra help applications and to make eligibility determinations for individuals who were not automatically eligible. In order to be eligible for the subsidy, individuals must have incomes below 150 percent of the poverty level applicable to their corresponding household size, and resources of less than $11,500 for single individuals or $23,000 for married couples.

Individuals with incomes between 135 percent and 150 percent of poverty are eligible for a subsidy amount based on a sliding scale. Individuals with incomes below 135 percent would be eligible for full premium subsidies, with no copayments or annual deductibles.

Additionally, SSA was charged by Congress with the collection of premiums for the prescription drug program itself, in cases where beneficiaries tell the prescription drug plans when they enroll that they want their premiums withheld from monthly Social Security benefits. This withholding of premiums is similar to the function SSA already performs for beneficiaries in the withholding of other Medicare premiums.

SSA was given these responsibilities because of its network of nearly 1,300 offices with 35,000 employees across the country, and because of its already existing role in administering some parts of the Medicare program. Over the past 70 years, SSA has gained a reputation for helping citizens in the communities where they live, and Congress realized that SSA's presence "on the ground" would be vital in the launch of the Medicare extra help program.

Also, the limited-income subsidy was designed with many similarities to the Supplemental Security Income (SSI) program, a means-tested assistance program for low-income aged, blind and disabled individuals, which SSA has administered for more than 30 years.

Development of Extra Help Application

Upon passage of MMA, Social Security immediately began planning for the implementation of the limited-income subsidy. We recognized from the onset that development of a simplified application for the extra help was essential for successful implementation. Thus, our goals were to develop an application that elderly and disabled Medicare beneficiaries, their caregivers, or other third party assistance providers would be able to understand and easily complete. SSA also wanted to maximize the use of automation, not only to process these forms efficiently, but also to process them in a timely manner.

To accomplish these goals, SSA conducted substantial testing of the extra help application form. The paper application changed significantly over time, going through many drafts before being finalized. Social Security, in collaboration with CMS, conducted focus groups with current Medicare beneficiaries to test potential applicants' understanding of the application, and conducted special cognitive testing of the subsidy application and design engineering evaluations. We also discussed various draft versions of the application with national and local advocacy groups and with State Medicaid Directors.

Our Office of Systems staff contributed to the design of the application as well, to make sure that the information on the form could be electronically scanned into our computers, thereby minimizing the number of employees needed to process incoming forms.

Realizing the need to reach our beneficiaries in new ways, SSA worked to develop alternatives to the traditional paper-based application. In July of last year, we had unveiled the Internet version of the application located at www.socialsecurity.gov, allowing people to

apply online for help with Medicare prescription drug plan costs. The online application has been a tremendous success, receiving one of the highest scores ever given to a public or private sector organization by the American Customer Satisfaction Index (ACSI). More than 2,000 Internet applications are being filed daily.

Telephone inquiries were also part of our efforts to make the extra help application process as simple as possible. Extensive training was provided to assist our teleservice representatives in answering subsidy-related questions. We also developed an automated application-taking system, allowing the teleservice representatives to refer callers directly to specialized claims-taking employees, who could then take applications by phone. This new system allows individuals calling our 1-800 number to immediately file for the extra help.

We also developed a computer matching process with the Internal Revenue Service (IRS) regarding the validation of certain income information provided by applicants. Using this computer match allowed SSA to build an application process that would not require applicants to submit proof of resources and income, as long as the applicant's statement on the application was in substantial agreement with the computer records.

In summary, although means-testing is by its very nature complex, we believe that we have created a simple application process, which allows individuals to apply for the extra help as quickly and easily as possible, while also taking advantage of current technology.

Outreach Efforts

I would now like to turn to the efforts SSA has undertaken to inform beneficiaries about the extra help available for prescription drugs. Efforts to educate the public about the new, extra help program began almost immediately after passage of MMA, and this outreach continues today. SSA has worked with CMS and other Federal agencies, community based organizations, advocacy groups, and State entities in order to spread the word about the available extra help.

During the past year, more than 66,000 Medicare outreach events have been held by SSA. Targeted application-taking events were held in Social Security offices throughout the country, and personal invitations to these events were mailed to beneficiaries who had not yet applied for the extra help, but had been identified as being potentially eligible for the program.

We continue to work with States that have their own pharmaceutical programs, State Health Insurance Programs, Area Agencies on Aging, local housing authorities, community health clinics, PDPs, and others to identify people with limited income and resources who may be eligible for the extra help.

Throughout these efforts, SSA's goal has been to reach every potentially-eligible Medicare beneficiary multiple times, in a variety of ways, for example, by targeted mailings, follow up phone calls, and targeted events. And while we are confident we have taken appropriate steps to reach out to those who may be eligible for the extra help, our outreach efforts will continue throughout the initial enrollment period (which ends May 15, 2006) and beyond.

Additional Outreach & Mailing of Subsidy Applications

Although the new Medicare prescription drug coverage did not begin until January 2006, SSA began mailing applications to individuals who were potentially eligible for extra help in May 2005. During the following three months, we mailed almost 19 million applications. Our goal was to have as many potentially eligible limited income Medicare beneficiaries as possible file for the extra help before the Medicare prescription drug program started in January 2006.

We also intended to cast the widest net possible in our efforts to reach the public. Thus, we sent the 19 million applications to potentially eligible individuals, even though we knew that not all of this group would meet the income and resource requirements. This initial effort also allowed us to begin making eligibility determinations for the extra help as early as July 2005.

As much as the initial mailing of applications was important, follow-up contacts with those individuals who did not return the application was just as important. We contracted with a vendor to remind individuals of the availability of the extra help program and to ask if they needed assistance. Of the 9.1 million people who were called by the vendor, 800,000 had applications resent to them, and 400,000 requested assistance and were referred to SSA. In addition, 5 million follow-up notices were sent because the vendor could not locate a phone number for the individual (for example, an individual who was displaced by Hurricane Katrina).

Success So Far

As of January 27, SSA has received applications from almost 4.4 million beneficiaries, of which almost 700,000 were unnecessary, because either the applicants were automatically eligible or because they had filed more than one application. We have made over 3.4 million determinations on the eligibility for extra help, and have now found nearly 1.4 million of these individuals eligible. We have also notified the individuals who filed unnecessary applications of their current eligibility.

While we are proud of the initial success that we have had with helping so many beneficiaries pay for their prescription drugs, there is much more that we need to do. Commissioner Barnhart has made it clear that we need to continue to aggressively promote this valuable benefit, and to this end, we continue to look for ways to reach those eligible for the extra help program.

As an example of SSA's ongoing activities, we are contacting beneficiaries who have requested that premiums for the new Medicare prescription drug coverage be withheld from Social Security benefits and who were also mailed a subsidy application that they did not return. SSA is planning to contact them by phone or by mail, to see if we can assist them in applying for the extra help.

SSA is also examining other ways in which we might reach individuals who could be assisted by the extra help program. We are currently working to establish cooperative projects with tax preparers, who deal with people filing for the Earned Income Tax Credit, to see if they would screen for the extra help.

Additionally, we continue to use Agency mailings to inform the public. For example, the cost-of-living adjustment notice that was sent in December 2005 to 52 million Social Security beneficiaries contained information about the new drug program and the availability of extra help. The 4.2 million letters SSA sent to individuals potentially eligible for Medicare Savings Programs, during September and October 2005, also contained information about the subsidy.

While SSA has no direct role in assisting individuals in either selecting or enrolling in PDPs, we have also provided instructions to the field offices on how to make sure those with the new Medicare prescription drug coverage questions are directed to the resources they need. In some cases this means our employees will simply refer the questioner to 1-800-MEDICARE, or to the beneficiary's PDP provider, but in other cases it means making a personal call to state coordinators, reprinting and faxing award notices, and even making emergency calls to CMS Regional Offices.

In short, we are committed to doing whatever we can to help make this new program accessible to our beneficiaries.

Conclusion

In conclusion, I want to express Commissioner Barnhart's thanks, and my personal thanks, to Congress for providing SSA with the resources we have needed to begin this challenging process. Your assistance in FY04 and FY05 has made possible the hiring of more than 2,500 employees to work on implementation of MMA provisions. It has allowed extensive training of thousands of employees, and made possible the design of critical new computer systems capable of storing

and exchanging information related to the new Medicare prescription drug coverage. It has also allowed us to work toward implementation of all of the MMA provisions that have been assigned to SSA. Your support has truly been crucial.

We look forward to a continued dialogue with your Committee as we progress with implementation of the extra help program. We very much want to hear your ideas. While we have found that there is no single contact method that guarantees success, we have learned that the more times we reach these limited-income beneficiaries, the more we are able to help them.

Thank you, and I will be glad to answer any questions you may have.

The CHAIRMAN. Mark, I think, obviously, the question in all of our minds is, while many of the problems we are raising today are problems we foresaw last March when we had a hearing here, but clearly the transition didn't go as smoothly as we would've liked. I mean, why, with all that advance notice, has there been such a difficult transition?

Dr. MCCLELLAN. We did have a lot of discussions about the transition issues for the new Part D benefit and I really commend the committee on a bipartisan basis for paying close attention and having many constructive ideas about how we could make the transition go smoothly. You will recall when we talked last spring, we raised a lot of issues around long-term care pharmacies, about making sure that plans would comply with the necessary support that those pharmacies needed for their nursing home beneficiaries. We talked about coverage of needed drugs for people with mental illnesses and other conditions where the specific drug really mattered.

In many of these areas, we were able to make further enhancements in the program to address concerns, about everything from packaging issues in nursing homes, to new kinds of support to help nursing homes identify the plans their beneficiaries are in and bill them properly, to expanding and being clear about the broad formulary coverage requirements for people with mental illness, HIV-AIDS, and other serious conditions.

We also talked about the transition issues for people who were dual-eligibles around January first and steps that we could put in place to make sure they got their medications at the pharmacy and we took those suggestions, like getting in place this automatic information system that many pharmacists have been able to use to avoid the phone calls that they routinely have to face when people start a new program.

The CHAIRMAN. Isn't it true you have also extended the enrollment deadline from 30 days to 90?

Dr. MCCLELLAN. The transition coverage has been extended to 90 days.

The CHAIRMAN. Ninety days.

Dr. MCCLELLAN. We talked last spring about the importance of transitional coverage and we are watching that very closely, as are the plans, to make sure we have got that in place for a long enough period for people to smoothly decide whether or not the drugs they are on now could be switched with alternatives. But again, we have got broad formulary requirements in place now for the drugs for conditions like mental illnesses and cancer and AIDS where it really matters.

So that dialog with you all has been extremely helpful and we are going to continue taking every step we can to make this transition go smoothly. It was a big change on January 1 with the entire dual-eligible population moving over, as required under the statute, and suggestions, the input that you all had in this process has been very helpful for limiting the number of cases where people have had significant difficulties and we will keep working very closely with you to address the cases that we are seeing, to find the problems and fix them.

The CHAIRMAN. I am also mindful that Secretary Leavitt announced or assured the States that their costs in this transition would be reimbursed.

Dr. MCCLELLAN. We did. We had an announcement about that last week. We have been working closely with the States on the best mechanism for providing this reimbursement and many of the State Medicaid directors, other State officials that I talk with frequently have had some very constructive ideas on how to do it. We have seen many States working closely with us, just like Senator Santorum mentioned, Pennsylvania's close work with our regional office. The same thing is happening in Oregon, Delaware, and many other States to limit the number of cases where there are difficulties and to get people connected with their coverage quickly.

So we have put forth a reimbursement program based on a demonstration, a model waiver. We have the details of that program coming out right away, basically just a checklist that States can go through for following these best practices to get people connected with their coverage and we will handle the reimbursement. The State submits the claims to us. We work on reconciling—we do the work for reconciling them with the plan payments, and for any difference in higher Medicaid payments than what these competitive plans are paying, we will make up that difference, too, and we will also pay for any reasonable administrative costs in the process.

The CHAIRMAN. I have heard horror stories, Mark, about long, long call waits for people trying to get information. Have you beefed up the call center?

Dr. MCCLELLAN. We have, and I know we have been working very closely with your staff on monitoring how the call center's work is going. In the very early days of the program, we had relatively long waits on our line at 1–800–MEDICARE. I am proud to say that we have kept those average wait times, even during the first week in January when we had the largest number of these complaints and transition questions. We had the wait times under 5 minutes. We have been monitoring it closely since then. It is under a minute for the most recent days and definitely no more than a few minutes at any time during this month.

We are also very pleased at how many of the prescription drug plans have responded. Many of these plans quickly, after the first week or two, staffed up their own help lines for customers, for pharmacists, and others. We have been monitoring those wait times and we have seen them come down substantially to acceptable levels of just a few minutes for many of the plans and we want to make sure all the plans get there, and that is why we announced yesterday that we are going to be taking some further steps to monitor and even publish the performance measures for these plans.

The CHAIRMAN. Senator Kohl.

Senator KOHL. Thank you, Mr. Chairman.

Dr. McClellan, why not allow Medicare to negotiate maximum discount from the pharmaceutical companies? These are actual tax dollars we are talking about, and if the program meets anywhere near its expected projected costs over 10 years, $750 billion—who knows what it will cost—a 20 percent discount is $150 billion.

Wouldn't you expect taxpayers to expect the government to get these prescription drugs at the minimum price necessary?

Dr. MCCLELLAN. I expect our program to get the best possible cost for implementing this program. That is why we are very pleased with the results that we are seeing so far based on the actual costs of the program that is coming in, where the drug plans are competing and getting the costs of coverage down way below what had been projected. We are seeing cost projections now, these numbers that we released today, showing costs that in 2006 are going to be 20 percent lower for the Federal Government than had been forecast. As our actuaries and other independent experts had said at the time, they do not believe that with the steps that we have in place to encourage strong competition, to encourage price negotiation to get lower prices to beneficiaries, that any additional government price negotiation would save more money.

Our concern about more government negotiation is, as you know, the way the government can get lower prices, the same thing that many of the plans have done but we regulate very carefully, they do it by narrowing the formularies. This is how the VA plan, which has a considerably narrower formulary than we have required the Medicare plans to have, means that many people would not be able to continue taking the drugs that they are on right now, the ones that their doctors have prescribed and that they have decided, or they may want to decide they want to continue, even if they are not on a formulary.

So we are very concerned about making sure that our formularies are broad enough and that the plans negotiate and get the lowest possible costs of coverage, and that is exactly what is happening. That is why the costs of this drug benefit for each person covered is coming in so much lower than people had expected, and that means savings for beneficiaries in the lower premiums, savings for the Federal Government, and savings for States, that 25 percent lower claw-back payment that I mentioned earlier.

Senator KOHL. Well, that is well and good and I am sure that argument in your mind is a very strong one, but when you have a single buyer, in this case Medicare, negotiating for a huge discount based on the size of their purchase, all the evidence is that you get a much bigger discount than if you have, like 46 different plans negotiating their own much smaller discount based on their purchases. All the indications are that the bigger your buy, the bigger your discount, and apparently you are saying that that law of business is not true.

Dr. MCCLELLAN. Well, these drug plans include—many of these plans are large health care organizations that already cover millions of Americans under 65, millions of Federal workers and retirees, and so have very large population bases, so they can drive those stronger discounts. Again, that is what we are seeing. If you include not just the low prices—there have been some studies that have come out recently that kind of tilt the scale by counting Medicaid rebates in the Medicaid price side but don't count the rebates that the private plans are also getting and that they are required to incorporate in the payments they get from us and the bids that they put in. When you do that, you see low costs.

That is why we are hearing from many States that in their Medicaid plans, where the State does the negotiation, their costs are expected to be higher than under the drug plans. That is why we are having to supplement what we are paying some of the States in this repayment program beyond what the drug plans would pay for the same drugs.

Senator KOHL. I appreciate that. I would just end the subject in terms of my inquiry this morning by saying that after 1 month, to make a projection is almost ludicrous, and to expect us to sit here and say, well, that is the deal, 1 month in, that is the deal, you know—you know that you should not make that with any certainty. It is just a number you are throwing out. It is no different than so many of the projections that come out from this administration about the costs of the deficit, the costs of this, the costs of that, and it turns out to be wildly inaccurate. So we take what you say this morning as being sincere, but as certainly not the last word.

Dr. MCCLELLAN. I agree with that. We should keep watching very closely on this and every other aspect of the program. This is the first time, though, that our independent actuaries have been able to incorporate actual data from the cost of this benefit as it is actually being delivered in doing their estimates.

Senator KOHL. On another subject, the pharmacies that have been filling prescriptions and not getting paid, Senator Burns said a minute ago that they are going to get reimbursed, but as you know, nothing has been determined with certainty with respect to that. As you also know, many of them are paying out money from their pocket, money they don't have, and they need to be reimbursed immediately and they deserve to be reimbursed as soon as they present the evidence. How we are going to get that thing done?

Dr. MCCLELLAN. Well, as I have talked to pharmacists and pharmacy leaders around the country, which we do on an almost daily basis—which I do on an almost daily basis and our staff all over the country is doing regularly, as well, this is now getting to be one of the top levels of concern, and one of the reasons is that we have had a change in the way the pharmacy contracts work. Up until now, for many of the people who are covered by the drug benefit, they were previously covered in Medicaid, which had one payment schedule, typically paying once a week, or people who were paying cash, and those are people who would pay right at the time, often very high rates, but right at the time, right at the pharmacy counter.

Under the contracts that the pharmacies have with the drug plans, they get paid several times a month based on claims submitted, and so we have had a period over the last couple of weeks where the claims have started going in but the checks haven't started coming out. Now, we are watching very closely to make sure that the drug plans pay according to the contractual payment schedules that they have set up. Those payments have started to come out recently. Some plans pay every 10 days. They have already sent out millions of dollars in payments. Others pay every 15.

Those checks are going out starting right now, and we want pharmacists to know that if they are having problems getting the contractual terms met, that is one of the areas where CMS monitors complaints and we will help enforce those contracts. But there are a lot more things that we can do to help pharmacists that I am sure are going to come up later in this hearing and I want to talk about those, too.

Senator KOHL. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Carper.

Senator CARPER. Thanks. Thank you for your testimony. I thought it was helpful. I want to ask for a clarification, if I can, from Ms. McMahon. I said in my opening statement that I think that there are about eight million eligible beneficiaries, low-income beneficiaries for this program, and I said, to date, only about 1.1 million people had been found eligible. That was through December 31. I think I heard you say that——

Ms. MCMAHON. As of January 27, that number is 1.4 million that we have determined eligible.

Senator CARPER. Here is my question. Does that mean that there are roughly another just under seven million eligible low-income beneficiaries that we still have to potentially be signed up for this benefit?

Ms. MCMAHON. Well, I would have to put the answer to that this way. We sent out almost 19 million notices to people to say, "you are potentially eligible". We knew that not all of them would be eligible, but we wanted to cast the widest net we possibly could to make sure that anybody that had any hope of being eligible, we would contact, and we are trying to follow up with those folks.

What is the actual right number of people? One of the things we are finding out is that there are more people who have higher resources than we expected, which in a way shouldn't be a surprise because a large part of the population are people who went through the depression and World War II. They saved money. Maybe they don't spend like my generation does. So they have higher resources than we expected. In fact, even with $10,000 and $20,000 resource limits, they have maybe $17,000 more over that. So we don't know exactly how many people are eligible.

Senator CARPER. We know it is more than 1.4 million.

Ms. MCMAHON. Yes, we do.

Senator CARPER. I would just urge you to increase your efforts, continue your efforts to help us find them, help them sign up, OK?

Ms. MCMAHON. We are going to do that, and in fact, we are hoping that we can get ideas——

Senator CARPER. That is all I want to say. That is all I want to say because I have got a lot of questions here I want to get into——

Ms. MCMAHON. All right.

Senator CARPER [continuing]. But thank you. Dr. McClellan, this is a question that could be for either of you. Just help me on this. If a person signs up, picks one of these plans, in my State we have got a whole lot of plans, I think a whole lot more than I expected, and I think it is part of the confusion for pharmacists and for seniors, as well. But if somebody signs up, as I understand it, in a particular plan, they think it is best given the medicines they take, do I understand that the plan itself can change and maybe, say, drop

out coverage, decrease coverage for some of the medicines, and we will say that happens in April, then do I understand that the beneficiary, the senior citizen, has to wait until the end of this calendar year in order to be able to change plans and pick out a plan that better suits their needs?

Dr. MCCLELLAN. Well, first of all, as you know, Senator, the drug plans all have to meet our broad formulary requirements. These are broader than the requirements in many Medicaid prescription drug programs, broader than the VA formulary requirements. Eighty of the top 100 drugs are typically covered by plans, so that the plans are having broad formularies to start with to make sure all medically necessary drugs are available.

Plans can change their formularies, and I want to talk about two different kinds of cases. One is when something new happens in medical knowledge or medical treatment availability, so there is new information suggesting that a drug shouldn't be used in certain circumstances or a new generic version of a medicine becomes available. Those are things that the plans should incorporate in their formularies to help make sure people get the right treatments for their conditions at the lowest cost.

Plans have an ability to change formularies otherwise, but only if they replace one drug with another drug that is in the same category, works in the same way, and offers as good of benefits to the patient. But in order to do that, several things have to happen first. First, they have to submit this information to us to have a CMS approval for making any such formulary change. Second, they have to give advance notice to their beneficiaries so that there is plenty of time for the beneficiary to determine whether they should stay on the drug they are on now or whether going to this other less expensive alternative is better for them.

So far, we have seen no cases of that occurring. We also had some experience with this with the drug card that was in place for a couple of years and that millions of people use to lower their prices. There were also concerns that this would happen then. We monitored. Again, we saw essentially no cases of such formulary shifting. We are going to watch very closely to make sure the plans continue to provide the level of coverage that they have promised from the beginning. I think they have generally every intention of doing that, but we are going to verify that that happens.

Senator CARPER. Be vigilant. Be vigilant.

Dr. MCCLELLAN. Yes.

Senator CARPER. We have established in Delaware a Delaware Prescription Assistance Drug Program when I was privileged to be Governor of our State. A lot of States have them, as you know.

Dr. MCCLELLAN. Yes.

Senator CARPER. CMS recently announced the waiver process would allow States to be reimbursed for costs that they incur in paying for drugs for dual-eligible beneficiaries. However, a number of States like my State, and I think like probably half of the States that are here represented on this committee, States where we are incurring costs for other low-income beneficiaries, like those in our own State Prescription Assistance Program, I am told that—I met with our Secretary of Health and Social Services recently and I learned from him that our State's Prescription Assistance Program

has over, I guess, over 10,000 enrollees now, which is a lot for a tiny State and has really stepped up to the plate to help enrollees navigate the new benefit and we are trying to blend the two together so that we really dramatically increase coverage and use the strength of both programs.

In some cases in Delaware, we are incurring costs for the Delaware Prescription Assistance Program enrollees who have enrolled or tried to enroll in a Part D plan but have not yet been recognized by the plan as enrolled. Here is my question. Will CMS open the waiver process to States like my own and like others who have established their own Prescription Assistance Programs and who have incurred unnecessary costs in other State programs? I would ask that if you can get into that now, fine, but if now, I just really would ask that you and your folks address it.

Dr. MCCLELLAN. The reimbursement plan that we have discussed does apply to State assistance programs for other low-income individuals, other partial dual individuals who were enrolled in the Medicare program and either they or their—because of issues with the pharmacy, they didn't get the coverage they should have received. So that is part of our program.

I want to say, as well, that the program in Delaware, like in many other States, is terrific. It is going to get a lot of help from the new Medicare coverage because you now only have to wrap around the basic Medicare benefit, and Senator, I would like to make sure we follow up specifically with you to resolve these issues in Delaware. We have had a very close working relationship with you and the State and I want to make sure that continues as we work through these transition issues.

Senator CARPER. My time has expired. I would just add, if I could, one last sentence, Mr. Chairman. The folks that are in our Delaware Prescription Assistance Program are not dual-eligibles. They are not dual-eligibles. They are low-income.

Dr. MCCLELLAN. Let me follow up with you. If they are not dual-eligible or low-income, we will work directly with you and the State on addressing this.

Senator CARPER. Thank you so much.

The CHAIRMAN. Thank you.

Senator Clinton.

Senator CLINTON. Thank you, Mr. Chairman. I want to start by trying to get some clarification. Senator Burns said that CMS is committed to reimburse pharmacies. My understanding based on what Secretary Leavitt told the Finance Committee is that he did not want to make such a commitment at this time to reimburse pharmacies and that, in fact, the pharmacies will need to seek reimbursement through private drug plans. Is that correct?

Dr. MCCLELLAN. Well, pharmacists that have done a terrific job in stepping up with the implementation of this program need to be paid for the drugs that they provided and we are going to make sure that the contracts with the drug plans are enforced, and if there are any difficulties in making those payments, we will help ensure the payments do take place.

Senator CLINTON. Well, that is an important commitment. I would just suggest, though, that given all the confusion, oftentimes pharmacists don't even know which plan a beneficiary is enrolled

in. They are going to have to go back and get that information. These contractual obligations may be difficult for them to enforce. I think many of us expect that these pharmacies will get reimbursed one way or another and we will look to CMS to ensure that that does happen.

I have a series of questions, Dr. McClellan, and I would appreciate brief answers because I know we all have a lot of information we are trying to get out.

Will you support our legislation to waive fees and copayments for dual-eligibles in assisted living facilities?

Dr. MCCLELLAN. We are strong supporters of getting people into assisted living. We need to hear more about how this legislation would work. We are already working with a number of States that are picking up those copayments and combining it with some of the home and community-based waiver services, some of the other programs that already exist to help people in assisted living.

So we would like to hear more about the legislation, and in the meantime, we are going to do what we can under current law to help States fill in those copays, and many States are already either doing that or considering doing that. As you said, they are limited copays from the overall budget standpoint of a State. They are very important for those particular individuals and we want to do all we can to help people get out of institutions. It is a strong commitment of this Administration and we will work with the States and definitely want to talk with you further about your legislation.

Senator CLINTON. Well, we will move quickly on that because right now, there is a tremendous burden being imposed. So as quick as you can get some assessment as to the best way to do that, we need to hear it because we can't let this just linger on, so I appreciate your willingness to work with us.

I am also concerned about the additional problems that we are encountering with respect to mental illness. Will you provide us with data on the numbers of beneficiaries that file appeals to plans, the number of successful appeals and rejections by plans, and information on the timeliness with which plans handle appeals?

Dr. MCCLELLAN. We definitely want to work with the committee on that. I think that is an important part of the oversight and our continuing interaction on making sure that implementation goes as smoothly as possible. I would point out that with our extension of the transition period for another 60 days, people who are on medications now are going to continue them. I also point out that we have very broad formulary requirements, essentially all drugs for mental illnesses, especially for people who are already stabilized on those drugs. So I wouldn't expect to see a lot of information on appeals from this particular area for a while because of these other steps that we have taken. But we definitely want to keep a close eye on that with you.

Senator CLINTON. Now, your announcement that you will reimburse States requires that States cease using State reimbursement systems and return to the Medicare prescription drug system by February 15. In light of the problems we have seen, would you reconsider continuing to assist States that may have to step in and pick up costs for their citizens who are not getting their benefits?

Dr. MCCLELLAN. Senator, the payment program does include an opportunity to extend its period beyond February 15. What we expect, based on what we are seeing from many States already, is that there are specific steps that States can take to minimize billing into the State systems. Those kinds of steps, we expect States should be able to put in place by the middle of February if not sooner, and that is going to drive down the use of State reimbursement in the cases where States haven't done that yet.

Senator CLINTON. But in the case of the exceptions——

Dr. MCCLELLAN. But if there are still exceptions needed, if there is still additional limited help needed beyond that, that definitely is part of the waiver process, as well, and we would discuss that with the particular State. The goal here that we have is the same as the States have, is to get these beneficiaries, all of these beneficiaries, transitioned to their Medicare coverage as quickly as possible.

Senator CLINTON. Dr. McClellan, with respect to the plans requiring forms, some as long as 14 pages, for doctors to fill out, you have requested that the plans discontinue this practice, but at least according to our information, it does not yet seem to have taken hold. Will you require the plans to end this practice?

Dr. MCCLELLAN. We have been watching this very closely, too. I am pleased that many of the plans have taken steps or already have in place steps to have a smooth and straightforward exceptions and appeals process. We have also worked very closely with pharmacy groups, medical groups, and others to develop a model form that is very straightforward, exactly as you are discussing.

I think we have talked about how some of the benefits of competition here, getting to lower costs, but obviously what many beneficiaries want right now is more simplicity and I think you are going to start seeing the market respond and the plans respond to that. That is what people want, is a straightforward way as possible to use these benefits. We are going to help push that along by working with the plans and pharmacy groups on things like a standard exceptions and appeals form. So I think you will be hearing more about that in the days ahead. Remember, we have got 60 more days with the extension of our transition coverage period to help make sure these processes work as smoothly as possible.

Senator CLINTON. I highly commend the idea of a single form. It has been my experience that insurance companies thrive on complexity and confusion in the health care arena, so the more it can be simplified, I think the more money we will save, the quicker we will get the services out to the people who need them, and the burden will be removed from doctors who shouldn't be spending their time filling out forms to make a case for a drug that they have prescribed for years for their patient.

Mr. Chairman, I really thank you for having this hearing. I hope we have a continuation of these hearings. I share my good friend Senator Kohl's skepticism about costs. I, a long, long time ago, took a course in consumer law and the concept of bait-and-switch has stayed with me ever since, so this has to be watched extremely closely if it is going to have the benefits that we want it to have for people. Thank you.

The CHAIRMAN. Thank you.

Senator Talent.

Senator TALENT. Thank you, Mr. Chairman.

Director McClellan, on page two of your statement, you have a graph which I have been trying to understand. In the statement introducing it, you say that there were 15 million people with drug coverage on December 21 and 24 million on January 14. Would you explain that a little bit?

Dr. MCCLELLAN. The increase in enrollment related to more people signing up on their own, more retirees registering for coverage to get support for their retiree coverage, as well, and that is what has gotten to the number that now exceeds——

Senator TALENT. So those retirees had the coverage, but what they now have is a subsidy in addition to it?

Dr. MCCLELLAN. They didn't have a subsidy, and what they didn't have was much security in keeping that coverage in place. As you know, in Missouri, a lot of retiree plans have been dropped or cut back. The plans now have new support from us to keep them in place and to keep high-quality benefits there, and there are hundreds of firms and thousands of beneficiaries in Missouri who are taking advantage of this new help.

Senator TALENT. So what you are saying is that there are nine million additional people who are receiving some benefit because of the new program.

Dr. MCCLELLAN. I would say it is even more than that. It is true that many of the people who are in the Medicare Advantage health plans—those are the HMOs and the PPO plans in Medicare that existed before, in many cases, before 2006, those plans did have some drug coverage in many cases. They all offer extra benefits and lower cost for the people who enroll in them. That is why many seniors, and more and more seniors are signing up for those plans.

What the drug benefit allowed them to do was enhance that coverage. So instead of having $250 worth of help for a quarter that just ran out, people now have a relatively comprehensive drug benefit and it costs less and it offers more coverage, less of a doughnut hole, no deductible, things like that, that are not available in the basic Medicare benefit. So people in Medicare Advantage——

Senator TALENT. Superior to what they had under the HMOs?

Dr. MCCLELLAN. Exactly. Similarly, the retiree coverage trends over the last years have been steadily downward. We have seen that halt with the result of the new subsidy being implemented. Then there are millions more people, including many, many in Missouri, who are getting new drug coverage who didn't have it before and saving a lot of money.

Senator TALENT. So the nine million figure is people who didn't have any drug coverage before who now have it, plus people who were on HMOs who are now on Medicare Advantage and getting improved coverage.

Dr. MCCLELLAN. I think the figure is even larger than that. I think that is—what you are looking at is a change in enrollment between the last part of December and early January. Going into the last part of December, there were already many people who had enrolled either through a Medicare Advantage plan or a retiree plan or something like that.

Senator TALENT. Well, since we may evidently have a debate on whether to scrap the whole thing, it might be a good idea for us to get down exactly the benefits people are getting, and my sense of it is that there are millions of people around the country——

Dr. MCCLELLAN. Oh, yes.

Senator TALENT [continuing]. Who are getting a substantial additional benefit, either coverage that they did not have or better coverage or stabilization of the private retiree coverage that they had.

Dr. MCCLELLAN. That is right, and they are——

Senator TALENT. I am certainly running into a lot of people in Missouri who are saying, "Boy, I was paying out of pocket before and I am not now," so maybe we ought to really get a total of the number of people in the country who would lose benefits if we went back to square one.

Dr. MCCLELLAN. That is many millions of people who would lose benefits——

Senator TALENT. Because that is the balance on the other hand. I mean, it is good to have a hearing on the problems, and I have been living with that because I have been out, as you know——

Dr. MCCLELLAN. I know you have.

Senator TALENT [continuing]. Because I have called you from the road on some occasions where I had cell phone coverage, and I have been living with some of those issues, also. But we have to have the balance and realize why we did all this and what is going to happen if we go back to square one with it.

Let me ask you a couple of questions. I am going to submit more for the record. One, and I have taken some real-life questions from people who have had issues. This one lady is trying to find out whether a particularly rather exotic and necessary drug that she has been taking since July of last year is covered under the plan that she was auto-enrolled in and she is having trouble getting a response from CMS. We hear about this. I mean, I hear some people say, "I called, I got through, no problem." Then I have other people who say, "We are getting a run-around."

How big is the problem, in your judgment, for people who are calling CMS and what is the difficulty? Is it that during peak hours everybody is calling and not enough on off-hours or whatever?

The second point that was raised with me, I thought was a very good one, and maybe we need to do this rather than you, but the Agencies on Aging have done heroic work on this, the senior centers——

Dr. MCCLELLAN. Yes, absolutely.

Senator TALENT. I mean, I don't know how they rolled out Medicare originally without these, but they have just been tremendous——

Dr. MCCLELLAN. Absolutely.

Senator TALENT [continuing]. Just great about it and so constructive, and they have had to put a lot of time and effort into it. I wonder, do you have any plans, or do we need to do this legislatively, to maybe help compensate them because they really put an enormous amount of effort. They didn't do it to get money from the government. They did it to help the seniors. But it would be good to compensate these because they have spent a lot of time and effort on it, and that was raised with me.

Do you want to comment on those two, and then I will submit the other questions?

Dr. MCCLELLAN. Absolutely, Senator, and thank you for all your effort. I appreciate the phone conversations and keeping in close touch about how things are working on the ground in Missouri.

Senator TALENT. That is very polite of you, because I have called up to complain on occasions——

Dr. MCCLELLAN. That is no problem. It is part of the job. The Area Agencies on Aging, senior centers, other local partners, we have tens of thousands of them around the country, are doing a huge amount of work to help people find out about the new benefits and take advantage of it and they really are a tremendous resource. They are helping people get through. They hear a lot of things. My gosh, there are a lot of plans. What does this mean for me? They turn it into, practically, you know, here is the plan that is relevant for you. Here is how you can sign up and save money in just a matter of minutes. They are helping around the country millions of seniors do that.

We have doubled our budget for supporting the State Health Insurance Assistance Programs. We have enhanced our collaborations with the Administration on Aging, which provides funding and enhanced funding for many of these groups. We are also adding to this effort with a grassroots network around the country. There are many faith-based organizations, many advocacy organizations, many seniors organizations that don't get government funding but now are working more closely together with these federally and State and locally sponsored groups than ever before. In States where this has happened most successfully, it has really taken a lot of the load off these Area Agencies on Aging to enhance and extend their resources substantially, so we truly value their support and we are going to continue this higher level of funding.

Senator TALENT. It has really validated the Older Americans Act structure, Mr. Chairman——

Dr. MCCLELLAN. Oh, absolutely.

Senator TALENT [continuing]. Because they have just been absolutely essential. I am sorry, 30 seconds. I know others have the same issue. My pharmacists are less concerned about what they do with transition issues. Obviously, they are concerned because people need to get the pharmaceuticals they need to get reimbursed, but the way the system is set up, independent pharmacies in smaller towns are going to be at a structural disadvantage in terms of reimbursement. You and I have talked about this. Tell me what your thinking is on it now and maybe what we can do to help them that will not undermine the basic structure of law, and then I am done. Thank you.

Dr. MCCLELLAN. The community pharmacists are doing terrific work, especially in rural communities. From hearing from them, there are several things that we know that we can do to help that I think they would find useful. One of them is making sure that the contracts that the plans have with the pharmacies are enforced, and that includes also other requirements like network requirements. In many of these rural communities, as some of you have mentioned, there is just one pharmacy there. Maybe Senator Salazar mentioned it. They are the main focus of support in the

community. Well, those pharmacies need to be part of the network in order for the plans to meet our access requirements under the drug benefit. So we will make sure that the plans meet the access requirements and that means that they are going to have to pay the pharmacies enough for them to meet their costs and participate in the program.

Also, many of the community pharmacies have faced added burdens because of differences in the messages that they are getting from the different plans because they may not have been able to use all the support tools that we have set up and we intend to be available for every pharmacy right off the bat. We have taken some new steps to work with the software vendors and the other organizations that support these community pharmacists, as well, so that we can help make sure they are able to continue to provide a high level of service.

This is going to be an ongoing concern for us. This is a big change in the way pharmacies bill, especially many community pharmacies, a big change in the way their work process goes and their business process goes. So I think the best thing for us to do is to keep in close touch about these issues and make sure that we are continuing to respond to the ideas that we hear out in the field about making the benefit work as smoothly as possible.

The CHAIRMAN. With the indulgence of my colleagues, the order is next Senator Burns and Senator Martinez. Senator Nelson has one burning question and needs to be across town in a minute. Do you mind if he asks that first?

Senator BURNS. Let him burn the barn down.

The CHAIRMAN. All right. Senator Nelson?

Senator NELSON. Thank you to my colleagues. This is just a follow-up to the earlier conversation. Dr. McClellan, could you tell us for the record CMS's, your shop's, position with regard to extending the Medicare deadline for 2006 and also whether CMS supports allowing seniors to change plans once during 2006 if they make a mistake?

Dr. MCCLELLAN. Senator, we are not supporting that legislation at this time. What we are focused on right now are the main topics that have already come up at this hearing, which is to make sure that everyone is able to take advantage of the new coverage, and we have seen a lot of progress on that because we have identified the problems, have been taking steps to fix them, and we are seeing millions of prescriptions getting filled. We are seeing tens of thousands of people signing up every day. That is still the No. 1 topic on calls to 1–800–MEDICARE. We are helping people find out about what the coverage means for them and sign up in a matter of minutes. So anybody who has questions calls at 1–800–MEDICARE and go to the many events going on around the State of Florida right now to find out about the coverage.

So that is where we are focused right now. I am sure we are going to have a lot more discussions about this in the days and weeks ahead, though.

Senator NELSON. Thank you, Mr. Chairman. We are going to take this issue up later today in the amendments to the tax reconciliation bill, and thank you to my colleagues for your kind opportunity for me to ask the question.

The CHAIRMAN. Thank you, Senator Nelson.

Senator Burns.

Senator BURNS. Thank you, Mr. Chairman.

I asked the question a while ago as far as what actions we take as Congressional offices and our attitude toward the program and why it is so important. I go back to the days when they issued the card, you know, the drug card. The rhetoric was so negative that a lot of people did not even attempt to go sign up for their discount card and therefore went and paid a lot of money out of their pockets when they could have been saving about $600 a year——

Dr. MCCLELLAN. Or more.

Senator BURNS [continuing]. Or more, because they were afraid of it. So I think the way we approach this will not only decide the fate of the program, but it will also provide seniors with some confidence that this is designed for them, and as we see glitches along the line, we will fix those. That is a point of legitimate debate here as a policymaker goes. So that is why I said that a while ago just absolutely throwing it out and saying, well, it is a bad program and then scare them further does not accomplish a great deal if this is for the benefit of them, and that is the reason I asked for that. I still say that—and we have got to have some way as Congressional, but I will say that the resource centers, senior citizen centers in Montana have been marvelous and that works.

Now, we have a little different circumstance in Montana. How about my reservations? When we say rural areas, Dr. McClellan, as you know, in Montana, we have got a lot of dirt between light bulbs out there and these smaller rural pharmacies have a hard time making a go of it in our smaller farm communities and now they are asked to do some things that sometimes puts a real financial burden on them. It was my understanding that that commitment had been made, and I think it has been, but we have got to make sure of that.

Have we made any kind of an effort by your office for an outreach to my reservations, because as you know, we are dealing in a different kind of a circumstance there than we are, say, with the average Montanan?

Dr. MCCLELLAN. Absolutely. I have participated in a number meetings with tribal leaders from around the country, including representatives from some of the tribes in Montana. The drug benefit is for people who are Native Americans, who are Alaska Natives, just as much as for any other beneficiary in the program. The drug plans have to offer contracts to the pharmacies on the tribal lands. Many of the plans are now serving people in Indian country and I am going to continue monitoring that very closely to make sure that we work out—there are some special issues in how, for example, Indian Health Service Funds interact with the drug benefit. But people who are living in tribal lands definitely should pay attention to this program. It can be real help for them, just as much as any other American, in lowering their drug costs.

Senator BURNS. We are going to start a program of outreach to those reservations and I would ask if you can have some resources, maybe some people or something that we could—and if you have done some real background work on it, that is most helpful.

Dr. MCCLELLAN. We can.

Senator BURNS. That outreach, I think, is really needed. I was talking to the Chairman of all the reservations that I have in Montana the other day and that seemed to be a topic of discussion. Of course, sometimes, you know, their people, they have a communications problem, too. We all have communications problems. So that outreach is very, very important. So we will be in touch with you and I thank you for your testimony here today. You have clarified a lot of stuff as far as I am concerned.

But how can we benefit you? What role do you see we should play in carrying that message and to make this work? We want to make it work to the maximum if we possibly can.

Dr. MCCLELLAN. I think your continued close work with us on identifying problems and letting us know about it. One of the things I have been most impressed with is the way that district staffs, the local staffs of your offices, have worked closely with our regional offices around the country when you identify someone who has a problem to get them into our casework system and get that problem fixed, and also to enable us to solve any systematic problems.

You know, we talked a little bit earlier about this very big concern I have about a particular group of people who are dually eligible, who have Medicare and Medicaid and were previously getting their drug coverage from Medicaid, who we are working right now to make sure they can all take advantage of the coverage effectively. That has been our biggest concern.

For the vast majority of seniors who sign up for this coverage, I think the main thing for them to know is if you give it a little bit of lead time, things will work very smoothly. So for a typical senior signing up, they can save half on their drug costs or more. There are lots of places they can go in Montana and every place else for help. About a week after they enroll, they will get a letter in the mail from their drug plan. Keep that until you get your drug plan I.D. card, which will come in a few weeks. If you allow that couple of weeks or so between when you sign up for the coverage and when you start to use it, you are likely to have a very good, smooth experience the first time you use your coverage and you are going to start saving on your medicines and have that peace of mind from drug coverage, which is a new thing in Medicare.

Senator BURNS. The only thing I am trying to do is cut down on the number of phone lines I am going to have to have to make it work. But we want to work with you and we want to work with the seniors because I don't want them left behind. I don't want anybody left out of this program that can take advantage of this program because it is designed for them——

Dr. MCCLELLAN. That is right.

Senator BURNS. To get it in place. Then if we have got some problems later on, then let us tackle those problems.

Thank you, Mr. Chairman, very much.

The CHAIRMAN. Thanks, Senator Burns.

Senator Martinez.

Senator MARTINEZ. Thank you, Mr. Chairman.

Dr. McClellan, we appreciate your being here today——

Dr. MCCLELLAN. Thank you, Senator.

Senator MARTINEZ. All the work that you are doing to make this program be a success, which I know it will be in time. It is already a success, but even a better success in time.

In my State of Florida, we have many nursing home residents and a number of them, quite a number of them, in fact, are part of the dual-eligible population and were auto-enrolled in Part D programs. However, many of the programs they were enrolled in do not cover the drugs that they need. Under the Federal and State regulations, nursing homes are responsible for providing prescription drugs to their residents, but they are prohibited by Part D marketing guidelines from helping dual-eligibles choose a plan that meets their needs.

So will CMS consider revising its regulations to allow nursing home professionals or pharmacists to assist residents in selecting Part D plans designed to meet their needs?

Dr. MCCLELLAN. Thank you very much, Senator, for asking that question. The nursing home administrators and staff, the long-term care pharmacy staff in the nursing homes are a great resource for information about the new drug coverage and they are working very hard with us to help all nursing home beneficiaries take advantage of it. This is a big help for many people in nursing homes and many States. The Medicaid payment rates have not been good and many of the other nursing home residents are spending thousands of dollars of their own money on prescriptions, so this is a very important benefit for them and we want it to work.

Our guidelines, and just to clarify this, do allow nursing home administrators and pharmacists to provide objective information about the drug plans. We try to draw the line with steering. So there may be a particular plan that—a drug the pharmacist may like that is OK from the pharmacist's standpoint, but when you are advising a beneficiary, it is important to use objective information, like what the beneficiary's costs are going to be, whether their current drugs are all on the formulary. Things like that are absolutely fine for the nursing home administrators, other nursing home staff to talk to their beneficiaries about.

If we need to clarify this further with some of the nursing homes in the State, I would be delighted to work with you on doing so. We have worked very closely with many of the nursing home associations, ACA, ASA, the Alliance, and others to make sure people in the nursing homes know what they are allowed to do, and they are allowed to provide objective information to help people choose a plan. They just can't steer based on financial, you know, direct financial incentives or something like that. But we want to make this work for everyone in the nursing homes.

Senator MARTINEZ. As we run into problems on that, we may get with you about seeing how we can break through, but——

Dr. MCCLELLAN. We would be delighted to do that. We have an ongoing outreach effort with the nursing home associations and through our regional offices with the State and local associations, weekly phone calls, things like that that we can use to help get any needed clarifications out.

Senator MARTINEZ. Let me say, I want to say a good word for your regional offices.

Dr. MCCLELLAN. Oh, they have been terrific.

Senator MARTINEZ. We have worked very closely with them. They have done a terrific job and have really been of assistance to our folks as they have tried to help people with the program. We had a series of meetings, as many others have done, to try to help folks to get enrolled and so forth and they have been a real great resource and we appreciate it.

Dr. MCCLELLAN. I will take that back to them. Thank you, Senator.

Senator MARTINEZ. With the implementation of the Part D program, Medicaid coverage of prescription drugs for dual-eligible population was transferred to the Medicare prescription drug program. Do you see any possibility of transferring those beneficiaries exclusively to Medicare so that all of their care would be under one roof eventually?

Dr. MCCLELLAN. Well, it is a very—the advantages of coordinated care for dual-eligibles are obvious. They have some of the highest costs in our health care system and have some of the highest rates of complications from medication interactions, from preventable complications like bedsores and other problems that lead to hospital admission, worse outcomes, and higher cost.

There are a number of plans in Medicare now called special needs plans that provide a broader range of services, including, in many cases, coordination with the long-term care services in State Medicaid programs. We are looking at ways that we can support Medicaid and Medicare work more closely together to provide this kind of coordinated care, and as you know, the State of Florida is working with us on a new waiver program in Medicaid that would give people with a disability and their caregivers more control over how they can actually get these kinds of integrated services so it is a lot easier to put some of the Medicaid traditional long-term care support services together with coordinated care for medical benefits and drug benefits with a reform program like Florida is working on right now.

I don't know that there is going to be major legislation on this right away, but I think under our demonstration authorities in Medicare, with the new plans in Medicare and with steps like the State of Florida is taking, there are some real opportunities to provide much better coordinated care with fewer complications and lower costs to dual-eligibles. So we will pursue that with you, as well.

Senator MARTINEZ. Sounds good. One last issue is the pharmacists and the State of Florida getting paid if plans take too long in doing so, so we would be interested in seeing how you will monitor this once a reimbursement system is established to make sure that timely payment is made to those that are due.

Dr. MCCLELLAN. We will be monitoring that closely. We have had this time lag now as people switch from one payment system to another that hopefully we are going to be getting past with the checks really starting to go out last week, this week, and so forth, but we will be monitoring that closely.

Senator MARTINEZ. Thank you. Thank you, Dr. McClellan.

The CHAIRMAN. Senator Wyden.

Senator WYDEN. Thank you very much, Mr. Chairman, and thank you for all your leadership and Senator Kohl's, and also a

bouquet to my colleague from Arkansas who is letting me go ahead of her because we have got the intelligence stuff.

Senator LINCOLN. Oh, we love bouquets.

Senator WYDEN. You are gracious, as always.

Dr. McClellan, when I came to the Congress after being director of the Gray Panthers for 7 years, I saw that a lot of senior citizens would have a shoebox full of private health insurance policies. They would have 10, 15, sometimes 20 policies. I wrote a law that drained that swamp so that now there are essentially ten policies in the private sector where people can actually compare the coverages one to another and actually use the market to make choices for them.

I don't understand why CMS won't do that for this prescription drug program. I refer you to the testimony of an Oregonian that Senator Smith invited, Mr. Kenny, who advocates that. Let me tell you what I think has been the consequence of your not using the kind of approach I am talking about, that is senior friendly so that older people can compare the choices. I think you have done great damage during this roll-out to the cause of private sector choice in American health care.

I voted for this program. I want to make it work. What has happened is instead of using an example like we had with these private policies sold to supplement Medicare, we now have in the State of Oregon more than 70 choices, more than 70 choices. So older people say they can't compare. They can't look and say, well, maybe this one rather than that one.

So I think you ought to be moving in a hurry to make this more user friendly, more understandable, and there is a model out there right in front of you that you can use, the Medigap model for the policies older people bought to supplement their Medicare. It is at the last page of Mr. Kenny's testimony where he specifically says something like that would be helpful. Can we start on that right away, trying to make sure that we do have innovation in the private sector. We are all for that. But making these choices more understandable and specifically will you support looking at this Medigap kind of model?

Dr. MCCLELLAN. Well, Senator, I know how much you have worked to make competition succeed for seniors and for other Americans and I do want to keep working closely with you on improving how this program is working, as well. What we have seen so far is more of a response from the private sector than many people, I think you and I included, expected there was going to be in this program when the law was passed. That is why the law didn't include, or may be one reason why the law didn't include these specific kinds of standards for types of plans.

The advantage of that is that we are seeing the costs come in much lower and benefits come in better than expected. People can now get drug coverage through Medicare that is better than the standard Medigap policy drug coverage for about a tenth of the cost of that Medigap drug coverage. So there are some real advantages to the competition and choice that we have seen so far.

But I absolutely agree with you. I talk to a lot of these seniors around the country, as well, that when they first approach this program and they haven't had a chance to talk to a counselor or talk

to somebody at 1–800–MEDICARE about which choices are relevant for them and how they can find out how to take advantage of the program, that can be a real challenge for them and we are trying to break through that now. I do think, also, that now that we have seen competition work to bring down costs and improve choices, we are going to see competitive give seniors the next thing they want, which is more simplicity and more understanding of how these choices actually work, and we will be pushing that process along. I want to keep talking with you about the best way to do that.

Senator WYDEN. I am still unclear why you think it doesn't make sense for government to try to structure these choices for older people so that instead of 70 policies—I am not wedded to a specific number—we have whatever the number is so that people can actually sit at their kitchen table and compare them, because I don't think that the private sector in and of itself is going to produce more simple, more understandable policies. It didn't happen with Medigap. It didn't happen. It happened because people like former Senator Dole and the late Senator Heinz worked with me, and we said that government and the private sector are going to structure the choices. So I will ask you once again, are you saying you won't look at that?

Dr. MCCLELLAN. I am saying that we do want to look at ways to make it easier for people to make—even easier for people to make choices among plans.

Senator WYDEN. Even easier? It is bedlam out there. When you use the word "even easier," talk to Mr. Kenny who is 78 years old about what his friends say.

Dr. MCCLELLAN. And I——

Senator WYDEN. Older people are saying, you can't even sort this out with an advanced degree. They don't say that with Medigap, with their private policies to supplement Medicare——

Dr. MCCLELLAN. I think looking toward simplification is absolutely the next step in this process, now that we have got the benefit in place. If we had tried to put in a standardized benefit back when the law was passed, we would have ended up with a deductible with a doughnut hole with things that people clearly don't want and they are not choosing now. We are seeing people choose plans that have the kind of coverage they want and now we need to—I agree. We need to help them get to more simplicity. But I think the drug plans are competing to do that, too, and that is what we want to help along.

Senator WYDEN. I didn't propose a Medigap-type amendment to this legislation for a reason, because I wanted the private sector to have the first crack at it. But I didn't conceive that the roll-out in the last few months would be bungled this way. I don't think it had to be this way. I think you could have worked with the private sector without a law on a voluntary basis and persuaded them, look, let us come up with some uniformity in the terms and make it possible for people to compare the choices. It could have been done voluntarily. It wasn't done voluntarily.

Now we have got a mess on our hands and I hope that you will work with myself and others because I think it didn't have to be

this way. There is a model that could be an alternative. Read Mr. Kenny's statement. He calls for that in his testimony.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Wyden.

Senator Lincoln.

Senator LINCOLN. Thank you, Mr. Chairman, and thanks for holding such an important hearing today. Many of us have been swamped by calls in our offices by our seniors and disabled across the State who are truly frustrated about the, as you say, the choices, which we do want choices, but certainly their ability to access the technical assistance they need to understand those choices, so we appreciate your patience. I do, certainly. I am at the end of the totem pole here.

Dr. MCCLELLAN. I appreciate all your——

Senator LINCOLN. I voted for adding this prescription drug benefit to Medicare and I want it to work and I think I have demonstrated that. I have met with more than—over 3,000 seniors across our State. We held meetings which your district division offices out of Dallas were very gracious in helping us with, trying to make sure that we could be prepared and that people would have the knowledge and information they needed to make wise choices.

We could quickly see that it was difficult. In time, I came back to Washington and joined my colleagues, concerned about the short 6-week transition period for particularly our dual-eligible beneficiaries. I had hoped that we could work with you to make that transition period longer. It is hard to believe that while everyone else on Medicare was given 6 months to make that transition, this group of individuals, which often can be considered some of the most at risk, perhaps, were given only 6 weeks. So I hope that as we move forward and we look for ways to improve on this legislation, as we did with the extension of that transition period, that as opposed to fighting, our deep desire is that you will work with us to look at the ways we can correct.

If there is anything that we did in moving into this proposal, and I think many of us that have supported it and want to continue to support the effort, is that we don't look at it as a work of art but a work in progress and that we can recognize the things that we can do better and that you will work with us in Congress to change those in a way that will make a difference.

As I said, these are beneficiaries that are, in many instances, our most vulnerable, and in Arkansas, it is a disproportionate share, a greater share of our seniors that fall into that category, and, as is the Arkansas way, our pharmacists, our medical providers have been working diligently to make sure that these individuals who are their neighbors and their friends in the community are going to get what they need.

I guess what we want to know from you is how we can, and you particularly at CMS, can continue to make these individuals, particularly our pharmacists, whole.

My office has received a tremendous number of calls from pharmacists who are concerned about the timing of their reimbursement——

Dr. MCCLELLAN. Right.

Senator LINCOLN [continuing]. From these prescription drug plans. The plans have in their contracts that they will be reimbursed every 2 weeks, and yet when the pharmacists finally make contact with the plans, one, they are not able to negotiate anything with them, and they are told that they won't get their payments in 2 weeks. It is crazy. I mean, I know that some of the larger pharmacy groups out there have got the technology and the capability to overcome that. They also have the resources to be able to make it through that period of time, but a lot—as Senator Burns mentioned, in rural America, your local pharmacists don't have that.

I have had at least three of my pharmacists call and say they have had to take out a loan from the bank in order to make it through and pay their suppliers and that is just inexcusable. I mean, these are people who are dedicated to their constituency and their customers and their community, and to take out a $500,000 loan just to make it through the month is something that, in my opinion, is not only unintended in this legislation, but it is unacceptable. So I hope that as we have led seniors to the doorstep of this opportunity of a new prescription drug component that we will not leave them or the people that serve them at that doorstep.

I guess my question to you is, what are you going to do in terms of the timing of this? Arkansas to date has spent about $3.8 million now, almost $4 million. You say you want to make it all whole, and I want to believe you on that, but I also think that the timing on this is incredibly important. I mean, are you going to guarantee us in 30 days that these people are going to be paid? Are you going to go back to these plans and be an advocate on their behalf?

Dr. MCCLELLAN. First of all, Senator, I would like to thank you for all your close work with us on the implementation of the benefit. As you mentioned, your office is working closely with our regional office, answering people's questions, helping any individuals who are having difficulty, and helping more people enroll. I think that is why Arkansas has one of the highest rates in the Nation of enrolling in this program——

Senator LINCOLN. We want it to work.

Dr. MCCLELLAN [continuing]. The program is having a big impact for people in the State who have been struggling with their drug costs. The State is going to be reimbursed. We have been in very frequent contact with Governor Huckabee, who has been a real leader on this issue and helping pharmacists, that we are having difficulty at the beginning and in working with us on getting an effective reimbursement plan in place. So the State is going to be reimbursed for those costs. But I want——

Senator LINCOLN. Do we know the timing on that?

Dr. MCCLELLAN. Well, the model—we are releasing a specific template, just a checklist. That is all the State has to fill out in order to get into this reimbursement program. That will be available as soon as today. We hope that the States like Arkansas will be able to quickly complete this agreement with us and then the reimbursement process will actually involve the State sending us the claims that they have that they haven't been able—where the pharmacist couldn't bill the Medicare plan properly and we will do the reconciliation with the drug plans and we will also pay for any

additional costs to the extent that any competitive drug plans come in at a lower cost than Medicaid. We will make that up, as well.

But I want to talk about the pharmacists specifically——

Senator LINCOLN. Good.

Dr. MCCLELLAN [continuing]. Because they do have a timing issue, and I have heard that from talking to many of these independent pharmacies around the country and their associations. They went from being paid by Medicaid, often on a weekly basis, to these contracts that you mentioned which often have 15-day payment cycles. Some of them are less. Some of them are less. Some of them are 10 days. Some of them are a little bit longer. Those checks are just now starting to come in. In the meantime, it has been a real stretch for many of the community pharmacies to meet their short-term expenses and to pay the distributors and others.

We have been in contact with basically everyone involved in the whole pharmacy drug distribution chain, the wholesalers and others. Many of them have relaxed the terms for payments during this transitional period to help pharmacists through that process, and now, now that those contract terms are coming due, we are watching very closely to make sure that the plans do pay on schedule so that they can get those costs covered and get through this transitional period.

Senator LINCOLN. Do you feel like you have the sufficient authority to regulate the plans?

Dr. MCCLELLAN. The plans have contracts with the pharmacies and——

Senator LINCOLN. But they won't negotiate with them. They won't talk to them.

Dr. MCCLELLAN. Well, our regulatory authority goes to making sure that plans meet our standards for having access to pharmacies. So if a pharmacy, especially in a rural area, it is the only pharmacy around, isn't getting a rate that they think is acceptable and permits them to serve Medicare beneficiaries, if they don't participate, the plan won't meet our standards for having——

Senator LINCOLN. So do they go through an appeals process? I mean, is that what you have in place?

Dr. MCCLELLAN. Well, the plan wouldn't even get approved if it doesn't meet our pharmacy access standards.

Senator LINCOLN. But the point is if they are not meeting that and they are still the plan that exists for that individual, that constituent, what is the pharmacist—what do they have? What power do they have? Do they have an appeals process? Do they come to you and say, this plan is not adhering to the contract?

Dr. MCCLELLAN. If it is not adhering to the——

Senator LINCOLN. Are you going to fight that contract for them?

Dr. MCCLELLAN. If it is not adhering to the contract, we want to hear about any complaints about failure to adhere to contracts and——

Senator LINCOLN. That is what they have been doing, is calling you about the timeliness.

Dr. MCCLELLAN. Well, we will take action, and we have heard about a few of these already. Some of the ones that we have seen so far were cases where the plan submitted, the pharmacy submitted its claims for services delivered, say, in the first couple

weeks of January. Then the plan has 15 days to pay and those checks are starting to go out now. We have this transitional issue. So we are watching very closely to make sure that happens the way it is supposed to happen, and if we see any systematic pattern of complaints about plans not following their pharmacy contract, we absolutely are going to follow up on that with the plans. We have specific compliance——

Senator LINCOLN. So you feel you have enough authority——

Dr. MCCLELLAN. We have specific compliance staff and compliance officers and specific contacts on compliance issues with the plans to make sure they are adhering to the contract terms.

Senator LINCOLN. You feel comfortable that you have enough authority and enough individuals on point to do that?

Dr. MCCLELLAN. At this point, we do. We are watching complaints that come in and making sure that contracts are being adhered to, and if we—we will let you know if there end up being bigger problems——

Senator LINCOLN. Where could I or a pharmacist get more information about these contracts?

Dr. MCCLELLAN. The contracts between the plans and the pharmacies are filed. Plans have to make available a contract for any pharmacy that potentially wants to do business with them. There is an "any willing pharmacy provision," and in order to meet our pharmacy access standards, the plans must have pharmacies available and convenient access for all of their beneficiaries. The plans have filed information with us showing that they have got a standard contract——

Senator LINCOLN. So the pharmacists call CMS to get that contract?

Dr. MCCLELLAN. Well, the pharmacists will have that contract directly because they have entered into the contract with the plan. So they have got their contract information directly and what we want to know about is, is a plan failing to adhere to the terms of their contract——

Senator LINCOLN. OK, and so——

Dr. MCCLELLAN [continuing]. That is something that the pharmacist is——

Senator LINCOLN [continuing]. Hopefully, you are the one that will help them as an advocate if there is a problem.

Dr. MCCLELLAN. Yes, as well as the pharmacy associations often help with these contractual issues with plans and we do want to provide some assistance, as well.

Senator LINCOLN. We also have a State law——

Dr. MCCLELLAN. If I could just add one more issue on this topic, early on, especially, the pharmacists were having real trouble sorting out billing issues because they couldn't get through to plans or couldn't get through to us.

Senator LINCOLN. Yes.

Dr. MCCLELLAN. As I said already in this hearing, we have taken some major steps to make sure any pharmacist can contact Medicare virtually immediately, with no waiting, on our toll-free pharmacist help line. That is working very smoothly now in terms of quick access for pharmacists with questions or complaints. Pharmacies also should expect a high level of performance from the

drug plans. Many of the drug plans have taken some great steps over the last several weeks to improve pharmacy access to them so they can resolve any of these contract or payment issues, and we expect all the plans to do that——

Senator LINCOLN. There was definitely a big problem in contacting——

Dr. MCCLELLAN [continuing]. That kind of smooth and direct contact with the plans can also go a long way to helping with these issues and that is why we are going to increase our monitoring of plan performance on their pharmacy lines. Again, we have seen lots of plans make big improvements. They are doing very well on quick access——

Senator LINCOLN. Their Washington offices probably called in, because I found when I couldn't get hold of you or to somebody in CMS that could answer my question, I called their government relations office here in Washington and started sending my constituents to them because the questions there just simply were inexcusable in terms of being required to pay deductibles and copays and other things that were clearly out of sync with what we had produced in the legislation.

Dr. MCCLELLAN. I am glad we are seeing progress there, but we are going to obviously keep watching this very closely until all these problems are fixed.

Senator LINCOLN. We have sent you a letter. Arkansas has a State law that allows patients to choose their own pharmacy. In long-term care settings, we are one of the few States which has historically interpreted the rule to allow each individual to decide which pharmacy they want to use. We sent you a letter on the ninth of January hoping that you could promptly clarify the intent of the patient's rights to choose a pharmacy as it exists under State laws. Can you give me an indication when I might get some guidance issued from you?

Dr. MCCLELLAN. I can. In fact, we have been working directly with community pharmacists on this. We have had an exchange of letters with the National Community Pharmacy Association to make clear a couple of things. One, we do expect some standards for long-term care pharmacies and plans that are contracting with them to meet. Basically, a plan must support the required level of services for a long-term care pharmacy and it must provide access to needed long-term care pharmacy services for every beneficiary in the plan, whichever long-term care pharmacy they happen to be using.

We have also made clear in this exchange of letters that the plans—that there is no restriction in our policy on which pharmacies a nursing home can contract with to provide services. In fact, in a number of States, we are seeing more competition where community pharmacies are taking advantage of the fact that we are trying to set up a level playing field here to supply access to services and pharmacies.

So there is nothing in our rules that prohibits beneficiaries from getting the long-term care pharmacy choice that they need. It is really more of an issue directly for the nursing home and we want the nursing homes to know that if they want or if their beneficiaries want to contact with or get their services from different

long-term care pharmacies, that is absolutely permitted under the Medicare rules.

Senator LINCOLN. Or local?

Dr. MCCLELLAN. That is right.

Senator LINCOLN. Not just long-term, but local pharmacies, too.

Dr. MCCLELLAN. Local pharmacies. Obviously, local pharmacies, too.

Senator LINCOLN. Just last, in the nursing home situation we have in Arkansas, they say their pharmacies are still experiencing a rejection rate of 25 percent. Twenty-five percent of the time, they are getting rejected, and the plans are still charging copays to the nursing home patients, which are actually prohibited, I think, under the law.

Dr. MCCLELLAN. That is right, and this is an example——

Senator LINCOLN. Can you tell me how you are addressing that?

Dr. MCCLELLAN [continuing]. I talked at the outset about this being one of the biggest problems that we are working on right now and that we are taking steps to fix. It has several sources. One is making sure that the plans all have complete and accurate data on the nursing home status of their beneficiaries and that they are using it. To help make sure that happens, we have sent out the complete lists of all the dual-eligible and low-income beneficiaries in a plan to those plans. We most recently sent another list of this information out on January 30. We also are handling casework and complaint issues. So if we see a pattern of a specific plan not having the right copayment information in, we can go work directly with that plan to try to get it addressed.

We still need to make more progress on this, but it is absolutely one of our top priorities to make sure everyone has the correct copayment information, including the zero copay information in the nursing homes——

Senator LINCOLN. Well, I would just say that in enforcing these plans and the policies, many of the pharmacists are reporting that when they call the plans, the staff that are answering the queries from the plan don't know about the policies.

Dr. MCCLELLAN. One of the technical issues that we have been dealing with with certain plans over the last few weeks is that there is a—I don't want to get too technical here, but there is a specific piece of information that we send out in the files that have information on beneficiaries in the plans on the nursing home status of a beneficiary and we do want to make sure that all the plans are using that. Most of them are using it just fine now, and we have, again, double-checked to make sure they have got the right information in place. So I think you should expect to see continued progress on this, but you should keep letting us know if you are seeing particular cases——

Senator LINCOLN. Don't worry.

Dr. MCCLELLAN [continuing]. I know you will, but that is why this is one of our very top issues for long-term care pharmacies right now.

Senator LINCOLN. I just hope and pray that you won't be afraid to make changes that need to be made in order to make this a success. There is clearly from so many of us, we realize that a prescription drug component of Medicare is essential, but I don't think

anybody has all the right answers and I hope that as we work through this, we are willing to make the changes that need to be made to make this a success. No pride of authorship or no, you know, I don't know, possession, of possessiveness in terms of what we have done here, but if we get it fixed and we can get it fixed in a way that will sustain it as a program and not, again, lose the confidence of the seniors out there, whether they are the dual-eligibles and the most vulnerable or whether they are those that are healthy and yet going to be looking to Medicare in the future, to engage in what we need to have them engage in, because participation is going to be critical in the long-term success of this.

So thank you for your help and I appreciate it. I know, Mr. Chairman, if I may ask unanimous consent to include my statement in the record, I apologize for running late. But I do appreciate working with you, and again, I hope you all keep answering your phone lines because we are going to keep calling.

Dr. MCCLELLAN. We absolutely will, Senator.

Senator LINCOLN. OK, thanks.

Dr. MCCLELLAN. Thank you for your leadership and your passion. We have taken some new steps that we just announced yesterday on exactly these issues and we will keep making changes to fix these problems.

Senator LINCOLN. I would say that you would get a resounding applause here if you gave a greater emphasis on timing, because that is what is killing people out there in the hinterlands.

Dr. MCCLELLAN. For the pharmacies, I know.

Senator LINCOLN. For the pharmacies, particularly, but the States, as well, I mean, to have a better idea of when those resources are coming and when they can expect. If it is just setting a deadline for yourself or for us, in a way, that we are going to make sure that that happens within a certain period of time, it gives them a great reassurance, not to mention the financial institutions that are backing them, so thank you.

The CHAIRMAN. Thank you very much.

[The prepared statement of Senator Lincoln follows:]

PREPARED STATEMENT OF SENATOR BLANCHE LINCOLN

Mr. Chairman, thank you for holding this important hearing today on the problems our constituents are having with the new Medicare prescription drug benefit, or Part D.

I voted for adding this prescription drug benefit to Medicare, and I want it to work. I know it's not a perfect law, and I have voted several times in the last two years to improve it. Last year, I and many of my colleagues grew concerned about the short, six-week transition period for "dual eligible beneficiaries," those 6.4 million Medicare beneficiaries who also qualify for Medicaid because they are low-income.

These beneficiaries are among the most vulnerable of America's citizens. They are disproportionately women and minorities and live alone or in nursing homes. Nearly three quarters of them have an annual income of $10,000 or less. Thirty eight percent of them have a cognitive or mental impairment. Over a third of them are disabled. Less then half have graduated from high school. And, they use at least 10 more prescription drugs on average than non-dual eligible beneficiaries. They are more likely to have chronic conditions like heart disease, pulmonary disease, or Alzheimer's Disease.

While everyone else in Medicare was given six months to enroll in a prescription drug plan, *these dual eligible beneficiaries were given only six weeks.* Moving 6.4 million seniors and individuals with disabilities to an entirely new system is a major undertaking. Even MedPAC, an independent advisory committee, had warned that

even large, private employers need at least six months to transition their employees' drug coverage from one pharmacy benefit management company to another.

It is obvious that the dual eligible beneficiaries have experienced the most problems since January 1st, and I believe the problems they have had were entirely predictable. I voted to add six months to the transition period for this vulnerable population, but officials from the Centers for Medicare and Medicaid Services said that our amendment was unnecessary. They said that they were ready.

Since January 1st, my office has been swamped with calls from upset seniors and pharmacists. Dual eligible seniors weren't in the computer system, the phone lines at the plans and at CMS were jammed, and pharmacists were uniformed of the various processes they needed to use. Seniors were placed in plans that did not cover their specific medications and were told to pay high deductibles and co-pays that they weren't allowed to be charged under the Medicare law. Pharmacists are not getting paid on time and have to take out loans to pay their bills and keep their doors open. Half the states, including Arkansas, have had to step in and fill in the blanks where CMS's transition plan has failed.

These problems could have been avoided. I feel that the administration failed to fully prepare for the implementation of this new program even after repeated warnings from me and other members of Congress. But, now that we are in this situation, we must fix it. The government must not leave our most vulnerable seniors at the doorstep to fend for themselves. I want to work with CMS to fix these problems and avoid them in the future. This hearing and other hearings are a necessary part of that process. Thank you, Mr. Chairman.

The CHAIRMAN. Dr. McClellan and Linda McMahon, as you can see, notwithstanding all that is going on in this world, this is what is going on in our communities.

Senator LINCOLN. That is right.

The CHAIRMAN. You have been on the hot seat and we thank you for your candor and your participation here, and with that, we will call up the next panel.

Many of my colleagues have been pulled in different directions, but we do want to hear from all of you who are on these panels because what you have to say is important to the Senate record. This is being broadcast by C–SPAN and there are undoubtedly many seniors who are anxious to hear what is being said this morning and your testimony, as well.

Bob Kenny is the first witness of the second panel. He is a Medicare beneficiary who hails from my home State of Oregon. He is from Tillamook. No doubt many viewers have been eating cheese from that area. He used the Internet to enroll in the prescription drug plan, and as a volunteer with the State Senior Health Insurance Benefits Assistance Program helped many other seniors enroll, as well. He will share his experience and offer his insight on how the drug benefit program has been working so far.

He will be followed by Mr. Mike Donato, who is a dual-eligible beneficiary from Mansfield, OH. Mr. Donato previously received his prescription drug coverage through Medicaid. He will share with us his experience with the new Medicare drug benefit thus far.

Then we will hear from Sharon Farr, who is Mr. Donato's counselor, and she will be discussing her role at the Center for Individual and Family Services.

Bob, welcome. Thank you for being here.

STATEMENT OF ROBERT J. KENNY, MEDICARE PART D. BENEFICIARY, TILLAMOOK, OR

Mr. KENNY. Good morning, Mr. Chairman, Senator Kohl. I am delighted to be here today to give the message that there really are successful sign-ups for Medicare D. I work with Medicare D both on a personal basis and as a volunteer for the Senior Health Insurance Benefits Assistance program, SHIBA.

At 78 years of age, I have recently undergone a triple bypass operation and have mild emphysema. My drug cost would be about $300 a month without Medicare D. With my Medicare D prescription plan, my total cost, including premium, will be cut to $141 a month, a savings of 53 percent, or a total of $1,908 a year. In addition, I just recently changed to a preferred drug from a non-preferred and will save an additional $30 a month that way, and I plan to save more money by going into mail order.

How did I go about signing up? Because of my SHIBA training, I knew the shortest route would be to use the government website Medicare.gov. I went to that site armed with my list of six prescription drugs and my Medicare card. The site was new to me, so I did site exploring and then started in earnest. I told the site that I wanted to compare plans, filled in the personal information and after that my drug usage. It was time consuming, about three-quarters of an hour. The comparison showed the plans from the least to the most expensive with the yearly cost for each. I checked pharmacies to make sure mine was included and identified the parent company of the plan as a stable firm. In addition, I went over the math to verify the yearly cost figure. Having decided that the lowest-cost plan was acceptable, I enrolled.

My membership card arrived in a little over 2 weeks. Shortly after January 1, I registered my plan with my pharmacy and ordered medication. The medication was quickly approved and provided at the proper discounted price. Since that time, I have filled more prescriptions with the same results.

I am sure that my good results in some measure reflected my half-day Medicare D training and my computer savvy.

My work as a SHIBA volunteer began in 1993. According to the last census, my county of Tillamook in Oregon has a population with 19.8 percent seniors as compared to 12.4 percent for the U.S. as a whole. I have counseled about 30 Medicare D patients since mid-November. The seniors that come to me for Medicare D are often very confused by the publicity that tells them they should be confused, or they have been talking to a plan salesman, or they have been looking into plans and are really confused.

In most cases, this confusion was either eliminated or considerably reduced by going through the steps required by Medicare.gov. Few of my clients know how to use a computer, and those that do may not have Internet access. At the end of the appointment, however, almost all were thrilled by the amount that they would save in drug costs. There has been only one client of mine who found there would be no reduction in her costs. She was a lady in extremely good health who did not spend enough to cover the $250 deductible. Even this lady decided to enroll anyway in order to avoid the 1 percent per month penalty which would be added to her premium if she did not enroll before May 15.

Lest I paint too pretty a picture, I know there are real problems in some areas. I work with the general population of seniors and that has yielded good results. At the same time, I have heard from those who work with dual-eligibles, those with Medicare and Medicaid, that they have seen serious difficulties in everything from getting clients into the right plan to straightening out computer records so medications could be dispensed.

In spite of all the real problems you are hearing about, Medicare D is a good thing for an overwhelming proportion of those eligible. In our county, there is even a plan available which will produce savings with drug costs of as little as $35 a month. Not many seniors have drug costs that low.

The Medicare.gov website is, in my opinion, now doing a good job leading people through the process. When the sign-up period started in November, it was often not available due to excess traffic, had errors in plan information, and was much harder to use. Since then, the information has been corrected, major improvements have been made, and the site is both faster and easier to use.

In spite of my satisfaction with the results and a real conviction that Medicare D is good for the elderly, it is obvious that improvements can be made. I would recommend to the committee the following changes be considered.

Provide a paper application for those that do not have computer access, and by that I mean a paper application to apply for the comparison. The actual enrollment is already available either by phone or by paper application.

On the Medicare.gov website at present, medications and their dosages must be entered one at a time in order to allow the program to make the notation. This results in a processing wait each time a single drug or change in dosage is entered. It would be much more efficient if all drugs and their dosages could be entered at the same time, resulting in a single but longer wait.

Stop the auto-enrollment to reduce confusion and save manpower.

Standardize the formulary for all plans to provide improved comparability.

As with supplemental plans A through J, reduce the number of prescription plans, not vendors, to a manageable number which can be compared one to the other. If you think about it, that is already almost in existence. It simply has not been categorized. If you look at the plans, they already either do or do not cover the $250. They either do or do not cover the doughnut hole. They either do or do not have mailhouse pharmacies. They either pay nothing for generics or a small charge. The small charges are very close together. For non-generic drugs, they either pay 25 percent or they have a fixed amount. Where it is a fixed amount, they are very close together. So there would be very little change and very little restriction of competition to standardize the plans.

There are more than 4,800 seniors in Tillamook County. Only about 500 of these have been helped, mostly because most of them do not know where to go for help. My schedule is now running empty. We could nationally provide local TV and radio announcements giving the telephone number of the closest SHIBA office or

its equivalent which can be called to get real help one-on-one in a timely manner.

Thank you.

The CHAIRMAN. Thank you very much, Bob. That is a terrific real world experience and some suggestions that we will certainly take to heart. We have a hearing in the Finance Committee next week on this same topic and I am going to grab your testimony and push your ideas. It is very good of you to come this long way to participate in this important discussion.

Mr. KENNY. Thank you for having me.

[The prepared statement of Mr. Kenny follows:]

Testimony of Robert J Kenny

Good morning Mr. Chairman, ladies and gentlemen of the Committee. I am delighted to be here today to give the message that there really are successful sign-ups for Medicare D.

I have worked with Medicare D both on a personal basis and as a volunteer for the Senior Health Insurance Benefits Assistance program (SHIBA).

At 78 years of age I have recently undergone a triple bypass operation and have mild emphysema. My drug cost would be about $300 a month without Medicare D. With my Medicare D prescription plan, my total cost including premium will be cut to $141 a month, a savings of 53% or a total of $1,908 a year.

How did I go about signing up? Because of my SHIBA training I knew the shortest route would be to use the government web site Medicare.com. I went to that site armed with a list of my six prescriptions and my Medicare card. The site was new to me so I did site exploring and then started in earnest. I told the site that I wanted to compare plans, filled in the personal information and after that my drug usage. It was time consuming, about three- quarters of a hour. The comparison showed the plans from the least to the most expensive with the yearly cost for each. I checked pharmacies to make sure mine was included and identified the parent company for the plan as a stable firm. In addition, I went over the math to verify the yearly cost figure. Having decided that the lowest cost plan was acceptable I enrolled.

My membership card arrived in a little over two weeks. Shortly after January 1, I registered my plan with my pharmacy and ordered medication. The medication was quickly approved and provided at the proper discounted price. Since that time I have filled more prescriptions with the same results.

I am sure that my good results , in some measure, reflected my half day Medicare D training and my computer savvy.

My work as a SHIBA volunteer began in 1993. According to the last census my county of Tillamook in Oregon has a population with 19.8% seniors as compared 12.4% for the US as a whole. I have counseled about 30 Medicare D clients since mid-November. The seniors that come to me for

Medicare D are often very confused by the publicity that tells them they should be confused or they have been talking to plan salesmen or they have been looking into plans and they are really confused. In most cases this confusion was either eliminated or considerably reduced by going through the steps required by Medicare.gov. Few of my clients know how to use a computer and those that do may not have internet access. At the end of the appointment, however, almost all are thrilled by the amount they will save in drug costs. There has been only one client of mine who found that there would be no reduction in her costs. She was a lady in extremely good health who did not spend enough to cover the $250 deductible. Even this lady decided to enroll anyway in order to avoid the 1% per month penalty which would be added to her premium if she did not enroll before May 15.

Lest I paint too pretty a picture, I know there are real problems in some areas. I work with the general population of seniors and that has yielded good results. At the same time, I have heard from those who work with dual eligibles (those with Medicare and Medicaid) that they have seen serious difficulties in everything from getting clients into the right plan to straightening out computer records so medications could be dispensed.

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The Medicare.gov web site is, in my opinion, now doing a good job leading people through the process. When the sign-up period started in November it was often not available due to excess traffic, had errors in plan information and was much harder to use. Since then the information has been corrected, major improvements have been made and the site is both faster and easier to use.

In spite of my satisfaction with the results and a real conviction that Medicare D is a good deal for the elderly, it is obvious that improvements can be made. I would recommend, to the committee, that the following changes be considered.

- Provide a paper application for those who do not have computer access.

- On the Medicare.gov web site, at present, medications and their dosages must be entered one at a time to allow the program to make the notation. This results in a processing wait each time a single drug or change in dosage is entered. It would be more efficient if all drugs and their dosages could be entered at the same time resulting in a single but longer wait.
- Stop auto-enrollment to reduce confusion and save manpower.
- Standardize the formulary for all plans to provide improved comparability.
- As with Supplemental plans A thru J, reduce the number of prescription plans (not vendors) to a manageable number which can be compared one to the other.
- There are more than 4,800 seniors in Tillamook County. Only about 500 of these have been helped because most of them do not know how to get that help. My schedule is now running empty. We could nationally provide local TV and radio advertisements giving the telephone number of the closest SHIBA office or its equivalent which can be called to get real one on one help in a timely manner.

The CHAIRMAN. Mr. Donato.

STATEMENT OF MICHAEL DONATO, MEDICARE PART D BENEFICIARY, MANSFIELD, OH

Mr. DONATO. Hi, Senator Smith. My name is Mike Donato. I live with my mom, Daisy, in Mansfield, OH. I was diagnosed with schizophrenia and bipolar disorder in 1995. I have been on the Social Security Disability program since then.

Senator, I take medications for many health problems, everything from asthma to high blood pressure. I particularly depend on mental health drugs to live in the community with my friends and family. When I am not on medications, I tend to get sick and end up in the emergency room or the hospital. This is my first time in Washington, DC and I don't want to offend anybody, but it is fair to say I don't like hospitals. Nice people, but the food is pretty bad.

I would say that things got off to a pretty rocky start with this new Medicare drug program. For example, I am in an AARP plan, but I never got a letter from them. Sharon Farr from the Center for Individual and Family Services, had to find my enrollment online. In fact, she has been helping me a lot these past few weeks. You will hear from her in a moment.

When I went to Walgreen's in early January to get my prescriptions filled, they said I owed them a total of $700. I was afraid and, honestly, pretty panicked, Senator Smith. Where I come from, that is a great deal of money. Most of all, though, I was worried about my mom. Daisy was very nervous about what would happen to me if I couldn't get my medications. Lord knows she doesn't have the money to buy all my drugs I need to live.

Today, I sit here feeling pretty lucky. Now that Sharon has got me enrolled in this new Part D program and we have ironed out all the problems, I can take all nine of my medications I need for the very first time. I was never able to do that under Medicaid. I also know for a fact that I couldn't have handled all this without Sharon's help.

But what about the seniors? What happens to people who don't have the help I had? I hope you will give them the assistance they need. I think Daisy feels the same way.

Thanks for having me here. I will answer your questions the best I can.

The CHAIRMAN. Thank you, Michael. I don't have a question. I just—you are a living example that this is a program that is working for you. For all the problems you have heard spoken of this morning, it is obviously worth the effort and the struggle to keep getting this program implemented and get it right.

Mr. DONATO. I agree.

The CHAIRMAN. Thank you.

[The prepared statement of Mr. Donato follows:]

TESTIMONY OF MICHAEL DONATO

DUAL ELIGIBLE CLIENT
CENTER FOR INDIVIDUAL AND FAMILY SERVICES, MANSFIELD, OHIO

ON BEHALF OF THE NATIONAL COUNCIL FOR COMMUNITY BEHAVIORAL HEALTHCARE
AND
THE NATIONAL ALLIANCE ON MENTAL ILLNESS

REGARDING

MEETING THE CHALLENGES OF MEDICARE DRUG BENEFIT IMPLEMENTATION

February 2, 2005

Hi, Senator Smith, my name is Mike Donato and I live with my mom Daisy in Mansfield, Ohio. I was diagnosed with schizophrenia and bipolar disorder in 1995 and I've been on the Social Security Disability Insurance (SSDI) program since then.

Senator, I take medications for many health problems....everything from asthma to high blood pressure. But I particularly depend on my mental health drugs to live in the community with my friends and family. When I'm not on my medications, I tend to get sick and end up in the emergency room or the hospital. This is my first time in Washington, D.C. and I don't want to offend anybody, but it's fair to say that I don't like hospitals. Nice people, but the food is pretty bad.

I'd say that things got off to a pretty rocky start with this new Medicare drug program. For example, I'm in an AARP plan, but I never got a letter from them. Sharon Farr from the Center for Individual and Family Services had to find my enrollment online. In fact, she's been helping a lot these past few weeks. You'll hear from her in a moment. When I went to Walgreen's in early January to get my prescriptions filled, they said I owed them a total of $700. I was afraid and, honestly, pretty panicked. Senator Smith, where I come from, that's a great deal of money.

Page 2

Most of all, though, I was worried about my mom. Daisy was very nervous about what would happen to me if I couldn't get my medications. Lord knows, she doesn't have the money to buy all the drugs I need to live.

Today, I sit here feeling very lucky. Now that Sharon's got me enrolled in this new Part D program and we've ironed out all the problems, I can take all nine of the medications I need – for the very first time. I was never able to do that before under Medicaid. I also know – for a fact – that I couldn't have handled all this without Sharon's help.

But what about the seniors? What happens to people who don't have the help I had? I hope that you will give them the assistance they need. I think Daisy feels the same way.

Thanks for having me here. I'll answer your questions as best as I can.

The CHAIRMAN. Sharon Farr.

STATEMENT OF SHARON FARR, ACCOUNTS RECEIVABLE SUPERVISOR, CENTER FOR INDIVIDUAL AND FAMILY SERVICES, MANSFIELD, OH

Ms. FARR. Good afternoon, Chairman Smith and members of the committee. My name is Sharon Farr. I am an accounts receivable supervisor at the Center for Individual and Family Services in Mansfield, OH. I supervise a staff of five case managers working with 140 persons with serious mental illnesses eligible for both Medicare and Medicaid who qualify for the new Part D prescription drug benefit. Today, I will briefly outline some significant challenges that one of my clients, Mike Donato, and many other dual-eligibles with mental disorders, are experiencing with the new Medicare prescription drug benefit.

Let us focus on Mike's case for just a moment. As you just heard, he takes medication for nine health conditions, including schizophrenia, bipolar disorder, diabetes, asthma, and high blood pressure. In late 2005, Mike was auto-enrolled into AARP prescription drug plan. When he attempted to get his prescriptions filled in early January, Mike did not appear in the Walgreen's computer system as dual-eligible. The pharmacy charged him a $250 deductible plus the copayment for all the medication Mike takes, about $700 in all. It is very important to note that his Social Security Disability check amounts to $694 per month for all his living expenses. Mike's mother stepped into the situation at that point and gave him $67 so he could at least purchase his mental health medication.

When I contacted AARP, I was told to wait 48 hours and a computer glitch would be corrected, but nothing happened after 2 days. I then began calling the Center for Medicare and Medicaid services, AARP, and Walgreen's, all with the objective of enrolling Mike as a dual-eligible so we could qualify for subsidies due him. I was calling these organizations three times a day for a solid week. At one point, I was on the phone for 3½ hours and endured multiple phone cutoffs. Meanwhile, the AARP website had no mechanism of identifying dual-eligibles upon enrollment.

By the way, Community Mental Health Centers across the country are reporting very similar experiences, particularly with respect to PDP prior authorization processes. Many consumers who, for example, are stabilized on anti-psychotic medications now find that the same drug is subject to PDP fail-first policies, requiring case managers to navigate often confusing new systems.

Finally, 3 weeks after his Part D odyssey began, Mike showed up in the Walgreen's computer system as dual-eligible. Mr. Chairman, I don't mind telling you that we had a little celebration. Mike can now afford all nine drugs in his medication regimen, which is something he could not do under the Medicaid program. Walgreen's was very accommodating through the process and even refunded Mike's mother her $67.

Throughout this process, I have been working with both the National Alliance on Mental Illness and the National Council on Community Behavioral Health Care, who have provided invaluable assistance.

Both NAMI and the National Council hope that CMS will successfully resolve the information technology problems that have plagued Part D to date. In addition, our colleagues in the mental health field, and including the American Psychiatric Association the National Mental Health Association, insist that PDPs provide a 30-day emergency supply of medications as required by the current CMS transition policy. It is also essential that CMS renew the all or substantially all formulary guidance requiring broad coverage of anti-psychotic, anti-depressant, and anti-convulsants for 2007 contract year and beyond. This is critically important to making the drug benefit effective for people with severe mental illnesses. In addition, as front-line safety net providers, we need a workable and transparent exception process to ensure that dual-eligibles are able to quickly access medications that are subject to prior authorization and step therapy.

In closing, there are some immediate issues that need the attention of Congress. For instance, CMHCs have found that copayment structures for dual-eligibles is unwieldy and confusing. This requirement has generated thousands of additional visits to CMHCs across the nation, and the tremendous staff time amounts to an unfunded mandate on safety net community mental health providers. In fact, I estimate that my five case managers have spent 200 to 300 hours attempting to enroll dual-eligibles in the new benefit. Moreover, people with Alzheimer's disease, mental retardation, and mental illness eligible for Part D need additional help, specifically one-on-one pharmaceutical benefits counseling. The House and Senate Appropriations Committee required CMS to provide additional assistance through the $150 million MMA education and outreach program, but it has not been materialized to date.

Thank you for listening. I look forward to answering any questions you may have.

The CHAIRMAN. Sharon, thank you very much for focusing on the mental health component or category in all of this. It is very important to me that this not take a back seat to other prescription drugs. I also thank you for serving and helping Michael.

[The prepared statement of Ms. Farr follows:]

TESTIMONY OF SHARON FARR

ACCOUNTS RECEIVABLE SUPERVISOR
CENTER FOR INDIVIDUAL AND FAMILY SERVICES, MANSFIELD, OHIO

ON BEHALF OF THE NATIONAL COUNCIL FOR COMMUNITY BEHAVIORAL HEALTHCARE
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February 2, 2005

Good morning Chairman Smith and members of the committee, my name is Sharon Farr and I am an accounts receivable supervisor at the Center for Individual and Family Services in Mansfield, Ohio. I supervise a staff of five case managers working with 140 persons with serious mental illnesses eligible for both Medicare and Medicaid who quality for the new Part D prescription drug benefit. Today, I will briefly outline some significant challenges that one my clients -- Mike Donato -- and many other dual eligibles with mental disorders are experiencing with the new Medicare prescription drug benefit.

Part D Challenges: Mike Donato's Success Story

Let us focus on Mike's case for just a moment. As you just heard, he takes medications for nine health conditions including schizophrenia, bipolar disorder, diabetes, asthma and high blood pressure. In late 2005, Mike was auto-enrolled into an AARP Prescription Drug Plan (PDP). When he attempted to get his prescriptions filled in early January, Mike did not appear in the Walgreen's computer system as a dual eligible. The pharmacy charged him a $250 deductible plus the co-payment for all the medications Mike takes – about $700 in all. It is very important to note that his Social Security disability check amounts to $694 per month for ALL his living expenses. Mike's mother stepped into the situation at that point and gave him $67 so that he could at least purchase his mental health medications. When I contacted AARP, I was told to wait 48 hours and the computer glitch would be corrected, but nothing happened after two days.

I then began calling the Center for Medicare and Medicaid Services (CMS), AARP and Walgreen's -- all with the objective of enrolling Mike as a dual eligible so he could qualify for the subsidies due him. I was calling these organizations three times per day for a solid week. At one point, I was on the phone for 3 ½ hours and endured multiple phone cut offs. Meanwhile, the AARP website had no mechanism for identifying dual eligibles upon enrollment. By the way, Community Mental Health Centers across the country are reporting very similar experiences....particularly with respect to PDP prior authorization processes. Many consumers who, for example, are stabilized on an anti-psychotic medication now find that this same drug is subject to PDP fail first policies requiring case managers to navigate often confusing new systems.

Finally, three weeks after his Part D odyssey began, Mike showed up on Walgreen's computer system as a dual eligible. Mr. Chairman, I don't mind telling you that we had a little celebration. Mike can now afford all nine drugs in his medication regimen, which is something he could NOT do under the Ohio Medicaid program. Walgreen's was very accommodating throughout the process and even refunded Mike's mother her $67 co-payment.

Policy Solutions

Throughout this process, I have been working with both the National Alliance on Mental Illness (NAMI) and the National Council on Community Behavioral Healthcare (NCCBH) who have provided invaluable assistance.

Administrative Issues: Both NAMI and the National Council hope that CMS will successfully resolve the information technology problems that have plagued Part D to date. In addition, our colleagues in the mental health field – including the American Psychiatric Association and the National Mental Health Association – insist that PDPs provide a 30 day emergency supply of medication as required by current CMS transition policy. It is also essential that CMS renew the "all or substantially all" formulary guidance requiring broad coverage of anti-psychotics, anti-depressants and anti-convulsants for the 2007 contract year and beyond. This is critically important for making the drug benefit effective for people with severe mental illnesses. In addition, as front line safety net providers, we need a workable and transparent exceptions process to ensure that dual eligibles are able to quickly access medications that are subject to prior authorization and step therapy.

Legislative Issues: In closing, there are some immediate issues that need the attention of Congress. For instance, CMHCs have found that the co-payment structure for dual eligibles is unwieldy and confusing. This requirement has generated thousands of additional visits to CMHCs across the nation, and the tremendous staff time involved amounts to an unfunded mandate on safety net community mental health providers. In fact, I estimate that my five case managers have spent 200 to 300 hours attempting to enroll dual eligibles in the new benefit. Moreover, people with Alzheimer's disease, mental retardation and mental illnesses eligible for Part D need additional help – specifically one-on-one pharmaceutical benefits counseling. The House and Senate

Appropriations Committee required CMS to provide additional assistance through the $150 million MMA Education and Outreach Program, but it has not materialized to date.

Thanks for listening. I look forward to answering any questions you may have.

The CHAIRMAN. Senator Kohl.

Senator KOHL. Thank you. Just a brief comment. I would first like to thank both of our Medicare beneficiaries for traveling so far to be here with us today and to make your comments. Mr. Kenny, I am pleased that your experience in enrolling in the Medicare drug benefit was a good one and that you have been able to counsel others that don't have access to the resources that you do.

Mr. Donato, the Medicare drug benefits certainly should not be an obstacle to proper health care, but as you have demonstrated, that is exactly what it has been for too many Medicare beneficiaries. Of course, you are very fortunate to have a strong advocate working on your behalf.

However, with all due respect, Chairman Smith, the stories we have heard today are far different from what I have been hearing in my State of Wisconsin. Just this past Monday in Milwaukee, Amy McHutchin, who is from the Wisconsin Coalition for Advocacy, painted a far different picture and I want to quote something she said to me.

She said, "In just under a month, I have worked with numerous Medicare beneficiaries with severe mental illness, recent organ transplants, diabetes, and other life or death illnesses that have had trouble accessing their medications. Many were turned away from pharmacies empty-handed or left the pharmacies having spent their month's grocery or rent money for their medications. The calls also seem to be much more urgent in nature as we near the end of the month, where beneficiaries have no longer been able to secure a temporary supply of medications from their pharmacy and have been without their medications for several days." This is an expert in Wisconsin who made that quote to me.

I share this with the committee because I want to be clear today. For far too many people, this drug benefit has not worked properly and we clearly have a responsibility to acknowledge them and to focus and refocus our efforts on making sure the many challenges people have been facing are adequately addressed and not in any way papered over.

Mr. Chairman, I thank you.

The CHAIRMAN. Thank you. I am grateful to our second panel and we will now call up our third.

The third panel will consist of Mr. Timothy Murphy of the Commonwealth of Massachusetts, Secretary of Health and Human Services. His state was one of the first to implement a stop-gap program to pay the costs of emergency supplies of medications for beneficiaries. He will discuss the state's role in the Medicare drug benefit as well as its efforts to receive reimbursement from CMS and drug plans for costs associated with its stop-gap program.

He will be followed by Ms. Sue Sutter. She is here representing the Pharmacy Society of Wisconsin. Senator Kohl will introduce her.

Then Mark Ganz, who is my friend and fellow Oregonian. He is the CEO of the Regence Group and is representing the National Blue Cross and Blue Shield Association. He will discuss his company's approach to implementation of the drug benefit, including its work with pharmacies and other interested parties to resolve problems encountered by beneficiaries.

We thank all three of you for being here. Tim, take it away.

STATEMENT OF TIMOTHY R. MURPHY, SECRETARY, EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES, MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH, BOSTON, MA

Mr. MURPHY. Thank you, Chairman Smith and Senator Kohl, for this opportunity to speak on this important issue. I also just wanted to introduce to the committee Beth Waldman, who is the Medicaid director for Massachusetts, who is joining me today, also with Paul Jeffrey, who runs our pharmacy services, so if any questions that we can answer for the committee.

I would also request, Mr. Chairman, that I just have my written testimony put into the record.

The CHAIRMAN. We will include it.

Mr. MURPHY. What I have done for the committee is also prepared a presentation, which I believe you have, just to walk through the Massachusetts experience.

Just by way of background, what you should know about Massachusetts is that we have two programs. One is obviously for the Medicaid or the dual-eligibles, and then we also have a State Pharmacy Assistance Program called Prescription Advantage, which is a very successful program. We serve in Massachusetts on our Medicaid program about a million people. It is about 17 percent of our population. Our dual-eligibles are about 190,000 individuals. Just to give some percentages on that, it is about 51 percent elderly and 49 percent are disabled. Our Prescription Advantage, or our SPAP, is 72,000 individuals, and that is for lower and moderate-income seniors that have received services from the Commonwealth to help with prescription benefits.

In addition, I would also say, and I think this is important to note, that there is about 700,000 elders in Massachusetts that will now benefit by having prescription Part D available to them.

In anticipation of Part D, we anticipated certain transitional issues that would occur with the program, and prior to January 1, the legislature passed and the Governor signed a bill that accomplished a couple of things. One was for a formulary assistance, and while we recognize that the Federal requirement did have a 30-day transition, we wanted to backstop that and make sure that that would be available, so the State agreed that that would pick up if someone went and changed to a new insurance product and a particular drug was not included, that the pharmacist could fill that prescription for 30 days and that the Commonwealth would pick up that cost. In addition to that, we also did a cost sharing assistance and such that we took down the copays on Part D to what they had been historically under the Medicaid program in Massachusetts. So we had done that in advance just to make sure that as we were moving to a new system, which we were very excited about, that we would not have issues with a number of our participants.

I would note on page four that we did, unfortunately, experience more transitional issues than we had anticipated. Our Office of Medicaid in 2002 established a Pharmacy Advisory Council. We work very closely with a lot of the major pharmacies within the Commonwealth to ensure that when we are delivering services through the Medicaid program, that it is done in the most effica-

cious way possible. We have had historically challenges with that, and I think through the work of Director Waldman and Paul Jeffrey that we have come a long way in Massachusetts.

So we were watching very closely as soon as the Medicaid Part D launch date of January 1 hit to have a good understanding of what was going on within our community, and what we did find was that a number of dual-eligibles were experiencing great difficulty being able to fill prescriptions, specifically, and you have heard this all today so I don't want to spend too much time on it, but there were issues about overcharging of copayments, extensive system glitches.

I think that this is one thing that CMS has been working hard on to fix, but data matches and the hand-offs between States to the Federal Government to the various plans, obviously, a number of complications. So people weren't seen within the systems when they were going into the pharmacies. Particularly, you had situations where individuals were signing up for the benefits or being auto-enrolled in the last week of December and then showing up the first day of January looking for a service and that was very difficult for individuals.

In addition to that, numerous phone calls from consumers, their families, from pharmacists, from doctors spending a great deal of time on the phone trying to talk to plans, you know, 30 minutes, 60 minutes, and obviously in the early weeks that was very challenging. So we did have situations where people were leaving pharmacies without drugs.

On page five of the presentation, Governor Romney, after kind of surveying what had occurred during the first week in January, directed myself and the Office of Medicaid to put in place a system such that people would make sure that there was a seamless transition to Medicare Part D, and primarily what we did, both for the dual-eligibles and for people who were on the SPAPs, was that we would step in as a primary payor. If you will, we lifted the edits in our system such that pharmacists could then go and bill our Medicaid program. Those emergency measures went into place on January 7 for the Medicaid program, on January 11 for our SPAP program, and then we were encouraging the pharmacists and working with our council for them to bill Part D and also to use the Wellpoint system. But we did allow them to use the Mass Health, our Medicaid program, as a primary payor.

I am pleased to report, however, that conditions are improving since we instituted these emergency measures. Through the countless hours of work of our program with consumers, with pharmacists in particular, we have been able to make dramatic improvements in such that what we have been able to do on January 26 is we have changed what the emergency measures that we are taking. So we are no longer allowing Medicaid to be, if you will, the first payer. We are making sure that the pharmacists are required to use the Wellpoint system or to bill the Medicare Part D plans, and they have to do that first before they are able to come to us on our program as a payor.

On page seven, I think that there is some interesting data that I would like to share with you that demonstrates the effectiveness of what we have seen. What we did is we took snapshots of Janu-

ary 9, January 23, and January 31 to see where we were, and we looked at claims submitted to the Part D program, how many claims we paid, and then what was our average cost of a claim.

So as an example, on January 9, we had 43,400 claims submitted to our plan. By the time January 31 rolled around, after we had, if you will, lessened the emergency measures by putting some edits back into our system, only 18,200.

In addition to that, our claims paid declined from 35,000 on January 9 to 5,000 claims on January 31, and our average cost per claim went from $45 on January 9 all the way down to $12 on January 31. So I think what we are seeing is that there are clearly systems issues that have occurred. CMS has been working very closely with us at the regional level in Boston and at the national level, our team at Medicaid has been working very closely with them to identify specific issues for individuals, systems issues for our total program, and they have been responsive.

I would note that on January 25, Secretary Leavitt flew up to Boston, sat down with Governor Romney and myself to explain where he saw where the problems were, to talk about the demonstration project they were going to put forth as fixes for the Medicaid Part D roll-out. It is refreshing in that both Secretary Leavitt and the folks at CMS are stepping right into this, understand what the issues are, trying to work with the States. We obviously want to have a constructive engagement with them. We obviously would like to be reimbursed for the costs that we have incurred, and so we are hopeful, of course, that that will happen.

Just some more facts just to give you a sense of what we have experienced in Massachusetts. Since we put emergency measures in place for the dual-eligibles, we have paid over 400,000 claims that would have been under the Medicare Part D. The total value of those claims, $16 million, and we have serviced 100,000 unique members of our 190,000 individuals on the Medicaid program.

Smaller information, or smaller numbers, I should say, for our SPAP but also equally as important to convey to this committee.

I would say in closing, Mr. Chairman, that we recognize that there have been significant issues that have occurred as part of this transition. We knew that some of those would happen. This is a massive system changeover, and for those of us who do this for a living in terms of dealing with large health care programs, when you are changing over IT systems and starting huge new programs, you always go through this. We also recognize that at the individual level, these are very stressful circumstances when you are looking to get prescription drugs and you go in and you are not found within a system. People have an expectation when something worked on December 31, why doesn't it work on January 1? We need to pay attention to that and make the right type of steps to remedy those situations.

Again, I think HHS and CMS have worked very closely with us. I know that they take this serious. We are looking forward to having a good dialog with them, and I would just suggest in closing that we want to make sure that the timeline and the process for reimbursement is easy for the States. We believe that we are being helpful in this transition and we need to have that recognized. We want to make sure that in the demonstration project that it is well

defined as to what the administrative costs are to be reimbursed. Make that very clear for us so that we can get timely reimbursement back from the Federal Government.

We would propose that the February 15 date be a date to aim for, but one that people need to take into consideration to see where we are at that particular time and that the SPAPs also do get reimbursed.

I thank you for your time.

The CHAIRMAN. That is excellent testimony. I hope that, based on what you have heard at this hearing today and your experience in Massachusetts, you are optimistic. That is my sense.

Mr. MURPHY. Yes, I am.

The CHAIRMAN. You wouldn't scrap the program?

Mr. MURPHY. No. I mean, I would just state that we obviously have a number of folks on Medicaid, 190,000, who are receiving this benefit. But I think sometimes lost in the conversation are the 700,000 other seniors and disabled within Massachusetts that this is a new benefit and it will take some time for those people to recognize that through more education, but I know that Governor Romney and I find that to be particularly exciting.

[The prepared statement of Mr. Murphy follows:]

Special Committee on Aging
Timothy R. Murphy
Secretary
Executive Office of Health and Human Services
Commonwealth of Massachusetts
February 2, 2006

Chairman Smith and other members of the Special Committee on Aging, I am Timothy Murphy, Secretary of the Executive Office of Health and Human Services for the Commonwealth of Massachusetts. Beth Waldman, Medicaid Director for Massachusetts' Medicaid program, and Paul Jeffrey, Pharmacy Director for Massachusetts' Medicaid program are both here with me before the Committee. I appreciate the opportunity to testify before this Committee today to discuss the issues regarding the transition to the Medicare Part D program for so-called dual eligible individuals and participants in the Commonwealth's Prescription Advantage Program, a State Pharmaceutical Assistance Program ("SPAP") for lower and moderate-income seniors and disabled individuals.

By way of background, the Commonwealth's Medicaid program serves over one million residents, or approximately 17 percent of our population. We have approximately 190,000 elderly and disabled Medicaid members who are also eligible for Medicare benefits, so-called dual eligible individuals, of which 51 percent are elderly and 49 percent are disabled. In addition, the Commonwealth's SPAP has approximately 72,000 members. Each of these individuals, along with the over 700,000 other Medicare eligible Massachusetts residents, will now benefit from the inclusion of prescription drug coverage in the Medicare program.

As you are aware, there have been many transitional issues since the January 1, 2006 launch date for the Medicare Part D prescription drug benefit. Consumers and their families, advocates, pharmacists and state governments have grappled particularly with the continuity of services for dually eligible individuals. In anticipation of a transition period, the Commonwealth enacted on December 30, 2005 legislation that required the state to pay for a one-time 30-day supply of any drug not covered by a Medicare Part D plan at the time a prescription is presented by a dually eligible individual or a SPAP member at a pharmacy. This program anticipated that dually eligible individuals may have transition issues around the coverage of certain prescription drugs by a specific plan. It did not anticipate wide-spread difficulties with the implementation of the Part D benefit. We hoped that this action would help contribute to the successful implementation of the Medicare Part D benefit and ensure that our residents were not denied necessary medications.

The Office of Medicaid and the Executive Office of Elder Affairs closely examined the implementation of the Medicare Part D benefit as it began on January 1, 2006. Specifically, the Office of Medicaid's Pharmacy Program worked closely with its

Pharmacy Advisory Council, which was established in 2002 and is comprised of key pharmacy providers throughout the Commonwealth, to monitor the situation. Unfortunately, consumers, doctors and pharmacists struggled with the transition to the new program. Stories of pharmacists' inability to determine Part D eligibility and enrollment for dually eligible individuals were commonplace. In addition, we also heard many anecdotes of drug plans not supplying a transitional supply of medications, overcharging of co-payments, extensive system glitches, excessive interactions with the new insurance plans, and consumers and pharmacists spending 30 to 60 minutes waiting to speak with government or insurance representatives were occurring too frequently. Many dually eligible individuals were leaving pharmacies without their needed prescriptions.

On January 7, 2006, Governor Mitt Romney directed the Office of Medicaid and the Executive Office of Elder Affairs to assure that all dually eligible individuals and SPAP members receive prescription benefits that existed as of December 31, 2005. We accomplished this directive by allowing pharmacies to bill the state's Medicaid program and SPAP as the primary payer for prescription drugs. The Commonwealth, along with 29 other states, determined this action was necessary to help facilitate the transition to a fully operational Medicare Part D program. As of January 31st, the Commonwealth has paid for 408,714 prescriptions for approximately 100,000 dually eligible individuals totaling $16,112,481. These expenditures equal approximately 80% of what the Commonwealth would have expected to pay for dually eligible members prior to the implementation of Part D. In addition, as of January 30th, the Commonwealth has been the primary payer for 34,094 prescriptions for 15,627 SPAP members totaling $1,433,837 that should have been covered first by Part D plans. Our SPAP only planned to be a secondary payer for members eligible for the Medicare Part D program.

Over the past three weeks, the Medicare Part D situation has improved in the Commonwealth. Last week, the Office of Medicaid took steps to test the improvements in the Medicare Part D transition by requiring pharmacists to first submit all claims to the Medicare Part D insurers prior to billing the state's Medicaid program. The average cost per claim has dropped from approximately $45 on January 7, 2006 to $37 on January 15, 2006 to $12 for the period January 26 through January 31, 2006. According to the Pharmacy Advisory Council, the changes made last week are proceeding as expected as pharmacists are climbing the learning curve. The pharmacists report that adequate safety measures are in place to ensure that pharmacies can fill otherwise valid prescriptions for dually eligible members. In addition, customer service lines for Part D plans seem to be improving and the Wellpoint transition system appears to be operating more successfully. Despite these improvements, there continues to be significant data issues that result in the failure of Part D plans to recognize some dually eligible individuals as members of a plan or as being eligible for the low-income subsidy.

I think it is important to recognize that Health and Human Services Secretary Michael Leavitt and the Centers for Medicare and Medicaid Services Administrator Dr. Mark B. McClellan have listened to our concerns and have presented solutions for states that have dealt with these transitional issues. Secretary Leavitt visited Governor Romney in

Boston on January 25th to discuss the challenges of the new program and outlined a demonstration project to ensure that states are reimbursed for the unanticipated expenditures caused by the transition to Medicare Part D.

The Commonwealth is prepared to work with the Department of Health and Human Services and the Centers for Medicare and Medicaid Services to make this demonstration project work and for Medicare Part D to be a success. In fact we have been working very actively and closely with our CMS Regional Office on a daily basis to address individual cases and to resolve problems. We look forward to continuing to work with the Centers for Medicare and Medicaid Services on specific issues such as the timeline and process for receiving reimbursement, the rate of reimbursement for administrative costs incurred, the proposed February 15 end date for state programs, and what steps states may take for SPAP reimbursement.

In closing, Medicare Part D has the potential to provide our senior and disabled citizens with an important healthcare benefit and better health outcomes. We are working through the challenges of this massive new program. Governor Romney took affirmative action to ensure that the residents of Massachusetts were protected through this transition period. We are pleased that our efforts, and those of other states, have been recognized by the Federal government and that the Commonwealth, along with other states, will be reimbursed in full for our expenditures. We look forward to continuing our collaborative relationship with the Department of Health and Human Services and the Centers for Medicare and Medicaid Services as we address these challenges.

I thank the Committee for the opportunity to discuss this important issue.

Commonwealth of Massachusetts Medicare Part D Transition

February 2, 2006

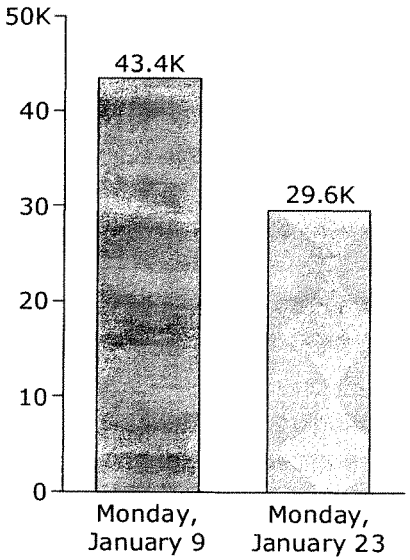
Massachusetts took three measures to benefit residents transitioning to Medicare Part D

For all MassHealth Dual Eligibles and Prescription Advantage members:

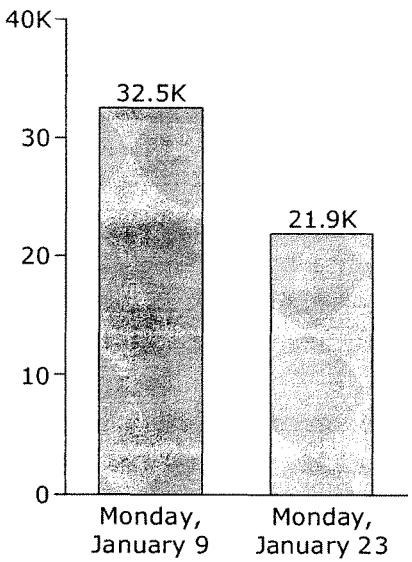
- Guaranteed dispensing of prescriptions
  - Effective **1/7** for MassHealth and **1/11** for Prescription Advantage
  - Emergency measure implemented to allow pharmacists to bill MassHealth or Prescription Advantage as the primary payer if they cannot otherwise dispense drugs
  - Pharmacists were strongly encouraged to attempt billing Part D plan or Wellpoint
- Formulary assistance
  - Legislation ordering the state to pay for one-time 30-day supply of any drug not covered by a Part D plan at the time a prescription is presented
  - Effective dates: 1/1/06 through 6/30/06
  - Program **suspended** 1/7 due to emergency dispensing measure
- Cost sharing assistance
  - Legislation ordering the state to reduce Part D cost-sharing to previous MassHealth and Prescription Advantage levels
    - Generally brings Part D co-pays down to $1 and $3 levels
  - Program **suspended** 1/7 due to emergency dispensing measure

Key MassHealth pharmacy metrics suggest an improving situation in the field

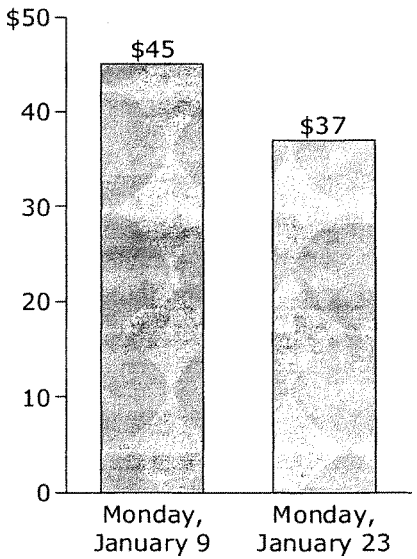
Part D Rx claims submitted



Part D Rx claims paid



Average cost per claim



Massachusetts primary spending to January 23 on Part D drugs

MassHealth (1/7 through 1/23):

- Total number of claims paid: 336,715
- Total value of claims paid: $14,103,007
- Unique members with at least one claim paid: 95,824

Prescription Advantage (1/11 through 1/23):

- Total number of claims paid : 23,181
- Total value of claims paid : $982,679
- Note: These are total primary claims. Prescription Advantage was going to provide secondary coverage around Part D so not all of these costs are inappropriately paid by the state

With conditions improving, MA has initiated transition away from emergency measures

- Recent conversations with pharmacists and advocates indicate that Part D systems are improving
  - Pharmacy data confirms anecdotal evidence
- Concern that pharmacists may have begun taking the path of least resistance by billing MassHealth without first trying to bill a Part D plan
- New directive effective 1/26 requires pharmacists to attempt to bill a Part D plan and only bill the state if unsuccessful
- Cost sharing assistance programs will be reinstated effective 1/26
- Reinstatement of formulary assistance will coincide with end of emergency dispensing measure

The CHAIRMAN. Senator Kohl, do you want to introduce Ms. Sutter?

Senator KOHL. Yes. We are very pleased to have Sue Sutter from Horicon, WI, with us today. She and her husband own two rural community pharmacies and Sue is the President-Elect of the Wisconsin Pharmacy Society, so we are delighted to have you and are excited to hear your testimony.

STATEMENT OF SUSAN SUTTER, PRESIDENT-ELECT, PHARMACY SOCIETY OF WISCONSIN, HORICON, WI

Ms. SUTTER. Thank you, Senator Kohl. Good afternoon, Chairman Smith, Senator Kohl. Thank you for conducting this hearing and for providing me the opportunity to address you.

Yes, I am Susan Sutter and I am very proud to be a pharmacist and proud to be from Wisconsin. My husband and I have both been practicing pharmacists and own these two pharmacies in Horicon and Mayville, which are approximately an hour from Madison and Milwaukee, for over 25 years, and I am the president-elect of the Pharmacy Society of Wisconsin, which is the State's professional society of pharmacists.

When it comes to Medicare Part D, I have been asked, which side am I on? It is critical for your consideration of my comments today to understand that my husband and I, as well as our pharmacist colleagues, are on the side of our patients. Pharmacists and seniors have been frustrated together with the rocky start of this new program.

It is important to emphasize that the provision of a pharmacy benefit for Medicare recipients is a valuable addition to the health care of everyone enrolled in the program, especially those without prior prescription drug insurance. However, implementation and use of the Part D benefit has been an enormous challenge for everyone involved. Calling these challenges merely glitches diminishes what tens of thousands of pharmacists and pharmacy technicians have had to do in our attempt to provide medications to our patients when the system has not worked the way it is supposed to work.

CMS has worked diligently to address many of the Part D problems and some have lessened, but significant problems remain and millions of seniors are yet to enroll in the program.

I won't waste your time today pointing fingers. Rather, my appeal to you is to acknowledge that the problems exist and for you to demand that they be corrected immediately.

I will begin with the complexity of the program. It must be made easier to understand, easier to enroll, and easier to use. I recognize that can't happen overnight, but steps to simplify and standardize the Part D program can and should begin in earnest.

As part of my written testimony, I have provided for your consideration a list of 15 specific problems and 15 corresponding recommendations for resolving those problems. Time does not permit me to review this list, but please consider it a pragmatic tool for making Part D work. Some of the solutions I have outlined must be implemented by the prescription drug plans, some may require changes at CMS, and others may require Congress to act, but each deserves serious consideration.

The health care needs of Medicare patients are as diverse as their last names. Because PDPs have built their programs on norms, many of those diverse needs are not being met. For example, discharges of some hospitalized patients are being delayed because their at-home medications can't be authorized. Thousands of seniors at home in assisted living facilities, mental health clinics, have lost the special packaging of medications they relied upon to take their medications safely and correctly because a PDP won't authorize these packaging. These examples are prevalent and they have significant cost and quality of care consequences.

I have been surprised to see that CMS makes requests, not mandates, to the PDPs to get the program right. I think that is unacceptable and perhaps so does CMS. It appears that CMS does not have sufficient authority to regulate PDP policies and activities. They should be given that authority and they should use it, and there should be significant financial penalties assessed to the PDPs when they fail to perform.

To illustrate this point, after learning of coverage problems in the first week of January, CMS asked for a second time that all PDPs remove prior authorization requirements and allow a 1-month transitional supply of each medication for every Part D enrollee. Some plans have complied with this request, but many have left various hoops and hurdles in place to make it overly difficult to provide essential medication therapies. Insurance plan rules have overruled patient needs and it should be the other way around. This burdensome process must change.

Medicare Part D was created so that recipients would be properly treated. In closing, I must emphasize that the nation's pharmacy providers must also be fairly treated. It hasn't happened and it won't unless Congress steps in. We pharmacists simply want to care for our patients and be paid for the services we provide. Rather than recognizing the valiant effort and sustained contribution of the nation's pharmacists over the past week, the Part D benefit is undercutting the financial viability of the very pharmacy infrastructure that it depends on.

I look forward to your questions and I ask for your leadership and resolve in ensuring fair treatment both for recipients and the providers of the Part D benefit. Thank you.

Senator KOHL. Thank you for your testimony.

[The prepared statement of Ms. Sutter follows:]

Testimony of

Susan Sutter, R.Ph.

Community Pharmacist
Marshland Pharmacies
Horicon and Mayville, WI
&
President-elect
Pharmacy Society of Wisconsin

Before the

U.S. Senate Special Committee on Aging

"Meeting the Challenges of the Medicare Drug Benefit Implementation"

February 2, 2006
216 Hart Senate Office Building
Washington DC

Good Morning.
Chairman Smith, Senator Kohl and members of the committee, thank you for conducting this hearing and for providing me the opportunity to address you.

My name is Susan Sutter and I am a pharmacist from Wisconsin. My husband and I are both practicing pharmacists and we have owned two pharmacies in the rural communities of Horicon and Mayville, which are between Milwaukee and Madison, for nearly 25 years.

I am also the President-elect of the Pharmacy Society of Wisconsin—the state's professional society for pharmacists.

On the Side of Patients
When it comes to Medicare Part D, I have been asked which side I am on. It is critical for your consideration of my comments today to understand that my husband and I, as well as our pharmacist colleagues, are on the side of our patients. Pharmacists and seniors have been frustrated together with the rocky start to this new program.

Implementation Challenges
It is important to emphasize that the provision of a pharmacy benefit for Medicare recipients is a valuable addition to the health care of everyone enrolled in the program—especially those without any prior prescription drug insurance. However, implementation and use of the Part D benefit has been an enormous challenge for everyone involved.

Calling these challenges merely glitches diminishes what tens of thousands of pharmacists and pharmacy technicians have had to do in our attempt to provide medications to our patients when the system has not worked the way it is supposed to work. CMS has worked diligently to address many of the Part D problems, and some have lessened, but significant problems still remain, and millions of seniors are yet to enroll in the program.

Defining the Problems
I won't waste your time today by pointing fingers. Rather, my appeal to you is to acknowledge that the problems exist and for you to demand that they be corrected immediately.

I'll begin with the complexity of the program. It must be made easier to understand, easier to enroll and easier to use. I recognize that can not happen overnight, but steps to simplify and standardize the Part D program can and should begin in earnest.

As part of my written testimony, I have provided, for your consideration, a list of 15 specific problems and 15 corresponding recommendations for resolving those problems. Time does not permit me to review this list but please consider it a pragmatic tool for making Part D work. Some of the solutions I have outlined must be implemented by the prescription drug plans, some may require changes by CMS, and others may require Congress to act, but each deserves serious consideration.

The health care needs of Medicare patients are as diverse as their last names. But because PDP's have built their programs on norms, many of those diverse needs are not being met. For example, discharges of some hospitalized patients are being delayed because their at-home medications can not be authorized. Thousands of seniors at home, in assisted living facilities and mental health clinics have lost the special packaging of medications they are reliant upon to take their medications safely and correctly because a PDP won't authorize the packaging. These examples are prevalent and they have significant cost and quality of care consequences.

Holding Responsible Parties Accountable

I have been surprised to see CMS make requests, not mandates, to the PDP's to get the program right. I think that is unacceptable and perhaps so does CMS. It appears that CMS does not have sufficient authority to regulate PDP policies and activities. They should be given that authority and they should use it. And, there should be significant financial penalties assessed to the PDP's when they fail to perform.

To illustrate this point, after learning of coverage problems the first week of January, CMS asked for a second time that all PDP's remove prior authorization requirements and allow a one month transitional supply of each medication for every Part D enrollee. Some plans have complied with this request but many have left various hoops and hurdles in place that make it extraordinarily difficult to provide essential medication therapies.

For example, I have a plan that has refused coverage and is still requiring an extensive prior authorization process because the quantity of medication prescribed for a particular patient is beyond what the plan would expect for a "normal" month supply of medication, even though that quantity is the amount that my patient needs and has been stabilized on for her condition.

Insurance plan rules have over-ruled patient needs and it should be the other way around. Further, I should not be the person required to serve as the policy administrator for the PDP in order for the patient to receive his or her medications. This burdensome process must change.

Providing Fair Treatment

Medicare Part D was created so that recipients would be properly treated. In closing, I must emphasize that the nation's pharmacy providers must also be fairly treated. It hasn't happened, and it won't, unless Congress steps in. We pharmacists simply want to care for our patients and be paid for the services we provide. Rather than recognizing the valiant effort and sustained contribution of the nation's pharmacists over the past weeks, the Part D benefit is undercutting the financial viability of the very pharmacy infrastructure that it depends upon.

I look forward to your questions and I ask for your leadership and resolve in ensuring fair treatment, for both the recipients and the providers of the Part D benefit. Thank you.

Part D Problems and Solutions List

— as determined by pharmacy providers —

1/31/06

General Prescription Drug Plan (PDP)/Medicare-AdvantagePrescription Drug Plan (MA-PD)

OPERATIONS

Problem: *Insufficient PDP/MA-PD support for pharmacy providers and prescribers. Problems range from insufficient technology support (telephone circuits are busy) to insufficient competent staffing (telephone calls often not answered; callers cut off after being on hold for hours; customer service representatives unable to answer questions regarding eligibility, co-pay and deductible amounts, transition supply procedures, prior authorization/step therapy/formulary requirements).*

Solution: Mandate sufficient competent staffing and broad dissemination of plan requirements/procedures. Help-lines (with competent staff) must be available at least 15 hours a day, 7 days a week. Plans must disseminate transition policies and prior authorization/formulary/step therapy procedures to pharmacy providers and prescribers, and post such information on their website. Plans should be required to follow uniform procedures for providing transition supplies and for communicating with pharmacies.

Problem: *Patients unable to access medication while their doctors and pharmacists navigate plan formulary requirements. Although plans purport to offer a transition supply, procedures to access the supply vary from plan to plan. In some situations, procedures are not available to pharmacists or physicians because customer service representatives are unavailable or ill-informed. The result of these inadequacies is that recipients are left without medications or pharmacies are dispensing medications with no guarantee of payment. Neither is acceptable.*

Solution: Extend transition supply requirement to at least 30 days for all prescribed medications unless disallowed by MMA; mandate standard process for authorizing transition supplies via the claims-processing system. Require PDPs/MA-PDs to phase-in their formulary compliance efforts.

Problem: *PDPs/MA-PDs provide wrong cost-sharing information for patients eligible for both Medicare and Medicaid, as well as for patients residing in long-term care facilities.*

Solution: Designate dual-eligibles on prescription drug benefit cards, allowing pharmacists to help patients determine appropriate cost-sharing and work with PDPs/MA-PDs to correct cost-sharing information. Require PDPs/MA-PDs to comply with claims-processing standards to determine whether or not a patient is residing in a long-term care facility.

Problem: *Patients confused by prescription drug benefit cards containing the logos of certain pharmacy providers. Many enrollees incorrectly assume that the card may only be used at those pharmacies listed on the card.*

Solution: Require removal of all pharmacy logos from prescription drug benefit cards.

STRUCTURAL FLAWS

Problem: *Some medications are covered under Part D or Part B depending on use of the particular product, creating administrative burdens for prescribers and pharmacists.*

Solution: Direct CMS to establish a method to administratively simplify this confusing situation.

Problem: *PDP's have generally not negotiated business terms with pharmacy providers. Instead, PDP's mailed pharmacy providers take-it or leave-it contracts with terms that do not adequately pay for the medication dispensing services required.*

Solution: Require PDP's to verify that the payment terms included in the plan's standard pharmacy provider contract meet the average pharmacy costs associated with acquiring and dispensing a medication in each region.

Problem: *Pharmacy providers have been unable to verify authorization of payment from a PDP for a medication needed by Part D enrollees and dual-eligible recipients during the implementation of the Part D program. Many pharmacies have dispensed prescriptions to beneficiaries to make sure the patient received the necessary medication. These actions have placed the pharmacy at financial risk in the event that a plan does not reimburse the pharmacy for the medication dispensed.*

Solution: Require prompt, efficient and adequate payment to pharmacy providers, by either a PDP or by CMS, for all medications dispensed by pharmacies, in good faith, to persons who were presumed eligible for the Part D program.

Problem: *Eligibility verification and enrollment systems cannot support the promise that a beneficiary who enrolls on the 31st of January will have coverage available in the pharmacy on February 1st. When the eligibility information does become available and pharmacy staff can look up eligibility information via the claims-processing system, pharmacies must pay to access the information.*

Solution: Change consumer communication to explain that while their coverage is effective the next month, they should refill their medications in their usual cycle, requesting the refill five to seven days before they will run out of medication. Change enrollment standards so that any enrollment form received by a plan by the 15th of the month will have coverage starting the first of the following month. Suspend charges to pharmacies for use of the eligibility verification system.

Problem: *Failure of PDPs/MA-PDs to compensate pharmacists for time spent determining eligibility, coordinating benefits, and participating in formulary compliance efforts.*

Solution: Mandate PDP/MA-PD payment to providers for these services, in addition to dispensing fees and compensation for medication therapy management services.

Problem: *Some dual-eligibles were auto-enrolled in PDP/MA-PD plans that are not accepted by their pharmacy provider. While the patient may change to a plan accepted by their pharmacy for coverage effective next month, their option for securing medications in the current month is to pay cash and await reimbursement from the plan or to move all of their prescriptions to another pharmacy for one month, if another pharmacy is even accessible.*

Solution: Require plans to pay out-of-network pharmacies (not beneficiaries) when beneficiaries' auto-assigned plan was not accepted at their pharmacy.

Problem: *PDP/MA-PD coverage of medication therapy management insufficient to improve medication use. There is no standard of MTM service expected by CMS.*

Solution: Mandate PDP/MA-PD coverage of baseline medication therapy management services and direct PDP's to contract with pharmacy providers for such services.

Problem: *PDPs/MA-PDs are not required to pay pharmacies in any specific time frame. With many eligibility problems still unresolved, many practices will be required to pay for medications dispensed to Medicare beneficiaries, but without payment or assurance of payment from PDPs/MA-PDs.*

Solution: Require PDPs/MA-PDs to pay pharmacies at least twice monthly.

Problems for Patients in Long-Term Care Facilities, Assisted Living Facilities, or Using Home Infusion Services

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Problem: *Patients in long-term care facilities may receive medications via unit-dose packaging for a calendar month (up to 31 days supply.) PDPs/MA-PDs are limiting medication supplies to 30 days.*

Solution: Require PDPs/MA-PDs to pay for one-month supplies if that is what is dispensed, not merely 30-day supplies.

Problem: *State law may require special medication packaging for patients who reside in assisted living facilities or other environments, but PDPs/MA-PDs refuse to pay for the safety packaging.*

Solution: Require PDPs/MA-PDs to pay for the medication packaging services needed by any given Medicare recipient.

Problem: *Patients are staying in the hospital longer than clinically necessary while their doctors secure approval from PDPs/MA-PDs for home infusion medications and supplies, medications requiring approval by the PDP, and for some medications needed in the long-term care facility. In some situations, PDPs/MA-PDs refuse to pay for supplies and services necessary for proper administration of the medication.*

Solution: Mandate 24-hour response time by each PDP for all medication approval processes, and mandate coverage of all necessary home infusion supplies and services.

Senator KOHL. I have just one question I would like to ask you. I am sure you have experienced, as other small and medium-sized pharmacies in Wisconsin and across our country have, going to the length of having at times to take out lines of credit or to extend credit for which they don't have the resources and shouldn't be doing it, but to see to it that their patients are served. What has been your experience and what do you suggest we do to remedy this situation as quickly as possible?

Ms. SUTTER. Certainly. There are a number of financial things on different levels. First of all, the amount of time, uncompensated time, the work that we are doing administratively within these pharmacies because of what was not set up properly and proper training at the PDPs, we have hundreds of hours across these pharmacies and across the country. In addition to that, pharmacists like ourselves have given free drugs, medications, to our patients with the hope and understanding that we will get some type of reimbursement. Certainly other pharmacies, and I have heard it a great deal in the last week, have gone to the point of needing line of credit because most of our wholesaler bills are now due.

That is only the first line of the financial issues. Senator Lincoln earlier commented about the issues with the contracts with the PDPs. It is take it or leave it. Yes, there are rural pharmacies that can use the access requirement to possibly get negotiations with these PDPs, but we still have two. One of our pharmacies meet that access requirement. We have two that have not negotiated in good faith to contract with us.

But I also want to state, there are pharmacies in the urban area where the density requirements or the access requirements, you are still asking patients to change pharmacies. One of the things that I hope that everyone understands, having gone through what they have gone through in this first month, is that many, many, many of these patients have patient-pharmacist relationships and you are taking away their choice of staying with the pharmacist that they trust. These contracting problems that we are having, they may have a certain set of pharmacies in an urban area, but they have to leave the clinic pharmacy that they have a relationship or a specialized pharmacy through a health system that they have been using.

So as we address those issues, I want you to understand that the contracting, the overall contracting issue is going to be an ongoing financial issue for us.

Senator KOHL. Thank you. Your testimony, your experience, the kind of perspective you bring to this issue is really important to this committee and I appreciate very much your coming here today.

Ms. SUTTER. Thank you, Senator.

The CHAIRMAN. Tim, you just heard Sue's testimony. Is that familiar to you in Massachusetts?

Mr. MURPHY. Yes. It was interesting, because when other folks were talking about that today, I turned to Paul and asked, what have we heard in Massachusetts, and it is a little different in that it is clear that a number of pharmacists have given free drugs to folks to kind of, if you will, tide them over while they were trying to find and identify them within the system. I think in Massachu-

setts, because we acted so early, though, in terms of, if you will, turning the edits off of our Medicaid system to allow people to bill, that we were able to address this problem such that our pharmacists aren't in the same situation that you are hearing from other parts of the country today, and so we haven't heard situations of people taking lines of credit or things like that, and I would turn to Paul just to make sure I am not overstating that case. It is consistent.

The CHAIRMAN. Sue, you had many good ideas there and we will continue to push them. Thank you.

Ms. SUTTER. Thank you.

The CHAIRMAN. Mark Ganz, Regence Group, Oregon. Welcome.

STATEMENT OF MARK B. GANZ, PRESIDENT AND CHIEF EXECUTIVE OFFICER, REGENCE GROUP, PORTLAND, OR; ON BEHALF OF THE NATIONAL BLUE CROSS AND BLUE SHIELD ASSOCIATION

Mr. GANZ. Thank you, Chairman Smith, Senator Kohl, for the opportunity to testify about an issue that touches so many. My name is Mark Ganz. I am president and chief executive officer of Regence Blue Cross Blue Shield, a taxable not-for-profit health insurer. We are one of the oldest plans in the country and the largest in our region, serving over three million people in Washington, Idaho, Utah, and Oregon.

Regence has been serving Medicare beneficiaries since the program began in 1965, so we know a lot about their needs and their expectations. To make Part D a success, we knew it would take one-on-one, face-to-face engagement, a huge investment of people and resources for our company. So it was only after careful deliberation that we decided to take on this challenge.

A key reason that we got involved with Part D was that we knew we could save seniors money on their medications. Regence operates one of the few in-house not-for-profit pharmacy benefit programs in the country. Our nationally recognized program has saved our members more than $370 million in drug costs over the past 5 years. We were, quite frankly, very excited about the opportunity to expand these savings to Medicare beneficiaries.

Also, I had personally experienced the plight of beneficiaries who existed without drug coverage. My mother has been spending more than $8,000 a year on drugs, paying full price at the pharmacy. She called me for help on Part D and we spent a few hours going over her drug list and different plans to see which might work best for her over the Thanksgiving holiday. As a son, it was a humbling reminder that this person who once took care of me now needed me to help take care of her. Thanks to the Part D program, she will save at least $4,000 a year. That is a big deal for her as she approaches 80 and beyond. For me, that is what this program is about.

We all share a commitment to Americans who need Part D and need our help to make it work for them. This commitment is what has guided our service to seniors for more than 40 years and is precisely how we approached our implementation of Part D, one person at a time.

So what did we do to gear up for Part D? First, we prepared ourselves, our partners, including all of the pharmacists, and our members for what was coming. We reached out to them early and often.

Second, we did our best to anticipate the inevitable problems and glitches. We developed "what if" scenarios so we could identify risks and develop solutions ahead of time.

My written testimony outlines the proactive steps we took beginning last summer. Let me simply say that it was a massive mobilization effort that required an all hands on deck attitude at our company, and our planning has largely paid off.

Even so, when October 15 arrived, we were immediately swamped. The response to this program was far beyond anything we had anticipated. Here are just a few examples.

In 1 month, we have enrolled 63,000 people, more than three times the total we enrolled in that market segment the prior 2 years combined.

Call volume to our government program line has more than tripled, from 12,000 to over 40,000 per month. Many seniors have called us ten, even 20 times for advice.

At the nearly 300 seminars and outreach sessions that we did, we engaged more than 17,000 people personally who wanted to get advice and answered questions, and I personally was engaged in some of those outreach sessions.

So how are we doing today? Overall feedback has been positive from our State governments, from pharmacies, and from our members. I don't want to mislead you. We have not been perfect. We have had our share of problems—fortunately, not with my mom, yet, although I am sure I will hear from her if we do.

But our primary objective has remained intact. We give seniors the benefit of the doubt if any question arises and we tell the pharmacies, fill the prescription. We will pay you. We are taking the financial liability, and if we end up overpaying, we do not intend to go and seek the reimbursement. We are just paying it now. We will sort out the discrepancies later. As a result, Regence members are getting their medications and they are calling to say, thanks for being on their side.

Here are a few more numbers. As of January 23, we have filled 120,000 prescription drug claims. As of January 20, we had paid out to pharmacies $7.5 million in medication claims.

While we are proud of our success, we are not sure that that performance is all that unusual. We believe that the health care industry has been working hard to help people through this major transition. During the moments of frustration, it might be tempting, even satisfying, to focus on the flaws and point the finger. But for those of us on the front lines, it is more important right now to persevere, work with our partners to solve problems, and keep a laser focus on the people we are here to serve.

Any human endeavor, especially one that involves 43 million Americans, will have challenges and have human errors. At Regence, our goal has been to minimize problems and maximize access and personal engagement, one beneficiary at a time. We think it is working and the effort is worth it for our members.

So on behalf of the 5,500 Regence employees that I am here representing, I am honored to share our story with you. Thank you for inviting me and I am happy to answer any questions.

[The prepared statement of Mr. Ganz follows:]

PO Box 1071
Portland, Oregon 97207-1071

WRITTEN TESTIMONY OF MARK B. GANZ
President and CEO, The Regence Group
United States Senate Special Committee on Aging
Thursday, February 2, 2006

Thank you, Chairman Smith, Senator Kohl, and members of the committee for the opportunity to testify before the United States Senate Special Committee on Aging regarding my company's experience implementing Medicare Part D.

My name is Mark Ganz. I am president and chief executive officer of The Regence Group, a taxable not-for-profit health insurer serving nearly three million members in Oregon, Washington, Idaho, and Utah. We are one of the oldest health plans in the country, with our roots dating back to the lumber yards of Tacoma, Washington in 1917. We now have more than 5,500 employees and nearly 39,000 providers in our networks. We are the largest health insurer in the Northwest / Intermountain region.

Regence delivers Medicare Part D through our Asuris subsidiary in Oregon and Washington and through our Regence Life and Health subsidiary in Idaho and Utah. The Regence Group and each of its affiliate plans are independent licensees of the Blue Cross and Blue Shield Association.

Regence has been participating in Medicare since the program's inception in 1965 as a Medicare Part A and B administrator. We offer three types of Medicare Managed Care Contracts: Medicare HMO or Medicare Risk since 1985; Medicare Cost since 1993; and Medicare Advantage since July, 2005. Our Medicare "First Choice Sixty-Five" product was one of the first Medicare HMO demonstration plans in the country. We are proud to say we have remained in the market consistently, even when low reimbursement rates made doing so a real financial challenge.

Because of our long experience with Medicare, we understand the commitment necessary to undertake the major changes required by Part D. We understood Part D would be an enormous challenge, and we deliberated about whether to participate; but we decided the opportunity to serve this population was well worth our efforts. Also, we believe Part D fits well within the Regence vision of a transformed health care system rooted in a deep sense of community.

The Regence Group is an independent licensee of the Blue Cross and Blue Shield Association

We knew this would be a difficult program to implement. Despite our decades of experience with Medicare, implementing Part D was significantly more difficult than we anticipated. So, it is worth the effort to examine what is working well, what improvements are needed, and how to make this program work for everyone.

One person at a time

I realize I was invited here today to represent a large health insurer as its chief executive. But inevitably, I also bring to my position—and to my testimony—my experiences as a husband, father and son. In these roles I can well identify with Americans who have difficulty navigating the health care system. I recently lost my father after a long illness --an illness stoically borne while doctor after doctor misdiagnosed his condition. I claim no more sympathy than others who have suffered such a loss—I have many friends and colleagues who have had similar experiences. The irony here is that my father was a physician himself, an old-fashioned family doctor who prided himself on listening to his patients—and listening to them, he said, was always the best diagnostic tool. At times, his and our experience with the health care system left something to be desired. But, putting our pain aside, my family was able to be there for Dad when he needed us.

Too many of our neighbors across this land do not have the support of family and friends. It is incredibly difficult to understand the true needs of this population unless you have taken the time to sit across a table and speak with them personally, with an open mind and an open heart about their hopes, their dreams, and their fears. These are people like you and me, who happen to need some help and support from their communities to live as healthy and fulfilling a life as they are able. They are our neighbors—seniors and people with disabilities—and it is our responsibility to help them in their time of need. Programs like Medicare Part D represent a critical component of this shared promise of community.

So when I sit with our community's elders and listen to their fears at a Medicare Part D seminar, I hear my own mother talking. She had to wade through this too, and without Dad. She spends $8,000 a year or more on medication—this program is vitally important to her, as it is to many citizens eligible for Part D, elderly or not. She called on me to help, and I spent a few hours with her at the kitchen table over the Thanksgiving holiday walking her through the options to see which plan worked best for her. As a son, it was a humbling reminder that this person, who worked tirelessly for many years to take care of me, now needed me to help take care of her. This exemplifies for me the nature of our commitment to the elderly and vulnerable in our communities across this country who need Part D, and need our help to make it work for them.

Last fall, I was fortunate enough to spend some time on the Medicare Part D bus with Health and Human Services Secretary Mike Leavitt as he toured our service area. As I observed his encounters with seniors, I realized that this program could work only if we engage people at the most personal level. I took that insight back to Regence, and

determined that was precisely how we would approach our participation in Medicare Part D: One person at a time.

Gauging Part D's challenges: Pre-October 15

With 43 million Americans eligible for Part D, nearly two million of them in our market, we expected our task to be monumental. A brand-new kind of benefit affecting a huge number of people poses massive challenges. We knew it would take foresight, planning and extensive financial and human resources to implement this new program. We developed "what if" scenarios to identify potential problems and how to mitigate them. We also identified the stakeholders and began our outreach.

PHARMACIES. We began an aggressive outreach effort last summer to pharmacists and their staff about Medicare Part D and worked with our network pharmacies to determine the best way to provide them with education, training, and assistance. We advised them of our plans and policies for implementation and made sure they had direct phone, fax and email contacts. We sent email notifications to network and independent pharmacies and mailed information to those not on the distribution list. At the time, pharmacists expressed great appreciation for our efforts, which they viewed as effective and timely. Clearly, they were hungry for this information.

We also created a user-friendly website for pharmacists, where we posted information on all our Medicare and Part D plans, benefit designs, and billing information. The website also shows our payer sheets, Medicare formulary, ID cards, and training materials.

Our award-winning, in-house pharmacy benefit management program is one reason we decided to implement Part D. We knew we could save seniors money. RegenceRx is nationally recognized, rated "best in class" for its ability to combine cost management, access, and savings. We have saved more than $370 million since 2000 by emphasizing medications with the best scientific evidence of effectiveness. As a not-for-profit insurer, we pass those savings directly to our members.

MEDICAID OFFICES. Well in advance of the January 1 launch, we also contacted the Medicaid offices throughout our four-state service area, offering direct contact for any problems they might encounter. Knowing we would receive auto-assignments of thousands of dual-eligibles, we wanted to make this transition as smooth as possible for everyone involved. We later heard from one of our Medicaid offices that no one did it better. We appreciate the compliment, but we remain vigilant on behalf of this vulnerable population.

COMMUNITY EDUCATION. Like many carriers across the country, we scheduled dozens of educational seminars on Part D for brokers and the public alike, and prepared extensive presentation materials and handouts to help people understand what Part D could do for them, and what criteria to use to decide which option was right for them, if any.

STAFFING AND INFRASTRUCTURE. We expected increased phone calls, so we staffed up member services and customer service, and added phone lines to handle the volume.

Hitting the ground running: Oct. 15 to Jan. 1

With all our preparations, we were still overwhelmed by the public response to Part D. Seminars for which 40 people responded were swamped by as many as 400, many wanting help to look up doctors and medications for coverage. Triple the usual number of calls clogged phone lines so badly that normal Medicare business was disrupted. We responded with a massive staffing plan.

CALL VOLUME. We quickly added more phone line capability and dozens more trained staff to take calls. These improvements reduced busy signals, wait times, and decreased the number of abandoned calls. While we expected increased call volume, we hadn't realized that so many seniors would call us repeatedly, in some cases 10 or even 20 times, to make sure they understood the program. Our staff takes as long as needed with each caller, which members have told us they greatly appreciate. Additionally, our Government Programs staff worked nights, weekends and holidays to ensure that timely responses were available when questions arose.

STAFFING SEMINARS. We also added personnel to process claims and address pharmacy issues. We even canvassed our own employees—senior management included—for help at the seminars. I joined the fray as well, attending seminars and working one-on-one with seniors. Hundreds of our employees volunteered, trained and attended seminars to keep our commitment of face-to-face engagement, one senior at a time. We also increased seminar bookings to 40 a week. By January 20, we had conducted nearly 300 seminars with more than 17,000 people attending.

DUAL-ELIGIBLES. We received our list of some 13,000 dual-eligible Medicare-Medicaid auto-enrolled members from CMS at the end of October, and promptly entered them into our system. A number of issues arose, from outdated addresses to incomplete information. We decided early on that any question about eligibility would be decided in the member's favor, and we would sort out details later.

LOW-INCOME SUBSIDY. There were data problems associated with this group, specifically, discrepancies in files that lacked information regarding co-payment eligibility. Again, our response was to put the member first: Pay the claim and work out the rest later.

MEMBERS FIRST; PAPERWORK SECOND. We made sure our pharmacy partners were well advised of our policy on this point: Any member who presents a Regence letter of acknowledgement—or even claims to be a Regence member—gets the benefit of the doubt, and the lowest co-pay rate: $1 generic and $3 brand (lower than the default CMS rate of $2/$5). A phone call to Regence to verify membership is all that's required to pay

a pharmacy claim. No matter the outcome of any later determination, members will be held harmless during the initial implementation period. Our goal is to get medicine into the hands of members.

Despite having our systems overwhelmed, we managed to enroll 63,000 people as of January 20, and expect another 10,000 to have been processed by the February 1 eligibility date.

Part-D-Day: January 1 to present

Having done our utmost to enroll members and submit their information to CMS, we mobilized employees to staff our phones on New Year's Day and the Monday holiday. The first call came at 7 a.m. and phones, faxes and email were busy all day to afford as much direct contact as possible with a live person who could solve a problem. We had plenty of company that holiday: At 10 a.m. that Sunday, we were able to reach a CMS administrator at his desk to help us clear up a pharmacy industry access issue.

From Day One, we monitored each point-of-service claim that came in. When any denied claim or questionable co-pay appeared on the list, we immediately contacted the pharmacy to inquire about the denial. If it was incorrectly applied, we educated the pharmacy and reviewed all subsequent claims that came through. Sometimes we were able to resolve more than 80 wrongful denials with a single phone call.

We didn't expect perfection in such a massive start-up and we received many calls from pharmacists. One thing they told us, though, was that Regence did a good job on communications; returning their messages with helpful information. Our staff is still working overtime to handle the call volume.

We've had our share of glitches, but Regence has processed 119,600 prescription drug claims as of January 23, and paid $7.5 million in medication claims as of January 20. When Secretary Leavitt came to Oregon last month, he asked Governor Ted Kulongoski and his senior health policy advisors: Who's doing it right? Regence is proud to have been singled out on this occasion as a plan that is having some success implementing Part D.

The bottom line: Part D is working, but there are real challenges

Even considering our years of experience participating in Medicare and despite all our early preparations, we still encountered enormous challenges. The interest in this program has been far greater than we or any other carrier anticipated. The magnitude of implementing Part D stretched our human and technological resources. For example, the number of applications we processed at Regence in the first months of open enrollment represents triple the applications we typically receive in a two-year period, a huge undertaking for any company. We experienced more than triple the average monthly call volume, which caused our wait times and abandonment rates to increase. Our experience is multiplied countless times across the country.

One lesson we've learned at Regence is that we cannot over-communicate in a program of this scope and complexity. Ads, brochures, handouts, presentations, websites, phone calls—all are useful but not sufficient. With this population, there is no substitute for one-on-one—preferably face-to-face—communication. As I mentioned previously, many people called Regence repeatedly to make sure they understood the rules, the deadlines and the coverage. We didn't anticipate that, and it clogged our phone lines and drained staff resources.

Everything we have learned better prepares us to face the continuing challenges.

Overall, we believe the health care industry has been working in good faith to deliver high quality prescription drug coverage to Medicare beneficiaries. Without pointing fingers, we all recognize that a number of systems issues and communications issues have caused disruptions for some beneficiaries. The good news is that hundreds of sponsors of prescription drug plans have formed a strong public-private partnership that is meeting these challenges. Behind the scenes—far from the media spotlight—thousands of resourceful government and health plan employees are working to resolve the issues that have gained so much attention in recent weeks. Because of their efforts, we are seeing fewer problems with each passing day.

Despite the difficulties you have heard, it is much too early to call for wholesale changes to Medicare Part D. With this new program, millions of seniors are getting the medicine they need. According to CMS, pharmacists are filling more than one million prescriptions a day. And when situations arise, all parties, including CMS, plan sponsors, pharmacy benefit managers, and pharmacists, are working hard toward solutions to ensure that beneficiaries get their medications.

We should not lose sight of the big picture. Implementation problems will be worked out and beneficiaries now have access to better drug coverage—especially for low-income Medicare beneficiaries and those with chronic health conditions. Millions of people are realizing a significant benefit from this program. And in the end, beneficiaries will save hundreds, even thousands of dollars on their prescriptions due to this first-of-its kind benefit in Medicare.

You have heard about problems today as well as some solutions and successes. I hope the Regence experience brings some balance and some hope to those concerned about Medicare Part D. For any hurdles yet to be cleared, Regence will stay focused on an approach that works: one person at a time.

On behalf of Regence employees, I thank you for the opportunity to testify before the committee. And we are pleased to expand our participation in Medicare so we can continue to meet the needs of the communities we serve.

The CHAIRMAN. Mark, your very insightful and helpful testimony is particularly memorable regarding your mom. Do you at Regence find that you are able to work with the seniors to get through the frustration and get them enrolled? Do they appreciate the amount of savings that are there for them? I mean, your mom, I am sure, is aware that there are $4,000 annual savings available to her.

Mr. GANZ. Right. I think it is early on, so I think that the appreciation will increase as people see the actual savings and can compare it to the full price they have been paying in the past, because they are not only going to get coverage, but they are also getting the benefit of a greater focus on generics and other things that will actually help lower their costs. So I think that that will increase over the year. I mean, we are very early on in this program.

But yes, I think the main thing we have heard from seniors is they have appreciated the personal outreach. That is how they like to process. That is how they learn. They are not going to learn it from just getting a brochure in the mail. They need to really go through it.

The CHAIRMAN. Our thanks to all three of you and our other two panels. You have added measurably to our Senate record and we clearly understand from you that it is not perfect, but it can get a lot better if we keep working on it. So thank you and thank you, Senator Kohl. I think this has been a very informative hearing for all members.

We are adjourned.

[Whereupon, at 1:09 p.m., the committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR LARRY CRAIG

Thank you, Mr. Chairman, for convening this important hearing to assess the implementation of the new Medicare Part D prescription drug program. I think one month into the roll-out of the program is an opportune time to reflect on the progress we have made, the short-comings we have already identified and to discuss possible solutions to some of the problems we face.

I do not want to suggest that all of the news surrounding this program is unfavorable. In fact, just the opposite is true. I think the American public has a lot to be proud of when we look back on our first month. CMS is reporting that over 1 million prescriptions per day are being filled for our nation's most vulnerable citizens. In addition—contrary to many predictions at the time of enactment—dozens upon dozens of companies are participating in a market-based system to provide medications to tens of millions of citizens. In my own State of Idaho alone, there are 19 different companies offering over 40 plans from which beneficiaries can receive prescription medications at significant discounts. One of those providers, The Regence Group, is here today to testify about their experience in implementing this important new program. I want to thank them for their willingness to come and offer their perspective and advice.

Of course, not all of the news is good either. As I mentioned at the outset of my statement, a few serious short-comings have been identified in the implementation of this program, particularly in the transition of our Medicaid patients from state coverage to Medicare coverage. This complicated transitional period has been weighed down by a lack of understanding at the retail pharmacy and consumer level as well as a lack of timely and helpful service at the industry and governmental levels. Pamphlets and mass mailings are important. But, I think most of you would agree there is no substitute for one-on-one human interaction where questions can be posed and answered correctly. I know CMS and industry have been training call center employees for months and recently have even increased their call center efforts. That is a welcome and important step. Now, it is time to pass on the best available, most accurate information to our beneficiaries, pharmacists, and providers.

Mr. Chairman, just three years ago, Congress and the President set out on a bipartisan mission to provide affordable prescription medications to America's seniors and Medicaid-eligible citizens. Together, we put our best efforts forward, forged many compromises, and to a large degree have accomplished what we set out to achieve. Is our program perfect? No. But, I believe that constructive reviews, such as this hearing, coupled with the best intentions of the American people will ultimately perfect this program for the betterment of all of our deserving seniors and citizens in need.

Thank you again, Mr. Chairman.

PREPARED STATEMENT OF SENATOR SUSAN COLLINS

Mr. Chairman, thank you for holding this hearing to discuss critically important issues related to the implementation of the Medicare Part D drug benefit.

The addition of a prescription drug benefit represents the broadest expansion of Medicare since the program's inception in 1965. This important new program has the potential to provide prescription drug coverage—for the first time—to more than 11 million Medicare beneficiaries who previously had to pay for their prescriptions out of their own pockets. Moreover, the program has the potential to improve coverage for millions more who had coverage that was less generous than the new Part D benefit.

Unfortunately, however, the implementation of this new benefit has been fraught with serious problems and missteps. Given the magnitude of the new program, I

think that everyone anticipated some start-up difficulties. But it is now evident that the Centers for Medicare and Medicaid Services has made some major errors and miscalculations. Of particular concern is the fact that some of our poorest and sickest seniors are the ones who have had the most trouble with the new benefit. We must therefore make every effort to identify and rectify these problems as quickly as possible.

I understand that CMS has taken some steps to address a few of the problems that have been identified. For example, they have dramatically increased the staff at the call center for pharmacists, and they have also improved the speed and accuracy of the "E–1" computer system that can be used to check a beneficiary's enrollment. The Committee will be hearing later from a pharmacy representative who I hope will tell us whether these changes have made their jobs any easier.

Maine was the first state to step in and say that, if a pharmacist is unable to confirm that a Medicare beneficiary is enrolled in a Part D plan because of a computer glitches or another problem—the state will cover the costs of the drugs. Governor Baldacci is to be commended for stepping in to provide this safety net, and I am committed to making sure that my State is not saddled with millions of dollars in costs due to the federal government's problems in implementing the new benefit.

Secretary Leavitt has given me personal assurances that Maine will be reimbursed for the money it is spending to prevent any disruption of benefits for our seniors. I have also joined a bipartisan group of my colleagues in introducing legislation that would require the Department of Health and Human Services to do so.

As problematic as the start-up has been, this new Medicare benefit has the potential to provide much-needed relief from high prescription drug costs, particularly for those seniors and disabled individuals who previously had no coverage at all. It is therefore imperative that we work together to identify problems quickly and make the changes necessary to make the program work.

Again, I want to thank the Chairman for calling this hearing.

PREPARED STATEMENT OF SENATOR RUSSELL FEINGOLD

I thank the Chairman for holding this hearing today. The implementation of the Medicare Prescription Drug Benefit has been of great concern to me as well as my constituents in Wisconsin, and I am pleased that the Committee on Aging is examining some of the serious problems that have occurred since January 1st of this year. I am also pleased that Senator Kohl has invited Sue Sutter, a community pharmacist from Wisconsin, to come and testify before the committee today. Sue and her husband, John, own two pharmacies in Wisconsin, and I know that she will provide a much-needed perspective on the effects of this program on independent pharmacies in rural communities.

Supporters of the Medicare Prescription Drug Benefit have touted it as the vehicle that would supply affordable, easily accessible prescription drugs for seniors. The program has so far fallen far short of that goal. The outcry that I have heard from pharmacists, beneficiaries, and health care providers over the past few weeks makes clear that the implementation of the program has been a disaster. This program has not provided either affordable or easily accessed drugs to many Medicare beneficiaries. Instead it has presented providers and beneficiaries with frustration, confusion, expensive medications, and sometimes no medications at all. It is unacceptable for individuals to go without life-saving medications, yet this is what has been happening in Wisconsin and across the country since this program commenced.

Since the beginning of January, I have received panicked phone calls from people in my state saying that they were unable to receive drugs that they had been routinely getting at their pharmacy every other month. Many calls were from people who could not receive essential drugs such as insulin, anti-psychotics, or immunosuppressants for transplant patients. At the same time as I was hearing from people suffering from pain because they did not receive their pain medications, I received press releases from the Centers for Medicare and Medicaid that expressed satisfaction with the launch of the program, and boasted on the millions of participants in the program. There may be millions participating in the program, but too many of them cannot receive their drugs and too many pharmacists are unable to comply with the complicated regulations in the program. CMS should be focusing its efforts on addressing this emergency rather than disseminating public relations messages.

I hope that this hearing will provide a forum in which important questions will be answered, and that solutions will be found to the multi-faceted troubles that have occurred as a result of this program. I have written Secretary Leavitt and Dr.

McClellan repeatedly to voice my concern about Medicare Part D, but I have not yet received a single response.

Some of the problems that I hope are addressed by the administration today include the supposed contingency plans for implementation that have failed. The transitional plans offered by the private drugs plans have often been inadequate. While a 30-day supply of drugs has been encouraged by CMS, it has not been required. I think it is time that CMS remember who this plan is supposed to serve: the people, not the drug and insurance companies.

I also hope that the many problems regarding dual eligibles are addressed in this hearing. I was disheartened to learn that some beneficiaries had to pay for their drugs on their credit cards, their only other option being to go without their medications. Those with little income will be paying for these drugs for months, with interest, and this is a sad burden for the federal government to place on the neediest in society. Other dual eligibles are entirely without drugs or have had gaps in their treatment. This is unacceptable, and I hope this is addressed today.

Additionally, I hope that CMS will properly address the issue of reimbursement for the state governments. Many states, including Wisconsin, came to the aid of the public when the federal government would not by enacting emergency provisions. Now, these states are depending on the federal government to act responsibly and reimburse them for funds that were spent out of tight state budgets. To date, the administration has put in place a complicated system that forces states to bill various private drug plans. This is an undue burden for states short on cash and personnel, and I hope that CMS will provide an adequate alternative.

We cannot sustain a great nation if we do not care for our elderly, sick, disabled, and home-bound. These are the people this drug plan is supposed to be serving, and I fear that they have been dismally let down the past month. Let us not wait any longer. There is an opportunity at this hearing to find solutions, and I hope that this opportunity will be seized by my colleagues and the administration.

PREPARED STATEMENT OF SENATOR RICK SANTORUM

Good morning, I would like to thank the Chairman for holding today's hearing and providing an opportunity to discuss a very important topic—the implementation of Medicare Part D. I would also like to thank today's panelists for taking the time to share their own experiences with the implementation of this important benefit and their suggestions for how it can be improved. As a member who represents a state with one of our nation's largest senior populations, ensuring that my constituents have access to medically necessary prescription drugs is one of my highest priorities.

Since Medicare Part D implementation began, all of us have heard the anecdotal reports of confusion and frustration that have stemmed from the inherent challenges of implementing the most comprehensive improvement to the Medicare program since its inception over forty years ago. As I have personally communicated to Secretary Leavitt and Dr. McClellan, it is unacceptable if even one of our most vulnerable citizens has encountered any difficulty in obtaining medically necessary drugs. Any problems that have been identified since the Medicare drug coverage began must be addressed immediately. I look forward to accompanying Secretary Leavitt to Pennsylvania later this month so that he can see first hand what my constituents are experiencing.

The Aging Committee is taking an important first step in delving into issues related to Medicare Part D implementation, and next week's Senate Finance Committee hearing will build upon today's discussion. Many of the questions and concerns we are hearing about Medicare Part D implementation mirror those from the early days of implementing the original Medicare program in 1966—problems which have long since been resolved. Over the past forty years, Congress has strengthened and improved Medicare to ensure that program has kept pace with improvements in health care. I would caution my colleagues that hastily drafted legislative "fixes" to improve this nascent program would be premature as the program is only in its second month, and each day we are hearing positive reports of continuing improvements. Just as Congress has acted to strengthen and improve Medicare over the past forty years, I am confident that Congress will continue to work with CMS to act as necessary to strengthen and improve Medicare Part D. Honest discussions such as today's are an essential step in ensuring that such improvements are the result of a policy driven process.

Last week I received a letter from a senior in Doylestown, Pennsylvania. She wrote, "Senator Santorum, thank you for supporting the Medicare prescription plan. Today I paid $9.60 for a 90 day supply of my hypertension medication which in 2005

cost me $45." Thanks to Medicare Part D, this Pennsylvania is not only saving on her drug costs, but she has the peace of mind of knowing that her financial health is protected against catastrophic drug costs. We cannot lose sight of the enormous potential of this benefit to improve the health of millions of Americans; yet, this potential cannot be fulfilled unless the problems the program is experiencing today are successfully resolved.

$190 Million in Highway Plans

HARRISBURG (UPI) — The state Highway Commission has approved construction plans for more than 1,300 state-aid project costing more than $190 million.

The commission said Monday that the projects will be under nation during the next six years. They are part of a $400 million program for improving so-called "secondary" roads.

Added to Staff

NEW YORK (UPI) —Theodore C. Sorensen, an aide to President John F. Kennedy, has become an editor-at-large of the Saturday Review.

Norman Cousins, editor of the magazine, said Sorensen "will contribute occasional signed editorials and articles" and "undertake special assignments not conflicting with his legal practice," which Sorensen resumed after he left the White House.

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GROUND FLOOR—ACROSS FROM SEARS

TOGETHERNESS — These six girls, children of Mr. and Mrs. William T. Adams of Terre Haute, Ind., all had their tonsils and adenoids taken out 24 same day. They are: (left to right) Margaret, 11, Cecelia, 14; Diane, 6, Mary T; Janet, 4, and Trina, 8. (UPI Telephoto)

Split for Koppers

PITTSBURGH (UPI) — Koppers Co. Inc., stockholders voted on Monday at their annual meeting for a 2-for-1 split of the firm's common stock. The split had been proposed last Jan. 31 by directors. Fred C. Fay, Koppers chairman, said the firm has signed a new bank loan agreement with a group of nine banks. The agreement replaces a previous $50 million line of credit and enables Koppers to borrow up to $25 million to finance current expansion programs.

Teen Smoking Is On the Upswing

FORT WAYNE, Ind. (UPI) — Cancer experts, shocked by the results of a survey of grade school smoking habits here, have called for a "new approach" to cancer education.

Results of the survey by the Fort Wayne-Allen County Cancer Society released Monday showed that almost one of every 10 pupils in grades six through nine smokes. The survey covered 13,000 students.

Marion Tuttle, who heads the American Cancer Society's research division, said the new approach to education is need ed "if these teenage smoking habits are to be prevented."

The survey showed that one out of 17 of the 10-year-olds smokes as does one out of 10 of the 14-year-olds. Tuttle said many of these do so with the consent of their parents.

Of the age groups surveyed, 17 per cent smoked this year and 17.4 per cent of the boys and they smoked daily. Of the total polled, 37.4 per cent were from homes where mother never smoked, 37.3 per cent where women smoked and 24.4 per cent where men smoked.

Tuttle said some of the reasons cited for not smoking were that it was harmful to health, wrong, prevented sports from education through news media and schools and it was too costly.

"One student said smoking stunts the growth and he was short already," Tuttle said. "Another said he didn't want to hurt his very late a grave."

Four Professors Quit in Dispute At Duquesne

PITTSBURGH (UPI) — Four philosophy professors at Duquesne University have submitted resignations in a dispute over the teaching of contemporary philosophy, it was reported today.

The dispute, which erupted two months ago, contains several charges that newly-appointed department head Dr. John J. Parsons, plans to de-emphasize teaching of phenomenological existentialism, the study of man as he is rather than as he should be.

Three submitting resignations effective at the end of the school term were Dr. Raymond Frings Jr., Bernard J. Boldon, John G. Yoest and Bernard J. Tomasko.

Marlor Dr. Alphonse P. Lin, who had submitted his resignation.

Electrical Charges May Reduce Strokes

PHILADELPHIA (UPI) — A New York surgeon reported Tuesday that sudden death from heart attacks and strokes may be an electrical weather and possibly can be prevented on short basis.

Dr. Philip E. Sawyer, associate professor of surgery and head of vascular surgical service at the State University of New York, Kings County Hospital Center, said a "wind tunnel" can be made for defibrillating accumulated blood clotting in the body as an "electrical phenomena."

Sawyer told the Biomedical Center vascular symposium that his electrical theories regarding the blood vessels have been used so far only to mean clotting and not to prevent it. He said the method of using an electrical current to induce clotting has also been tested in helping people with severe bleeding problems.

He said an advanced cancer patient with uncontrollable stomach bleeding was treated with "direct current coagulation." The bleeding stopped, he said, and seven years later

The theory is based on a finding that both blood vessel walls and key blood cells have small but vital negative electrical charges which repel each other, causing the blood to flow smoothly under normal conditions.

When a blood vessel is damaged, he said, an inner surface layer loses positive ions (charge, attracting the negatively charged blood cells, which can clog up the vessel wall while a clot is forming.

He said such a process could explain most sudden, shots which have so figured or ob-flowed water or at the heart and magnets to such sensitive areas such as the lungs or the brain.

Miner Killed In Rock Fall Near Apollo

APOLLO, Pa. (UPI) — Richard G. Longenbaugh, 28, of Apollo, was killed and a fellow miner injured Tuesday when a rock fell in the Dorothy Mine of the Canterbury Coal Co.

Longenbaugh, the mine foreman, and Alex Nesdeck, 47, of Indiana, Pa., were 4,200 feet from the mine entrance when they were caught under a slab of rock three feet thick and 20 feet long.

Nesdeck was admitted to Indiana Hospital for treatment of a hip fracture and possible internal injuries.

Majority Sign For Medicare Plan B Program

By United Press International

Approximately 1,250,000 residents of Pennsylvania 65 or older — or by July 1 will be eligible — for benefits under the federal Medicare program.

But thousands still face a deadline this Thursday.

March 31 is the last day to sign up for "Plan B" of Medicare. It also is the last day for persons not receiving Social Security or Railroad Retirement benefits to sign for the hospitalization plan.

Some "Automatic Coverage" Those now receiving payments from Social Security or Railroad Retirement and who do not wish to take Plan B will be covered automatically by basic Medicare Plan A. It covers hospitalization and most medical services.

Also covered automatically under the hospitalization provisions of Medicare are persons receiving federal Civil Service retirement annuity and, in most cases, persons receiving state public assistance payments.

As the deadline approached authorities were full of fears that many Pennsylvanians who have signed for Medicare in the Keystone State, however, are not or just can also signed for Plan B coverage

A spot check across the state showed

Philadelphia: With 10 days left before the deadline, Charles McCoy, manager of the district Social Security office, said that of the estimated 350,000 eligible in the City, about 180,000 had signed. And of the 350,000 McCoy said between 30 and 40 per cent had taken Plan B.

Allentown: The Allentown office of Social Security, which handles all of Lehigh and parts of Berks and Northampton, said 30,000 persons were eligible and about 20,000 had signed. Only about 5 per cent of the signers enrolled Plan B.

Harrisburg: An estimated 1,000 of the 40,000 persons eligible in Dauphin - Cumberland - Perry County area had not signed for the voluntary portion of Medicare, John Lobaugh, manager of the regional Social Security office, said about 2,000 persons had turned down Plan B of the program.

Scranton: About 20,000 in the Lackawanna-Pike Wayne County area are eligible and had sought Medicare and signed. Plan B arrangement was about 10 per cent.

Pittsburgh: Oral Ernst, district manager of Social Security, said signups in Allegheny County were running about 10 per cent behind those with the national average of 10 per cent.

Lancaster: There were 45,000 persons eligible in Lancaster and Lebanon counties and at last count 35,000 had enrolled. Of the latter number, about 10 per cent took Plan B.

In consideration of a last-minute rush, many Social Security offices across the state stayed open extra hours. Some stayed open at night and some opened on Saturday.

According to Social Security officials at sign up stations, the questions asked most often have been:

"What do you think I should do?" And, "What is Blue Cross going to do?"

Blue Cross and other hospitalization groups have approved, of. They will offer supplemental plans which will not overlap basic Medicare and Plan B. bills.

Will Pay Fees

The state Public Welfare Department has been urging those eligible to sign for Plan B. It concluded that it will pay the monthly fee for elderly persons who are on public assistance.

Department Secretary Max Romer said:

"I am deeply concerned that many Pennsylvanians 65 years and older have not yet signed up for medical insurance under Medicare. Under the provisions of the law, countless thousands of Pennsylvanians are eligible for medical benefits beginning July 1 and these are not on Social Security may apply for here March 31."

But Medicare in Pennsylvania has not its numerous critics.

In Pittsburgh, a woman critic of Medicare would help her transfer her father to another nursing home because he has been abusing the nurses. She said that is it.

Another woman applicant asked if Medicare would pay for anti-narcotics pills.

One man, who said he had been accused of being an elevator bolt, said it wasn't on. He said I drink "only for medical purposes." He wanted to know if Medicare would pay for his "medicine."

And a Pittsburgh woman, who complained of an error was found in a made or her filing card, said:

"Is that's what is required for Medicare, forgot it?"

Just Can't Stop Junk

WASHINGTON (UPI) —When your mailman gets an embarrassed smiling for and your mailbox starts to overflow, don't complain to postal officials, there's nothing they can do about it.

Child Postal Inspector Chief B Montagne told a House appropriations subcommittee it necessary made public laws that his hands are tied. There is no law against mailing lists and they are sold, exchanged or rented with ease.

In addition, Montagne said, he believes some junk mail has become "more lurid" over the years as publishers and dealers skirt the pornography line. For some unknown reason, he noted, most of this kind of mail seems to originate in Los Angeles.

Scranton Okays Head Start in Connellsville

HARRISBURG (UPI) — Pilot and anti-poverty grants totaling $206,772 were approved by Gov. William W. Scranton Monday for operation of five local start child development programs in Erie, Lackawanna, Somerset and Fayette counties.

The Erie County Anti-Poverty Commission will sponsor classes at the Presbyterian Church of the Covenant for 20 children and for 40 children at the South East Side Methodist Mission, using $42,480 in federal funds and $4,664 in local money for the two projects.

The Scranton - Lackawanna Human Development Agency will receive $42,480 in federal funds to establish 10 centers in Scranton. Local funds of $10,620 also will be used.

The Turtlepoint Valley Area Schools of Coudersport, Potter County, will receive $4,080 for training 40 children from the temples of Addison, Oswayo and Genesee, and Addison and Lower Turtlepoint Twp.

The Connellsville public schools will receive $22,320 in federal funds for a similar project to train 100 children at pre-school age from low-income families.

How Area Lawmakers Voted

Here is the list of record votes in the U. S. Congress last week:

Senate

Passage of the $13,100,000,000 Supplemental Defense Appropriations Act, most of which is for military operations in Vietnam

(Passed 87-2)

For: Joseph S. Clark (D., Pa.), Hugh Scott (R., Pa.).

Senate

To take up for consideration the bill to authorize construction of an official residence for the Vice President.

(Motion adopted, 256-125).

For the motion: John E. Dent (D., Jeannette), Thomas E. Morgan (D., Pennsylvania).

Passage of the above bill.

(Passed, 197-191).

For: Dent, Morgan.

To provide air - mail service at surface postage rates for mail to and from service overseas, including packages up to five pounds.

(Passed, 303-0).

For: Dent, Morgan.

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PREPARED STATEMENT OF SENATOR MEL MARTINEZ

First, I would like to thank the Chairman and the Ranking member for holding this critical hearing.

Clearly, the implementation of Medicare Part D has been a massive undertaking. And, with most undertakings of this proportion, problems can and have arisen.

But we must not lose sight that the kinks in the system are being addressed and their impact minimized more each day as the process continues to move forward.

A project of this magnitude is going to have rough spots as it starts. The goal must be to improve and so so in a timely manner.

However, I have been greatly concerned about the impact on some of Florida's most vulnerable population the roughly 400,00 dual eligibles that reside in the state.

It has been reported that a portion of these low income individuals are experiencing great difficulty in gaining access to much needed medications.

To stave off a crisis situation, I am very pleased that the Centers for Medicare and Medicaid Services (CMS) announced a state reimbursement plan for costs associated with the successful transition of dual eligible Medicare beneficiaries into their new Medicare coverage.

Governor Bush, after consultation with Florida House and Senate leadership, also signed an Executive Order providing authorization for Florida's Agency for Health Care Administration (AHCA) to apply for this waiver.

Florida's temporary waiver will provide one more tool for AHCA to handle cases-particularly those in the low-income subsidy category-to transition successfully to Medicare without the burden of unwarranted deductibles, co-insurance or excessive co-payments.

This waiver will allow the state to focus its efforts on those who are still confronting problems and to resolve those issues as quickly as possible.

With that said, I look forward to hearing from Dr. Mark McClellan for an update on the situation and the views of the other panelists we have here today. Thank you.

QUESTIONS FROM SENATOR SANTORUM FOR ROBERT KENNY

Question. What advice would you offer to a Medicare beneficiary who may be reluctant to find out about or enroll in Medicare drug coverage?

Answer. The new Medicare Part D Prescription Drug Coverage bill seems to be either liked or disked. I will not attempt to settle that argument here.

The real question needs to be, "Now that it is here, should I join or not?" The answer is, "Yes, join."

Yes, join even if you do not like the law, the people who wrote it are anything else about it. Join even if you think it is big, dumb and overly complicated.

Yes, join if you spend as little as $35 a month for prescription drugs. There is a plan that will save you money. Yes, join even if you do not spend $250 to use the deductible. Most of us use more drugs as we age and even if you are not spending it now, there is an excellent chance you will spend much more than that in the future. Joining now may seem like a waste of money but there is a 1% a month additional charge if you wait to join until after May 15, 2006. Plans are available, in our area, for as little as $6.93 a month, so it does not cost much to avoid the stiff penalty.

QUESTIONS FROM SENATOR SANTORUM FOR SUSAN SUTTER

Question. You criticized the prescription drug plans' efforts to provide support to pharmacists-can you speak to how effective education efforts have been on the part of CMS and prescription drug plans since January 1st? How do you believe these efforts could be approved?

Answer. Quite frankly, pharmacists have gone from a severe lack of information from the plans prior to January 1st to "information overload" from both CMS and the plans as the challenges and problems of implementation have been identified. Pharmacists are now faced with tons of documents from the plans which can only be implemented if the pharmacist continues to shift their professional time to these administration issues instead of serving their patients and their needs. The problem with the volume and variety of information we are now receiving confirms what I stated in my testimony—the Medicare Part D benefit needs to be simplified and standardized.

Until the larger issue of standardizing the plan can be addressed, CMS should be directed to clearly delineate what information CMS will provide and that which

should come from the plans. For example, CMS could define what areas of information all plans must have policies on and direct the plans to provide that information in a concise common format for easy review for the pharmacist.

All of this written information does not help patients receive their medications if the individuals on the plan's "help" desk are not adequately trained or educated to implement the plan's policy correctly. After two months, some plans still have pharmacists working through a maze of phone numbers or individuals to get a problem resolved.

Finally, let me share a personal example of obtaining information, but finding it difficult to use the information to actually serve the patient. A patient (not a dual-eligible) came in my pharmacy yesterday to have his medication refilled and presented his Part D card that he had finally received. I asked when his benefit was effective and he stated January 1st. I offered to send his January claims to his plan and refund any difference. I made the offer because I had read that CMS requested that the plans open their claims processing "windows" (which often are only open for 30 days or less) to accommodate this type of situation. I received the message "claim too old" and confirmed through the PBM's help desk that the patient would have to file paper claims to be reimbursed. I contacted the plan's Director of Pharmacy to confirm that the plan had decided to ignore CMS's request. He stated that the plan wants the claims to be accepted but that the PBM is saying no to the plan and it remains a point of "discussion" between the plan and the PBM. In summary, it only confuses the situation to communicate directives from CMS if the plans, or in this case, the plan's PBM, can ignore the request. Again, CMS needs the authority to mandate, not simply request, such directives to the plans.

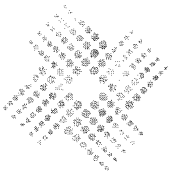
Question. Have recent efforts on the part of CMS, such as pharmacy call-in sessions, been helpful in clarifying confusion?

Answer. Pharmacists appreciate CMS's outreach efforts but not all pharmacists are able to participate in the call-in sessions. In addition, the session conducted on Part B versus Part D drug coverage was very useful. However the most common problem for pharmacists is that the Part D plans themselves are not clear on the issue. CMS must follow through and audit the Part D plans' proper coverage of these drugs.

The most effective method CMS has used is communicating through the pharmacy professional associations. As a member of several of these associations, I appreciate the outreach to them.

Going forward, CMS should identify one method of communication—one spot on the CMS website or one e-mail listserv—to communicate with pharmacists. If such an effort was made, pharmacists would know there was a simple, quick way to find information on Part D and look for updates.

Thank you for your interest in the challenges pharmacists are facing with the implementation of Medicare Part D.



LTCPA

Long Term Care
Pharmacy Alliance

Testimony for the Senate Special Committee on Aging
Meeting the Challenges of the Medicare Drug Benefit Implementation

We are pleased to provide testimony to the Committee on this important subject.

The Long Term Care Pharmacy Alliance (LTCPA) represents the nation's leading providers of comprehensive pharmacy services to over sixty percent of the residents of long term care facilities.

The LTCPA has been involved in the debate over this important benefit since its inception three years ago. We have continuously advocated for important protections for our nation's most vulnerable seniors.

As you know, nearly two-thirds of the residents of the nation's nursing facilities are dually eligible for both Medicare and Medicaid. Until January of this year these beneficiaries received their drug coverage under State Medicaid programs. While not perfect, the chief advantage of Medicaid drug coverage is that it is consistently applied and the rules apply to most residents of the nursing facility. Also, as we had earlier noted, the Medicaid statutes provide a clearer set of protections for access to medically necessary medications.

Random Assignment

Beginning January, 2006, dual eligibles found themselves randomly assigned to as few as six prescription drug plans (PDPs) in Florida and Arizona, to as many as sixteen different plans in South Carolina, Texas and Virginia. These plans all have different formularies, prior authorization criteria and transition plans.

Since the average nursing home has 107 beds, the problem of tremendous variation over a small number of beneficiaries poses profound clinical problems. Clearly, the long experience in healthcare demonstrates that variation across small populations does not enhance quality.

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The statute requires random assignment of dually eligible beneficiaries, primarily as a method by which to assure that they are enrolled in a plan, since Medicaid drug coverage terminated for these beneficiaries after December 31, 2005.

However, beginning in January, pharmacies were able to ascertain plan assignments for only about 60 percent of the dual eligibles. This was due to a systems problem between CMS and its contractor NDC Health. Long term care pharmacies continued to dispense prescription drugs to beneficiaries in nursing facilities without assurance from any plan that these drugs would be covered.

CMS arranged an agreement with WellPoint to provide point-of-service enrollment services whereby unidentified dual eligible beneficiaries could be enrolled immediately. This solution provided some relief, but WellPoint's agreement with CMS included a provision that allowed for a 14-day supply of drugs. Common practice in long term care is for maintenance drugs to be supplied in 30-day increments. As a result, many LTC pharmacies continued to hold claims until the system could identify a responsible plan.

One of the foreseen complications with random assignment across so many different plans is the administrative and clinical burden associated with obtaining plan permission to dispense drugs. Some plans had relatively open formularies, with few requirements for prior authorization, while other plans required prior authorization for entire classes of drugs. In the early part of January, plan phone lines were almost inaccessible due to tremendous call volumes. Meanwhile, our member pharmacies continued to supply needed medications to beneficiaries without an absolute assurance that any plan would agree to payment.

CMS Marketing Guidelines

As the LTCPA had earlier warned, random assignment of nursing home residents across several plans led to a chaotic situation. We believe much of this could have been avoided if knowledgeable health professionals had been free to assist residents in finding plans that were particularly appropriate for the needs of their residents.

CMS' concerns about the prospect of care providers "steering" beneficiaries into plans based on some financial incentives to either the pharmacy or the nursing facility led it to issue marketing guidelines that effectively prohibited caregivers to make informed recommendations. We

believe that many of the problems associated with random assignment could have been prevented had the caregivers been authorized to make specific recommendations to their residents on plan selection. This would have allowed caregivers to facilitate enrollment in appropriate plans and have some confidence that the enrollment had been made prior to January of this year.

Prior Authorization

We are happy to report that the problems with identifying the plan assignments for dual eligibles and other residents seem to be abating as we enter the second month of the benefit. This issue has been replaced by the plethora of issues related to plan requirements for prior authorization for prescribed drugs.

Prior authorization is a common methodology used by benefit managers to control access to expensive drugs or drugs deemed to be less cost effective than other available medications. It is a tool in common use among State Medicaid programs and our pharmacies are familiar with its use.

However, once again, the tremendous number of plans within any given region, the lack of plan familiarity with long term care and the complexity of prior authorization procedures within plans has resulted in thousands of phone and fax inquiries to plans from pharmacies and increasing frustration with the time required to obtain approvals.

Many plans require direct physician involvement in the prior authorization approval process. Most physicians do not have hours available to spend waiting on hold on telephone calls to access the system and obtain the approvals. In the past, these duties have fallen to the pharmacists that understand better how to work through the process.

Some plans have a huge variety of different forms to use in order to request prior authorization. It seems that there is a different form for nearly every drug requiring prior approval.

Finally, despite CMS' notice to plans in June 2005, that they would be required to provide a "first fill" for non-formulary drugs for residents of LTC facilities, most plans continue to demand prior authorization.

Recommendations

We believe CMS has done an admirable job of attempting to resolve many of the problems encountered during the early phases of MMA implementation. However, we believe that both Congress and the Administration can make important changes that enhance the effectiveness of this benefit for these vulnerable residents:

- Provide a clear opportunity to caregivers to identify and recommend specific prescription drug plans that are most suitable for the needs of LTC beneficiaries and facilitate enrollment in these plans. We are confident that Congress or CMS can develop appropriate safeguards that prevent inappropriate referrals based on variables other than the residents' best interests.

- Instruct prescription drug plans to suspend prior authorization edits for a minimum of 90 days, while the system adjusts to this new benefit. Access to necessary medicine should trump the need for plans to control utilization.

- Create a universal prior authorization process that applies to all approved prescription drug plans and doesn't require, except in rare circumstances, the direct involvement of a physician.

Once again, we thank the Committee for its oversight of and interest in the implementation of this important benefit and we look forward to providing any additional information you may need.

Statement on

Meeting the Challenges of Medicare Drug Benefit Implementation

U.S. Senate Special Committee on Aging
Thursday, February 2, 2006

National Association of Chain Drug Stores (NACDS)
413 North Lee Street
Alexandria, VA 22314
703-549-3001
www.nacds.org

Statement of National Association of Chain Drug Stores (NACDS)
"Meeting the Challenges of Medicare Drug Benefit Implementation"
February 2, 2006

Chairman Smith, Ranking Member Kohl, and Members of the U.S. Senate Special Committee on Aging: The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide the Committee with an overview of the issues that pharmacists and beneficiaries are experiencing in implementation of the new Medicare Part D prescription drug benefit program.

NACDS represents more than 200 chain pharmacy companies that operate more than 32,000 community retail pharmacies. Our members are the primary providers of outpatient prescription medications in the United States, and are the primary providers of pharmacy services to Medicare beneficiaries under the new Part D benefit.

Our industry recognizes that this is the most significant expansion of Medicare since its inception and that there will be issues and problems in starting up a program of this magnitude. Millions of additional seniors now have access to prescription drug coverage as a result of the new Part D benefit. This is good news, but may unfortunately get lost in all the stories that we are hearing regarding program implementation issues. There have, in fact, been several important challenges for beneficiaries and pharmacists in transitioning to the new Part D benefit. We appreciate all that CMS and the states are doing to try and ease this transition for beneficiaries and pharmacies.

Pharmacies are committed to helping seniors obtain their medications. Most of our pharmacists have taken extra time and effort to learn the "ins and outs" of Part D so that they can help beneficiaries understand how to make the most of the new drug benefit. Pharmacists are also doing all they can to be sure that Medicare beneficiaries' prescriptions are filled in a timely manner. At the same time, pharmacists are trying to be reasonably sure that they will be paid for the prescriptions that they are dispensing to the beneficiary and billing to the Part D plan. Many pharmacies are experiencing cash flow problems as a result of the many prescriptions they have provided to Medicare beneficiaries without actually knowing whether or when they will be paid for these prescriptions.

While progress has been made on several fronts since program implementation, there are several challenges that remain for pharmacies, beneficiaries, and other health care providers in implementing Medicare Part D:

Provide More Accurate Data to Pharmacies: We appreciate the fact that CMS worked together with the pharmacy community to develop a point of service capability – known as the "TrOOP facilitator" – to help identify individuals who are eligible for Part D. This system can provide the pharmacist with the identity of the actual Medicare Part D plan in which a beneficiary has been enrolled. This TrOOP facilitator will also help in the coordination of benefits with other prescription drug coverage programs that wrap around Part D.

Making an "E1 query" to the TrOOP facilitator has been a tremendous help for pharmacists in identifying a beneficiary's Part D plan, as well as obtaining the correct and complete billing data. These data are known as the "4Rx" data because they give the pharmacist four key pieces of billing information. If pharmacists do not have these data, it is almost impossible to accurately process a claim. In the early days of the program, there were times when the system was not providing this information to pharmacists in a timely manner. This caused significant delays in processing prescriptions.

This system is working much better now than it did in the first few days of the program, but it is still not providing pharmacists with full and accurate information about a Medicare beneficiaries' "4Rx" in all cases. Sometimes, the TrOOP facilitator only returns information about the Part D plan in which a beneficiary has been enrolled, but not the important "4Rx" data. The pharmacist then has to call the plan to get the billing information, which in some cases has taken between 20 and 30 minutes to obtain. That is because of the volume of calls that are going into the plans' "call desks".

CMS and Part D plans must reduce the time is takes to include accurate "4Rx" billing information – including appropriate low income subsidy information – in the TrOOP facilitator. Therefore, the key to resolving the many administrative issues that have developed with Part D is improving the quality and timeliness of the information provided to pharmacists.

Address Issue of "Enrollment Lag": Enrollment in a Medicare Part D plan is effective the first day of the next month. Thus, a beneficiary that enrolls in a plan the last week of the month would expect to be able to have their prescriptions filled in a pharmacy by the first day of the next month, and have those prescriptions paid for by the plan that he or she just joined. However, it may be unrealistic to expect that CMS and the plans can process the application, confirm eligibility, and provide information to the plan and the TrOOP facilitator – so that it is in the pharmacy system - in such a short timeframe.

Right now, it appears that it takes about 10 days from the time of enrollment in a plan, until the time that the data are available to the pharmacist through the TrOOP facilitator. Thus, it is obvious to see why there must be more time between the submission of an application to a Part D plan and the time that the enrollment and billing information can be obtained and active at the pharmacy.

Additionally, dual eligibles can change plans each month, and other populations can enroll in a Part D plan toward the end of the month, and still expect that plan enrollment to be effective the first of the next month. Such expectations are unfair to the beneficiary, unfair to the pharmacist, and will undoubtedly create delays at the pharmacy. Thus, this "enrollment lag" appears to be a structural issue that needs to be addressed soon to reduce the problems that many beneficiaries and pharmacies are experiencing.

Policymakers may want to consider establishing a monthly enrollment deadline (i.e. 15th of each month) after which any enrollments received would be effective the first day of the month after the next month. This would provide sufficient time for the correct data to be entered into the TrOOP facilitator.

Address Transition Issues with Dual Eligibles: The beneficiary group that has had the most difficult transition issues with Part D are those individuals who have been switched from Medicaid to Medicare. The reasons for these problems are multifaceted, and we acknowledge that CMS and the states are working hard to ensure that these low-income individuals do not fall through the cracks.

There are many specific reasons for the problems with dual eligibles. In some cases, information about the plan in which a dual eligible was auto enrolled was not entered into the TrOOP facilitator, or not entered correctly. In some cases, the individual was not auto enrolled in a plan at all. In some cases, the TrOOP facilitator system is not returning the correct payment information for the pharmacist, incorrectly indicating that the dual eligible should pay a deductible or a higher cost sharing amount than $1 for a generic or $3 for a brand. This happened because the low-income subsidy information may not have been sent by CMS to the Part D plan or may not have been received by the TrOOP facilitator.

Now that CMS has sent the files of the dual eligibles and their low-income subsidy status to the plans, it will help plans to "cross check" whether individuals enrolled in their plans are dual eligible. This means that plans will not have to wait for an eligibility response from CMS before they are aware that the person is low-income subsidy eligible.

Some of the dual eligibles were not auto enrolled in any plan, which means that their coverage information would not have been included at all in the TrOOP facilitator. CMS did establish a "safety net" plan option late last year that would allow a pharmacist to provide prescription drugs to assumed dual eligible individuals who were not auto enrolled in a plan. Many pharmacists go to great lengths to first try and determine if the individual has been enrolled in a Part D plan, and if they cannot find their Part D plan, they will try to enroll them in the Anthem/WellPoint Point of Service (POS) "safety net" plan. In addition, many states have developed emergency programs to pay for the drug costs of dual eligibles if the pharmacist cannot identify the dual's Part D plan, or if the pharmacist is unsuccessful at enrolling them in the Anthem POS plan.

These "safety net" mechanisms are good in theory, and should be tried first before a pharmacy bills the state Medicaid program as a last resort. However, it could take pharmacists a significant amount of time to jump through all these hoops before they are able to bill the prescription claim to a plan that will pay for the prescription. Even then, payment is not guaranteed. Some pharmacies feel that there is significant risk in billing this "safety net" plan because there appears to be no guarantee of payment from this plan. Moreover, there seems to be a reasonable chance that many of the claims billed to the POS plan could ultimately be reversed, leaving pharmacists potentially "holding the bag" with many unpaid prescription claims. Nevertheless, pharmacists are going to great lengths to try and make sure that all Medicare beneficiaries – including dual eligibles – leave the pharmacy with their necessary prescription medications.

Eliminate Transfer of Co-pay Risk to the Pharmacists: Under CMS' guidance to plans issued in mid January 2006, plans can choose one of two options to assure that individuals who are assumed to be eligible for reduced co-pays – but whose information may not as yet be entered into the TrOOP facilitator –are charged no more than $2 for a generic and $5 for a brand at the pharmacy.

Under one option, the plan allows the pharmacy to charge the $2 or $5, adjudicates the claim, and assumes the risk if it turns out that the beneficiary was not subsidy eligible, or the beneficiary was only eligible for the higher-level subsidy amount (i.e., 15% for their prescriptions.)

Under the other option, the pharmacy fills the prescription, the pharmacy charges either $2 or $5, but the plan does not allow the pharmacy to adjudicate the claim. Instead, the pharmacy is required to hold the claim until the plan can affirmatively identify the low income status subsidy of the individual, and then allows the pharmacy to bill the claim.

Under this second option, the pharmacy is responsible for collecting from the beneficiary any difference between the co-pay amounts that the beneficiary should have ultimately paid and the amount that was actually paid. Thus, if the beneficiary should have paid a higher co-pay (i.e. 15%) than a low-income co-pay (i.e. $2 or $5), the pharmacist has to collect the difference. This is the same as a transfer of insurance risk to the pharmacist, which is prohibited under the MMA. The pharmacist should not be placed at risk for these financial losses because correct information about low income subsidy amounts cannot be returned to the pharmacist at the time of dispensing.

Improve Part D Plan Transition Policies: Pharmacies have had difficulties in obtaining approval from some Part D plans to override the formulary and provide a transition supply (such as a 30-day supply) of drugs to Medicare beneficiaries. In addition, some plans cover a 30-day supply while others cover a 34-day supply, but this information may not be sent back to the pharmacist in the plans' electronic messaging. There is a need to create more uniform transition policies among plans and more consistent, uniform messages from plans as to how pharmacies override "non-formulary" messages at the point of sale.

HHS announced on February 1, 2006 that plans would be required to extend their transition supplies for another 60 days, for a total of 90 days. While this is welcome news, it is important that plans assure that pharmacists do not experience the same administrative issues in filling transition supply prescriptions under the extension of this policy as occurred under the initial policy. That is, plans should not require prior authorization or initiate step edits that require phone calls by the pharmacists to plans to obtain approval to dispense the additional 60-days supply. Moreover, during these additional 60 days, plans should be working with beneficiaries to transfer them over to drugs that are on the formulary, or be sure that beneficiaries and their physicians understand their rights of appeal so that they can seek approval to continue on their non-formulary medication.

Start Process to Switch Beneficiaries to Formulary Drugs: Over the next few weeks, beneficiaries will be returning to pharmacies to obtain a refill of their medications. Although they can now obtain an additional 60-day prescription for the transition supply drug, plans and beneficiaries should start thinking about how they transition over to a formulary drug, or appeal to the plan to continue on their existing non-formulary medications. It is in everyone's best interest to assure that we avoid a situation where physicians and pharmacists are overwhelmed over the next few weeks by beneficiaries seeking approvals to switch to a formulary drug, or appealing the non-formulary status of their drugs.

To facilitate this, plans should return information to pharmacists through the claims processing system that identifies the Part D plan's formulary products. Plans should also be working with the beneficiaries on a regular basis so that they become knowledgeable about the alternative formulary products for the prescription drugs they are taking.

Create Consistent Plan Messaging to Pharmacies: Part D plans need to develop a set of consistent and meaningful messages to pharmacies regarding transition policies, covered drug policies, and formulary overrides. Messages such as "non formulary drug" could mean that the drug is not covered under the Part D plan's formulary, or the drug is a not a covered drug under Part D. Plans should also return information regarding formulary options for the pharmacist if the beneficiary's prescription is for a non-formulary drug.

Reduce Plan Call "Wait Times" for Pharmacists: Wait times on the plans' "call desks" are improving, but they are still too long for some plans, sometime 20 to 30 minutes. While this is better than the longer times that pharmacists experienced earlier this month, pharmacists or support personnel cannot be expected to stay on hold for this long a time to obtain necessary billing information or other information. Moreover, sometimes, the plans' Customer Service Representatives (CSRs) do not have the information that pharmacists need to fill the prescription even after staying on hold for a long period of time.

Reduce Burdens in States' Temporary Coverage Programs: Many State Medicaid programs have chosen to establish temporary or emergency programs to help dual eligible Medicare and Medicaid recipients obtain their medications in certain situations. These include situations when the pharmacist cannot identify or obtain the billing information for the plan in which the dual eligible has been auto enrolled, or when the co-pay amounts being retuned to the pharmacist are higher than the co-pay amounts that the individual should pay.

To the extent possible, all plans that supplement Part D, including Medicaid and state pharmacy assistance programs, should coordinate their programs with and through CMS and the TrOOP facilitator. The TrOOP facilitator was designed to provide information to pharmacies on wrap around programs that, among other important features, will help track a beneficiaries "true out of pocket spending." Using this process will improve the administrative efficiency of the Part D program, facilitate the adjudication of claims, and reduce the waiting time of beneficiaries.

Community retail pharmacists will strive to only bill the state Medicaid program as the payer of last resort. However, pharmacies cannot be expected to devote unlimited man hours to remaining on phone lines, or making multiple phone calls, to obtain billing information or ancillary documentation to validate Medicaid billing when a Medicare beneficiary is waiting for prescriptions to be dispensed. Some Medicaid programs are requiring special forms to be completed and faxed before providing temporary coverage. These steps create additional burdens for pharmacists.

States must not instruct pharmacies to bill for co-pays or drugs in potentially non-HIPAA compliant formats. Such requirements place pharmacies at risk for penalties and fines. In addition, some states are asking pharmacies to submit manual paper claims, fax approval forms to state agencies, and engage in other activities that are time consuming, burdensome and potentially non-HIPAA compliant.

Once a state Medicaid claim has been adjudicated under these programs, states must seek any recovery or recoupment directly from the Part D plan, not the pharmacy. CMS and plans have both publicly indicated that they will work directly together to achieve this plan to plan reconciliation, or state to plan reconciliation, rather than reverse and re-bill claims through the pharmacies. States must engage in a "pay and chase" approach to recouping monies for these claims with the plans and not place pharmacies in the middle of these recovery or recoupment activities.

After the dual eligible individual has been auto enrolled in a Part D plan, and the state has been notified, the state should electronically return that information to the pharmacy so the pharmacy can billing the appropriate Part D plan.

Address Issues Relating to Co-branding of Identification Cards: Under current CMS Part D plan marketing guidelines, Part D sponsoring organizations are permitted to "co-brand" by entering into relationships with one or more separate legal entities. These co-branding relationships, some of which are between Part D plans and retail pharmacies, allow an organization and its co-branding partner to promote enrollment in a Part D plan. The symbol or logo of the Part D plan and any co-branding entities' symbols or logos are also permitted to be included on the standard Medicare prescription ID card.

As a result of some of these co-branding relationships, we understand that some Medicare beneficiaries believe that they can only obtain their prescription medications from a pharmacy whose logo or symbol appears on the Part D plan's standard ID card. That is, some beneficiaries believe that they cannot obtain their medications from their current retail pharmacy provider because that pharmacy is not co-branded on the card. This is obviously not the case, and we believe that this might be an unintended consequence of co-branding. As we know, beneficiaries can use any pharmacy in the Part D plan's network to obtain their medications.

To help address this issue, we believe that CMS should ask Part D plans that use co-branding relationships to assure that their enrollees know that they can use any pharmacy in the plan's network. Plans' CSRs should tell the beneficiary that they can use any network pharmacy, not just those whose logos appear on the card. Finally, the plan's written and online pharmacy network directory should also conspicuously indicate that any network pharmacy can be used.

Taking these steps will help reduce the confusion that may exist among some beneficiaries about these co-branding relationships. We all want beneficiaries to have complete and full information about their choices of pharmacy providers so that they can select the one that best meets their needs.

Address Economic Implications of Part D for Pharmacies: The early stages of Medicare Part D implementation have created significant economic and administrative challenges for retail pharmacies. Pharmacies have spent thousands of uncompensated hours on the phone trying to obtain correct information for beneficiaries. Many pharmacies have provided medications to beneficiaries during these early stages of implementation without any commitment by plans or CMS that they would eventually get paid for these expensive prescription drugs.

Now, many states are stepping in to temporary fill the gaps in Part D coverage for dual eligibles, and pharmacies are being told that once again their may be no guaranteed payments. Worse yet, states may try to recoup these payments through retail pharmacies if states can not recover them from CMS or the plans.

The lack of payment for some of these dispensed prescriptions, combined with the fact that Part D plans are paying pharmacies less frequently and at lower rates than Medicaid, is creating cash flow problems for many pharmacies. That is especially the case for those that serve a significant number of Medicare beneficiaries, especially those that are dual eligibles. Pharmacies still have to pay their bills and replenish pharmacy stock in spite of the fact that they are not able to bill Part D plans for many prescriptions, and they have to wait longer for their payments from Part D plans.

In addition, some pharmacies are also seeing some of their prescription business go to mail order pharmacies because some pharmacies were not allowed to provide a 90 day supply of medications, even though the MMA allows for that. Many other pharmacies are providing a 90-day supply of medication at mail order rates, even though they do not have access to preferential mail order pricing. The bottom line is that Medicare Part D is creating significant economic issues for community retail pharmacy.

Conclusion

We appreciate the opportunity to go on the record regarding these implementation issues in the early stages of the new Medicare Part D benefit. We are committed to working with Congress, CMS, states, plans and beneficiaries to assure that the benefit is delivered in the most efficient manner. We know that many of these issues will eventually be resolved, but that other issues will develop down the road that will also have to be addressed.

We also have to be cognizant of the economic implications of Medicare Part D for our nation's retail community pharmacies and commit ourselves to assuring that policies are adopted that foster the development of this important health care infrastructure. Access to community pharmacies is important not only for millions of Medicare beneficiaries, but also to millions of other Americans who rely on pharmacies for easy access to health care products and services. We appreciate the opportunity to submit this statement for the record.

Senate Special Committee on Aging

hearing on

Meeting the Challenges of Medicare
Drug Benefit Implementation

February 2, 2006

Statement for the Record
Submitted by the

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The American Society of Health-System Pharmacists (ASHP) respectfully submits the following statement for the record of the Senate Special Committee on Aging hearing on Medicare Part D Implementation.

ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. This includes working with patients to help them access the medications they need and to use them safely and effectively.

ASHP appreciates the opportunity to comment on Medicare Part D implementation issues. The transition to the new benefit has not been without its problems and frustrations for our members. ASHP recognizes the complexities of implementing such a significant change to the nation's largest health insurance program and would like to start by commending the Centers for Medicare & Medicaid Services (CMS) for its efforts in planning the implementation and in addressing issues as they arise. ASHP would like to continue to work with the U.S. Congress and CMS toward the implementation of a benefit that meets the needs of our nation's seniors and disabled beneficiaries. This means addressing some ongoing implementation and policy problems related to the new benefit. It is in this vein that ASHP comments on the issues that our members have experienced with Medicare Part D implementation and offers some recommended solutions.

Health-system pharmacists play a unique and important role in the successful implementation of the Medicare Part D benefit, interacting with eligible beneficiaries at several points of care. Pharmacists working in hospital-based ambulatory-care clinics and long-term-care facilities often treat the "highest-risk" beneficiaries, those with multiple chronic conditions or taking multiple medications and a significant number of dual eligible beneficiaries, particularly in safety net hospitals. Some hospitals have outpatient pharmacies that are open to the public and serve Part D beneficiaries. Other hospitals have closed pharmacies that do not dispense medications to patients beyond those receiving care at the facility, but in many cases have pharmacies contracted with drug plan sponsors to meet the needs of patients in its long term-care-beds or hospital-based long-term-care facility. This testimony will address issues arising in these care settings.

Eligibility and Enrollment

ASHP members have been and continue to be affected by many eligibility and enrollment issues, some of which have been widely discussed in the media and by others and many of which CMS is already working to address. These include:

- Difficulty in verifying the eligibility and enrollment of beneficiaries, forcing pharmacists and pharmacy technicians to spend an inordinate amount of time trying to contact CMS or plans for information or to dispense medications to beneficiaries without assurance of payment;

- Long wait times and difficulty contacting the appropriate person at a plan who has information necessary to answer the pharmacists' or pharmacy technicians' questions, at times resulting in incomplete or inaccurate information from plans' customer service lines;

- Lack of continuity of care resulting from the auto-enrollment of dual-eligible beneficiaries, leading to plan selection that does not match beneficiaries' needs in terms of formulary requirements and pharmacy accessibility, with confusion and lack of understanding of the options limiting the beneficiaries' ability to change to a plan that could better meet their needs;

- Difficulty transitioning certain community mental health patients who received Medicaid benefits previously, but did not qualify for auto-enrollment in a plan, and who have not proactively enrolled in a Part D plan;

- Lack of information about beneficiaries who sign up for or switch plans late in the month and then attempt to fill a prescription early the following month; and

- Many non-reimbursed emergency prescriptions dispensed to beneficiaries in need, for whom sufficient information was not available about eligibility and enrollment.

ASHP appreciates the effort CMS has made over the last few weeks to alleviate some of these problems, particularly CMS guidance documents to providers and plans, access to CMS staff to pose individual issues, and CMS follow-up with plans on some of these issues. ASHP offers the following additional recommendations:

- Enhance CMS authority to require, rather than suggest, changes to plans' processes and procedures;

- Change eligibility requirements so that only enrollment forms received by a plan by the 15th of the month will result in a beneficiary having coverage starting the first of the following month or dedicate resources to educating beneficiaries that changes to plan selection late in the month may requiring waiting a few weeks to fill their first prescription, encouraging the beneficiary to plan accordingly;

- Provide prompt payment to pharmacies for prescriptions dispensed in good faith. ASHP members are concerned that emergency prescriptions will not be reimbursed in a timely manner, as well as medications that are dispensed based on post consumption contracting between a plan and a hospital pharmacy.

Transition Policies

Variations in plans' transition policies and plans' understanding and enforcement of their transition policies have created a substantial burden on pharmacists. In many cases, transition policies have not been made available to pharmacists. As a result, pharmacists have had to call each plan to verify its policy. Many plans have also not been honoring transition policies that require them to provide access to both formulary and non-formulary medications. By requiring prior authorization or step therapy to be implemented on first-fill for formulary drugs, plans are harming beneficiaries' continuity of care, and pharmacists are being buried in exceptions to the formularies, thus making the transition more burdensome for the pharmacy.

ASHP recommends that CMS require plans to honor their transition policy for both formulary and non-formulary drugs, to better educate their pharmacy help-line staff to comply with their transition policy, and to make these change in enforcement retroactive to January 1 in order to promptly pay for all prescriptions previously dispensed.

The transition period for certain beneficiaries who enrolled prior to January 1 ended on February 1. ASHP fears this will cause more confusion, with beneficiaries not understanding why they cannot access the same drug that was covered in the previous month with the same co-pay. Physician offices will likely be inundated over the next few months with requests for approval to change beneficiaries to formulary drugs. To alleviate the tension this volume of requests may cause between the patient, pharmacist, and physician, ASHP encourages CMS to require plans to extend their transition period to allow time for any necessary changes to the patients' medication regimen. In addition, CMS should require plans to provide uniform messaging to explain any denials of coverage.

Formularies

ASHP members have had to explain changes in plans' formularies to several beneficiaries who used the Medicare's Prescription Drug Plan Finder in late 2005 to select a plan only to find that the plan had made changes to its formulary even before the January 1 implementation date, resulting in the beneficiary's medication no longer being first-tier on the formulary. ASHP encourages the Congress to work with CMS to monitor the frequency and nature of formulary changes.

ASHP members also found that some drugs that were excluded by statute from Medicare Part D coverage (for example Niaspan, which is classified as a vitamin, and benzodiazepines) cannot be easily converted to another drug to treat the beneficiary's condition. That lack of coverage threatens continuity of care. ASHP encourages the Congress to reevaluate these exclusions and to allow such treatment determinations to be made by the plans' pharmacy and therapeutic committees or by CMS through a notice and comment period.

Part B versus Part D Billing

Several ASHP members have expressed concern about when it is appropriate to bill Medicare Part B versus Medicare Part D. ASHP believes the CMS and the Congress should consider ways avoid this confusion in the future. In the meantime, ASHP will continue to make CMS resources and other educational tools available to clarify how to appropriately bill certain drugs to Medicare.

ASHP members have reported that some Medicare Part D plans are rejecting outright claims for certain injectable drugs, noting that the pharmacist must first submit a claim refusal from to Medicare Part B. This can result in a delay in treatment and unnecessary paperwork for the pharmacy and the Medicare program. CMS must also work with plan sponsors and providers to better educate them about the appropriate policies and procedures for billing these medications.

Home Infusion Drugs

While many home infusion drugs are covered under the Part D benefit, related clinical pharmacist services, supplies, and equipment are not currently covered by Medicare. Congress should investigate ways to separately and appropriately cover the expenses related to ensuring the safe and appropriate use of medications. Pharmacists should be recognized under Medicare Part B as health care providers, in a similar manner as nurse practitioner, physician assistant and other non-physician provider services are covered.

Hospital LTC Contracting

Hospitals with long-term-care beds serving beneficiaries who have exhausted Medicare Part A coverage or with a hospital-based long-term-care facility serviced by the hospital pharmacy, must either contract with all of the plan sponsors with whom their patients are enrolled or allow an external pharmacy to service their patients. Contracting with all plans in the region could potentially have a significant impact on a hospitals' resource utilization. In many cases, hospitals have chosen not to contract with plans with whom they do not currently serve patients and as a result may have to do retrospective contracting if they later serve a patient covered by a particular plan. Some hospitals have experienced difficulty contracting with plans. ASHP suggests CMS put in place and enforce some minimum reimbursement rates to ensure appropriate access for beneficiaries when receiving care in these settings. In addition, plans must be educated to ensure that hospitals with closed pharmacies are appropriately listed as such in all plan communications.

Congress should also work with CMS to require plans to make adjustments to ensure that appropriate quantities and packaging for dispensing medications are used based on the

care setting of the beneficiary. Long-term-care patients for safety reasons often receive a 31-day supply of their medications in a blister pack. Current plan reimbursement policies and procedures limit reimbursement to a 30-day supply. This is also an issue for prescriptions for Schedule II controlled substances, which in long-term-care settings are often dispensed as several partial fills in order to reduce waste and diversion. Many plans are not set up to recognize multiple partial fills during a month.

Manufacturer Prescription Assistance Programs

ASHP encourages the Congress to work closely with CMS to monitor the impact of the Part D benefit on pharmaceutical manufacturer prescription assistance programs (PAPs). These programs provide a significant benefit to patients and we must ensure they are not unnecessarily restricted or deterred, thereby limiting extra assistance to beneficiaries in need.

Medication Therapy Management Programs (MTMP)

ASHP strongly supports CMS's statement in the Medicare Part D final rule recognizing that medication therapy management programs will likely become a "cornerstone" of the Medicare drug benefit. Limited information about different plans' medication therapy management programs is currently available. ASHP encourages CMS to make this information publicly available and to incorporate it into future tools to help beneficiaries make informed decisions about plan offerings. This is particularly important for high-risk beneficiaries who are at greatest need for assistance in managing their medication use.

Quality measures will be important to evaluating the value of these programs. ASHP supports CMS's ongoing efforts to develop uniform measures to evaluate plans' medication therapy management programs. ASHP has significant experience in medication safety and quality and hopes to continue to work with CMS on this effort as it evolves.

ASHP would also like to work with the Congress to realign financial incentives for plans to provide medication therapy management programs that are of true value to beneficiaries.

Self-Administered Medications

Hospitals provide beneficiaries with self-administered medications when beneficiaries are in the emergency room or an observation clinic. In the past, such medications have not been covered by Medicare and in most cases have been billed to the beneficiary with the explanation that Medicare does not cover outpatient drugs. The new Part D benefit creates a dilemma for health-system pharmacists, since most plans are not ready to

accommodate prescriptions for a single dose or one day supply of medications. CMS has advised hospitals to bill the beneficiary for the self-administered medication and provide them with information to attempt to recover payment from their plan. In most cases, it is recognized that it will not be worthwhile for the beneficiary to pursue reimbursement since formulary requirements, pharmacy network requirements, and co-pays will apply, and the reimbursement will be based on the negotiated rate for the portion of the drug dispensed.

ASHP advises additional CMS guidance on what information should be provided to beneficiaries. In addition, in order to avoid confusion, CMS should further educate beneficiaries on this limitation in coverage.

Conclusion

ASHP appreciates the opportunity to share our views on how to continue to work towards a Medicare outpatient prescription benefit that is successful in meeting the needs of Medicare beneficiaries, providing access and continuity of care in all practice settings, particularly for vulnerable high-risk Medicare beneficiaries. ASHP and its members are committed to working with the Congress, CMS, and beneficiaries to address both implementation and longer term policy issues that will need to be addressed to ensure the success of this program.

Statement of the

American Psychiatric Association

for the

Senate Special Committee on Aging

on

Medicare Part D Implementation

February 2, 2006

The American Psychiatric Association (APA) represents more than 36,000 psychiatric physicians nationwide who specialize in the diagnosis and treatment of mental and emotional illnesses and substance use disorders. The APA thanks Chairman Smith, Ranking Member Kohl, and members of the Special Committee on Aging for your commitment to ensuring that the Medicare Part D program plays an effective role in the nation's efforts to provide the highest quality medical care to our seniors and disabled adults.

INITIAL IMPLEMENTATION PROBLEMS

Unfortunately, a number of widespread problems accompanied the early implementation of the Medicare Part D program. Many of these problems concerned the transition of Medicare/Medicaid dual eligibles to Part D drug plans, and more than two dozen states have spent millions of dollars covering the medication costs of these beneficiaries on an emergency basis. Common problems included inaccurate enrollment data, excessive charges for deductibles and co-payments, drug plans failing to provide a temporary transition supply to beneficiaries stabilized on drugs, and ineffective use of the fallback drug plan. As a result, thousands of Part D beneficiaries were unable to access their medications.

The APA has received numerous reports of patients forced to go without mental health medications due to these problems. For example, in Alabama, two patients were hospitalized when they were denied medications and experienced a relapse of acute psychiatric symptoms. In Massachusetts, beneficiaries were unable to obtain clozapine, an antipsychotic often employed for the most severe forms of schizophrenia. In Wisconsin, beneficiaries were unable to obtain coverage for dosages of mental health drugs recommended by practice guidelines. Plans would only cover lower doses. These examples are only a small sample of the experiences of psychiatrists across the country.

ENSURING CONTINUITY OF CARE

The APA is deeply concerned that patients unable to access psychotropic medications will suffer serious consequences. When mental disorders such as schizophrenia, bipolar disorder, or major depression are inadequately treated, the risk for loss of function, hospitalization, co-morbid medical conditions, and mortality is substantially elevated. Elevated risk for negative patient outcomes begins when patients are unable to continue taking their medications. Interrupting a regimen for even a day or two may result in a psychiatric crisis for a patient. CMS recognized the vital importance of psychotropics by including antipsychotics and antidepressants among the six categories of drugs for which plan formularies were required to provide access to "all or substantially all" available medications in order to comply with a June 2005 CMS guidance.

It is urgently important that Part D enrollment and data problems be resolved so that patients can access medications without being told at the pharmacy that they are not covered by the plan in which they enrolled, that they must pay a deductible or co-pay that does not apply to them, or that no information is available about a plan's prior authorization policies.

Other widespread problems may emerge. As the program enters its second month, millions of beneficiaries and their doctors will be faced with decisions about switching medications. Required temporary "transition supplies" of medications will be depleted, and patients whose

medications are not covered by the plans they have enrolled in will need prescriptions for covered drugs. Doctors will have to work with patients to weigh a number of factors in deciding which medications should be switched, including the drugs available on plan formularies, the history of treatment with different medications, side effects, drug interactions, and co-morbid conditions. Often, it will be necessary to employ Part D appeals processes to obtain exceptions to plans' coverage determinations for medications.

It is vitally important that the widespread data and customer service difficulties experienced by drugs plans in January not continue into this "medication switching" stage of implementation. Ensuring continuity of care for beneficiaries requires that Part D processes be transparent, user-friendly, and timely. To avoid further problems, it will be necessary to address a number of issues:

- **Coverage explanations.** Reports are emerging that plans are not providing beneficiaries with the coverage explanations CMS requires so they know what drugs each plan covers. This information should be made available to beneficiaries on Web sites, by telephone, and through printed documents.

- **Notification of appeal rights.** There have been complaints that plans are not notifying beneficiaries of their right to appeal coverage determinations and that inadequate directions are communicated to those who wish to file appeals.

- **Continuity of care policies.** CMS issued guidance directing plans to provide flexibility in their formulary policies to accommodate the needs of beneficiaries transitioning from other drug coverage into Part D. This "transition guidance" recommended that 30 day supplies of the medications be provided before beneficiaries are required to switch. It also recommended that flexible formulary policies be maintained after the transition period, since beneficiaries can be expected to experience "unplanned transitions," such as a change of medications after a hospital visit. Further, beneficiaries may need exceptions to formulary policies when required for unique clinical situations. In this regard CMS stated, "In all cases, we make it clear [in our final rule] that a Part D plan sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires." This flexibility in formulary policies is crucial to ensuring continuity of care in drug therapies.

- **Administrative burden.** Patients and practitioners face significant resource demands in dealing with the Part D program. They will spend significant amounts of time learning about formulary policies, assessing the clinical factors involved in switching medications, and considering the costs patients are able to bear. Information tools should assist patients with these activities and physicians should be compensated for clinical decision making.

RECOMMENDATIONS

These issues must be addressed to ensure the success of the Medicare Part D program. The APA recommends that the Committee consider the following approaches to improving the program:

- Request that CMS re-state its "all or substantially all" guidance to the plans, directing them to have formulary policies that allow ongoing, flexible access to exceptionally important categories of drugs (such as antipsychotics, antidepressants, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs).

- Ask CMS to monitor the plans' exceptions and appeals processes and report on the number of beneficiaries filing appeals, the timeliness of response, and the final resolution of appeals.

- Establish a CMS advisory committee, with wide stakeholder representation, to identify persistent problems and short- and long- term correctives to these problems.

We look forward to working with you to help the Medicare Part D program effectively support high quality medical care.

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STATEMENT FOR THE

SENATE SPECIAL COMMITTEE ON AGING

ON

MEETING THE CHALLENGES OF MEDICARE DRUG BENEFIT IMPLEMENTATION

February 2, 2006

WASHINGTON, D. C.

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AARP is pleased that this Committee – and Congress as a whole – is examining the issues arising from the implementation of the Medicare prescription drug benefit. AARP continues its strong support of the Medicare drug benefit, which provides long overdue help to older persons and persons with disabilities, particularly those with low-incomes, those with catastrophic drug costs and those without other sources of drug coverage.

With recent press reports highlighting some of the start-up problems of this new benefit, it is easy to lose sight of the fact that the Medicare prescription drug program is already providing millions of Americans access to needed medications and saving them money as a result of the new Medicare prescription drug coverage. Since January 1, 2006, Medicare beneficiaries have been filling millions of prescriptions. For example, we were recently contacted by a couple from Delaware. Ted is 80 years old and Marge is 77. They told us that they had to spend about $4,000 on medications last year – she takes one medication and he takes five.

In January, they went to the pharmacy for the first time after having enrolled in a Medicare prescription drug plan. They filled one of Ted's medications and ended up spending $68 less than usual for the prescription drug. They look forward to the amount of money they will save when they fill all six of their meds later this month. Because they have enrolled in a Medicare prescription drug plan, Ted and Marge expect to save more than $2,000 a year in drug costs between them.

Prior to Medicare's drug benefit, Ted and Marge had no prescription drug coverage.

Implementation Issues

As expected with a new program of this magnitude, there have been start up problems in connection with the implementation of the Medicare prescription drug benefit. Some individuals, including some dually eligible and others who qualify for the low-income assistance, have been unable to get the drugs they need or were charged higher than necessary copayments. Other low-income individuals continue to wait for a Social Security Administration (SSA) determination as to whether they qualify for the low-income assistance.

In both cases, these individuals are incurring out-of-pocket costs higher than the subsidized copayments to which they are entitled. We urge Congress to provide SSA with adequate resources so that it can process low-income subsidy applications in a timelier manner.

Some pharmacists have also reported incurring thousands of dollars in unpaid prescription drug claims. We encourage CMS to work to ensure that pharmacists are reimbursed for drugs that should have been covered by a Medicare prescription drug plan.

Recently, a majority of states stepped up to provide prescription drug coverage for the dual eligibles, in much the same way as state Medicaid programs did prior to January 1, 2006. We commend the states for their actions and are encouraged by recent CMS announcements that they will reimburse states who have incurred costs for prescription drugs for their dual eligible populations.

AARP takes all enrollment issues very seriously. We have brought to the attention of CMS and others problems that have been identified. We stand ready to work with this Committee, the Congress, CMS, prescription drug plans, States, and others, to ensure that we all take the necessary steps to solve enrollment problems. We need to work together to address these issues as they surface to ensure that the Medicare prescription drug program benefits those who enroll. Above all, we must ensure that individuals who can prove eligibility do not leave a pharmacy empty-handed or pay more than is required for their prescription drugs.

Broader Improvements

In addition to the above-mentioned problems, which CMS and others are trying to address, there are some changes needed to ensure the success and longevity of the Medicare prescription drug benefit. We will work with Congress and the Administration to ensure that these improvements are made.

First and foremost, the asset test for people who need the Part D low-income subsidy should be eliminated. The asset test has proven to be fundamentally unfair to low-income persons and has been a serious barrier for many people the subsidy was meant to help. For example, the application form requires people to report such obscure details as the cash value of any life insurance policies – information people simply do not have on hand.

The difficulty in filling out such an invasive application is, we believe, a key reason why only a fraction of those estimated to be eligible for the subsidy have applied. While nearly 7 million Medicare beneficiaries who are not automatically enrolled in the subsidy may be eligible, only 3.4 million have applied. Of those who have applied, only 1.4 million have been approved. That means that well over 5 million people – the vast majority of those who should qualify but must apply for the limited income subsidy – are not getting it. According to SSA, of those who have applied and been rejected, the number one reason is the asset test.

We urge CMS to examine what administrative changes can be made to alleviate the burden of the asset test. If an administrative solution cannot be found, legislation will be necessary.

In addition, Congress should remove the provision in the Medicare Modernization Act that prohibits the Secretary of HHS from interfering in negotiations between

pharmaceutical manufacturers and the Medicare prescription drug plans. We believe that in order to put downward pressure on drug prices the government should have the authority to negotiate for lower costs on behalf of Medicare beneficiaries.

AARP's Education Efforts

When the Medicare Modernization Act passed, AARP pledged to reach out and educate our members and the public at large about the changes to the Medicare program. And we've done just that. In 2004, our state and national offices conducted extensive education and outreach on the new Medicare prescription drug benefit, including the Medicare discount cards.

Last year, we ramped up those efforts with a greater focus on the January 1, 2006, implementation of the drug benefit. We began the year focusing on outreach and education to low-income populations and encouraging those who may qualify to apply for the low-income assistance. We have continued these efforts in 2006, with a renewed emphasis on education and outreach to encourage Medicare beneficiaries who choose to take advantage of the Medicare prescription drug coverage to do so by the May 15, 2006, initial enrollment deadline.

AARP has produced numerous beneficiary-oriented publications explaining the new changes to the Medicare program, including a general information publication entitled The New Medicare Prescription Drug Coverage: What You Need to Know and a companion publication, The New Medicare Prescription Drug Coverage: Extra Help for People with Limited Incomes. These publications are made available free of charge to our members and the public via the AARP website and our toll-free number.

In addition, we've reached out to our members and the public at large in other ways. AARP publications, including the AARP Bulletin, AARP The Magazine, and Segunda Juventud, have all run articles to educate our members on the new prescription drug benefit. In early September and mid-October, we ran advertisements in three Sunday supplement magazines featuring information and resources about the Medicare prescription drug benefit. These advertisements reached nearly 130 million households. Our state offices are also working with state and local partners to conduct education and outreach.

In light of the recent implementation concerns, we are working to inform our members and the public to bring all enrollment documentation, their government-issued Medicare card, and photo identification to the pharmacy. If individuals are having trouble at one pharmacy, we recommend they try another. In addition, we are encouraging people to sign up at the beginning of a month for drug coverage to begin the following month. This gives CMS and the plans time to ensure that

the individual's enrollment is properly recorded in the appropriate computer systems.

Conclusion

The implementation of the Medicare prescription drug benefit represents the most significant change to Medicare since its inception in 1965. Implementing this new benefit will take some time to work out all the systems issues so that individuals have the prescription drugs they need. Clearly there are some changes that can and must be made. But we cannot lose sight of the fact that older Americans and those with disabilities have already begun to rely on this new benefit for the prescription medication they need. We look forward to working with this Committee and Congress as a whole to help alleviate challenges involved in the implementation of the new Medicare prescription drug benefit and to ensure that older Americans have access to affordable prescription drugs.

Statement
of the

American Pharmacists Association

Submitted to the Senate Special Committee on Aging

On "Meeting the Challenges of Medicare Drug Benefit Implementation"

February 2, 2006

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Statement of the American Pharmacists Association (APhA)
To the Senate Special Committee on Aging

On "Meeting the Challenges of Medicare Drug Benefit Implementation"

February 2, 2006

The American Pharmacists Association (APhA) welcomes the opportunity to present the pharmacist perspective on the implementation of the new Medicare prescription drug benefit, Medicare Part D. As the medication experts on the health care team, and the front-line health professionals dedicated partnering with patients to improve medication use, pharmacists have a unique perspective on the benefit. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

Pharmacists' recent efforts to implement Part D highlight the fact that they are the most important health care professional to successful implementation of Medicare drug benefit. We are the glue that holds the health care system together when it comes to medication use. Pharmacists have worked hard to ensure that the challenges with this benefit do not disrupt patient care, and that patients who were previously unable to afford their medications now can. The Medicare program needs to include coverage for prescription drugs so it is imperative that we make this benefit work.

A Rocky Start

Unfortunately, the start of the new Medicare prescription drug benefit would be described by many patients and pharmacists as a nightmare. Community pharmacists, bearing the brunt of implementing the new benefit, discovered that the 'choice' Congress required in the benefit led to a cumbersome number of plans, yielding chaos. Some of those plans were well-prepared to implement the benefit. Many were not. Simple steps were unnecessarily challenging. For the first month of the new benefit, many pharmacies have been more of an eligibility verification center and insurance benefits manager than a health care facility. Many patients were confused about their new coverage, many simply did not know the name of their new plan, or in some cases, that their medication coverage changed from the Medicaid to the Medicare program. Because prescription drug coverage programs are often navigated at the pharmacy counter, pharmacists endured the following:

- Dual eligibles being auto-enrolled in plans that do not have in-network pharmacies in their area and the plans offering to these beneficiaries the options of paying cash or driving a long distance — neither of which is a likely option for this patient population.
- Calling plan's customer service lines and being placed on hold for hours. When the call was answered, pharmacists were often told to call back when the plan was less busy, or, worse, was provided with incorrect information. Some calls were simply terminated by the plans—they hung up on pharmacists.
- Plans that confirmed enrollment with beneficiaries had not yet entered the beneficiary's information into their system—so a pharmacy's claims for that patient were rejected because the patient was 'not in the plan'.

- Calling the dedicated pharmacy line established by the Centers for Medicare & Medicaid Services (CMS) only to find out that the customer service representatives were unable to answer pharmacists' question because the pharmacist needed more information from the patient, who may have already left the pharmacy or may not have had the additional, necessary information with them.
- Wide variation in plan procedures to authorize the CMS-mandated transition supplies of medications.
- Finally completing the process to secure billing information and submitting claims for a patient's prescriptions, only to have the plans return the wrong co-pay and deductible information—particularly for patients moving from the Medicaid to the Medicare program.

Pharmacists Answered the Call

Pharmacists' commitment to helping patients access their necessary medications has never been more evident than in the last few weeks. Amidst all the chaos, pharmacists answered the call and patients were served. While pharmacists' efforts were not always successful, many more patients would have gone without their medications during this implementation phase without a concerted effort by pharmacists. It is not often that one hears reports of health care providers giving away care for free, yet pharmacists gave away medications to patients because of their belief that patient care should take precedence over insurance red tape. But in some situations, the price of the medication—and the uncertainty of insurance coverage—precluded pharmacists from simply handing out medications. Having some assurance that insurance coverage was available made it easier to provide a few days supply of medication and work through the challenges. But in some situations, pharmacists were unable to find any information. Pharmacists' ability to provide medications on blind faith is limited. At the end of the day, pharmacists want to care for their patients, but they also have to be able to keep the doors open and the lights on. Pharmacists do what they can, but there are limits.

Many patients have expressed great appreciation to pharmacists for the efforts the profession has undertaken on their behalf. Without pharmacists' efforts, patient care would have been damaged. Unfortunately, pharmacy's efforts were met with negative consequences to the practice of pharmacy — both economic and clinical. Because of the size of the program and the realization that implementing a benefit of this magnitude would likely have its challenges, CMS required plans to provide patients with a transition supply of their current medications— most often a 30 day supply—regardless of plan formularies or other drug coverage policy. The purpose of this supply was to ensure that administrative glitches didn't result in patients going without necessary medications. A transitional supply could be used when a patient's current medication is not included on the plan's drug formulary. Transitional supplies are critical to ensuring that patient care is not disrupted. Unfortunately, the procedure for securing the transition supply for one plan differed from the next, so the red-tape burden continued to mount for pharmacists.

The humanitarian response of pharmacy was similar to pharmacy's response to the hurricane crises. Patient care trumped red tape. But that red tape must be addressed. Requiring pharmacists to provide free drugs or face hours of telephone calls to secure insurance information or secure authorization for a month's supply of medications should not be considered a viable option. Such protocols are system flaws that cannot be sustained on the backs of pharmacy. Administration of the benefit should not take pharmacists away from their primary role of taking care of patients. The solutions to the problems, such as State efforts to cover medication supplies

until transition issues are addressed, are welcome but only helpful if the associated red tape with those safety net programs is minimal.

Thankfully, pharmacists were not alone in their efforts. CMS worked closely with interested parties, including APhA and our members, to identify and resolve issues as they arose. Many of CMS' efforts prior to implementation were also helpful, such as the computer communication system that allowed pharmacists to request information about a patient's eligibility. In fact, it is something from which the private market would benefit. Throughout implementation, CMS has been a good partner. As a result, improvements to the system were made daily. For example, CMS' dedicated pharmacy line's availability changed from 'normal business hours' to twenty-four hours a day/seven days a week and staffing increased dramatically; eligibility query response time was reduced from minutes to seconds; and CMS instructed plans to increase the number of customer service representatives available to assist pharmacists and to be sure those people were prepared to answer pharmacists' questions. While problems remain, CMS' efforts should be commended.

The Weakest Link

So who is responsible for the implementation problems? A primary culprit is the prescription drug plans that weren't prepared. Only some plans were ready for January 1st. Some plans improved their operations; others have yet to show improvement. To be fair, some of their challenges were created by the structure of the program — it really wasn't realistic to assure beneficiaries that they could sign up for a plan on December 31st and use that plan at their local pharmacy on January 1st. Furthermore, the 'choice' directive from Congress compounds the challenges of implementing this benefit. For example, the numbers of companies providing stand-alone prescription drug plans along with the number of managed care plans also serving Medicare beneficiaries in each state and territory are staggering. Each of these plans has a different formulary, a different system for processing claims, and different capacities for addressing problems.

Maintaining the current level of choice and supporting that level of inconsistency creates a heightened demand for plans to take ownership of their role in making the benefit work and fix their structural flaws. Some plans have done this and their network pharmacists and patients have benefited from their commitment. But more plans need to be prepared for the next potential for chaos — formulary management. We are pleased that CMS decided to extend the 30-day transition supply to a 90-day transition supply. These eight weeks will provide pharmacists, prescribers, and patients time to work on formulary compliance issues. However, more needs to be done. Transition supplies that were provided to patients will eventually run out. To prevent disruption of patient care, prescribers must begin working through each plans' formulary management procedures (such as prior authorization requests). The first few weeks provided many 'lessons learned'. Identified program flaws must be addressed to ensure the benefit is a success. Plans that are unable to meet their contractual obligations should face stiff penalties. This market-based system is reliant upon the market for success, and to date, some elements of that market have failed.

In the end, it is patients who suffer from these system flaws. To better ensure that Congress is getting what it paid for, there must be greater assurances that we are receiving a fair return on investment in the new program. If patients are unable to get the medications that they were prescribed and pharmacists are unable to help patients make the best use of those medications because the pharmacist is busy trying to process claims, can we claim success at having added drug coverage to Medicare? Pharmacy's ability to navigate administrative duties or to be

'emergency responders', providing medications and care without payment, is sustainable for only a limited amount of time. Not addressing these issues, which place the economic burden of implementing the Medicare drug benefit onto pharmacy, will have a negative impact on patient care by limiting patient access to pharmacists — either limiting a pharmacist's time to provide patient care or eventually damaging pharmacy's economic infrastructure to a degree that results in limited access to pharmacies. If nothing else, the first month of Part D suggests that it is time to re-examine our infrastructure.

Re-evaluating the Infrastructure

Something that distinguishes pharmacists from other health care providers is that pharmacists provide expensive inventory to patients. These products represent a major part of our income. We can only give away so many medications before we must close their doors. The heroic efforts of most pharmacists over the last month to implement Medicare Part D resulted in economic losses that may not be recoverable, because much of their practice's income is in medications. Unfortunately, these expenses are soon to be compounded by recently adopted changes to the Medicaid program. Despite extensive outreach by the pharmacy community, Congress retained significant Medicaid cuts to pharmacy in their final budget package. The potential for serious patient harm from these cuts is real. Trusting that pharmacists will be available in the future to provide services is misplaced proceeding with these payment cuts.

It is imprudent to damage the infrastructure on which one relies to implement the largest change to Medicare since the program's inception. Unfortunately, that is what Congress did. It is time for policymakers to ask, how would patients have been served during implementation of the Medicare drug benefit with reduced access to pharmacies or pharmacists? Clearly, far more problems with the new benefit would have touched far more patients.

Another distinguishing characteristic of pharmacy is that it is one part of health care where the payor is intimately involved in what the patient receives. It is not like physician services, where perhaps a health insurer requires a second opinion before a procedure is 'covered'. That evaluation is completed before the point of service. Drug coverage decisions, however, are rarely addressed until the patient is facing the pharmacist, and the red tape clouds patient care.

We don't debate what will be covered – anesthesia or cesarean sections – in the delivery room. It is time to stop having those debates at the pharmacy counter, when the patient is trying to understand medication regimens that are critical to their health care needs. As we have moved to more outpatient care that relies heavily upon medications and patients' ability to manage those medication regimens, we have removed health care providers from the mix and inserted insurance companies. Pharmacy benefit management can be helpful—it can yield savings to the health care system and promote the use of effective, lower-cost interventions. But those savings should not come about because patients are denied necessary therapy. We must improve the system.

Safety Net Providers

The safety net pharmacists and health care entities that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured and other vulnerable populations have additional concerns about the program. In addition to the issues that have already been discussed, these entities face their own challenges to implement Part D. While the law 'encourages' plans to include safety net pharmacies in their networks, in reality, many Part D plans have ignored these pharmacies in their contracting activities, and others have made it impossible for safety net pharmacies to participate in the context of the uncompensated care they provide. Consequently, these already-vulnerable patients are less able to reap the

benefits of Part D. Even Part D plans that are trying to work with safety net providers are encountering problems that stymie their efforts. Also, safety net pharmacies are often limited to treating targeted patient groups, such as AIDS, Black Lung, or hemophilia. As a result, they will not and could not meet many of the basic requirements to be a Part D pharmacy, or their formularies will not match the PDPs' formularies. Until the business and financial incentives for the program are aligned with the public policy concerns of including safety net pharmacies, these pharmacies – and their patients – will likely continue to be excluded from meaningful participation in Part D.

Recommendations

Although we have identified some problems with the new benefit, it is important to distinguish between what is and is not improving and what we believe are long-term issues that require further discussion. Our recommendations are below.

Immediate: Enrollment/Eligibility

The current lag between enrollment and availability of eligibility information is a major reason for the ongoing patient and provider confusion about patient eligibility.

- Clearly define enrollment periods and cutoff dates. This is not an uncommon practice. Telling Medicare beneficiaries that they can fill out a form today and have coverage the next morning is misleading. This problem may re-emerge June 1st with facilitated enrollment for the low-income subsidy population and/or if many beneficiaries enroll in May as the initial enrollment period ends. It is a problem that will also continue as beneficiaries age-in to Medicare.
- Until Congress changes these eligibility rules, inform Medicare beneficiaries that while their coverage is effective the next month, they should refill their medications in their usual cycle, requesting their refill five to seven days before they will run out of the medication. There is no need for Medicare beneficiaries to 'check out' their new benefit on the 1st of the month.
- Change the eligibility parameters: enrollment forms received by a plan by the 15th of the month will result in beneficiary coverage starting the first of the following month; limit dual-eligibles to changing plans every quarter; suspend E1 query (eligibility) transaction fees until July 1st and permanently suspend these fees for dual eligibles (because of the frequency with which they may change plans); suspend E1 transaction fees every January to help beneficiaries who changed plans.

Immediate: Eligibility — Patient ID Cards

Although the law requires plans to meet standards developed by the National Council for Prescription Drug Programs (NCPDP), cards do not appear to meet these standards.

- Review cards and mandate compliance with NCPDP standards.
- Prohibit plans from issuing cards that list some pharmacy providers. Beneficiaries have interpreted the pharmacy logos on their ID cards as an indication that the cards may only be used at those outlets, an incorrect assumption.

Immediate: Prompt Pay

Pharmacy contracts with wholesalers, pharmaceutical manufacturers, and plan sponsors, like other contracts, often include penalties to pharmacies that do not pay their bill promptly. While we understand that the entities want to get paid for their products, pharmacies are facing long lags in payment for their products and services. Additionally, pharmacies who had been serving dual eligibles through State Medicaid programs were accustomed to payment schedules that were

more frequent than the payment schedules established by PDPs and MA-PDs. Consequently, some pharmacies are facing a significant cash flow problem.

- Require plans to pay pharmacies every 15 days.

Immediate: Payment for Medications Dispensed/Services Provided Since January 1st

- Require plans to pay out-of-network pharmacies for medications dispensed when beneficiaries' auto-assigned plan isn't accepted at the beneficiary's pharmacy of choice.
- Continue to coordinate state efforts to wrap around coverage. State announcements that they will take care of all its residents without a plan to make it happen is good politically but operationally unsound, and puts the pharmacist in an uncomfortable position at the pharmacy counter when they need to be focusing on patient care.
- Indemnify plans for low-income eligibility errors. We support efforts to enroll people quickly. However, these efforts put plans at risk if they mistakenly put enrollees in their low income program instead of the commercial pool. Without indemnification, plans may attempt to recoup these costs from the providing pharmacies. Or, plans may ask pharmacists to recoup these costs from beneficiaries. The errors were not generated by pharmacists; therefore, pharmacists should not be forced to be part of the solution.

Immediate: Impending Formulary Compliance

We are pleased that CMS decided to extend the 30-day transition supply to a 90-day transition supply. These eight weeks will provide pharmacists, prescribers, and patients time to work on formulary compliance issues. However, more needs to be done.

- Require plans to share their formulary information with pharmacists, prescribers and patients so that patients can make better informed plan choices, prescribers can make better educated decisions about what drugs to prescribe their patients, and pharmacists will better understand their patients' options when faced with a plan rejection of a medication.
- Require plans to phase-in prior-authorization and formulary compliance efforts over the first six months of 2006 to allow more time for this process to be completed for this large, new Medicare population.
- Increase outreach to the prescribing community about formulary compliance and the steps needed to begin the prior authorization process so that the next time the patient comes into the pharmacy for a refill, all formulary compliance-related steps have been taken and the pharmacist can focus on the patient's care.
- Compensate pharmacists for their formulary compliance efforts. Only through their work with patients, prescribers and plans are these tasks accomplished. Yet, even though the required steps may take hours out of a pharmacist's day, there is no compensation for their work to implement these guidelines, many of which result in savings for the plans and the program.

Long-Term: Operations

- Strengthen CMS' ability to sanction underperforming plans.
- Consider capping the number of plans available in a region to provide more manageable choices.
- Increase CMS oversight of plans.
    - Pharmacists have been presented with contracts that do not cover their costs for the medications or their services. CMS should take a more active role in helping ensure that pharmacy's costs are covered.

- While plan offerings and formularies may differ, benefits would be gained from standardizing some elements. CMS should consider setting stricter formulary parameters, standardizing plan features such as the messages plans send to pharmacies regarding patient eligibility, formulary requirements, days supply, etc.

- To address the need for increased participation by safety net pharmacies, incentivize plans to contract with such pharmacies. Additionally, allow plans flexibility in designing contract terms with safety net pharmacies that recognize the realities of these pharmacies and their capabilities.

Conclusion

Amidst the chaos and confusion, there is good news. The new prescription drug benefit was a success for many patients. Medicare beneficiaries are finally receiving financial relief for their medication costs. Some pharmacists have reported that patients are returning to their pharmacy because the patient is now able to afford their medications.

To the degree the program has and will be a success is reflective of pharmacists, as well as the efforts of CMS and other agencies. We applaud those who have recognized the critical role pharmacists play in assisting patients with the new drug benefit. Efforts by CMS, State Governors, and Members of Congress to address the issues raised during the transition to the new drug benefit were essential as well.

However, we must also recognize the absurdity of undercutting the very infrastructure responsible for making the Medicare drug benefit work. Congress' cuts to pharmacy in the Medicaid program are misguided; they will not 'reform' the infrastructure as Congress' portends, and do not include assurances that pharmacy can cover their costs for providing care to patients. Without such assurances, pharmacists cannot serve any patients —Medicaid or Medicare. Policymakers must begin reflecting that reality in their decisions.

It is time to learn from the last month's lessons and begin creating systematic changes to the program that have been identified as weaknesses and when addressed will make the benefit a better benefit for Medicare patients. Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to develop a more effective system of providing prescription medications to Medicare beneficiaries.

TESTIMONY OF

JACK VOGELSONG
APPRISE PROGRAM DIRECTOR

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGING

STATE HEALTH INSURANCE ASSISTANCE PROGRAMS & THE NEW MEDICARE PRESCRIPTION DRUG BENEFIT

Before the

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

February 2, 2006

Chairman Smith, Senator Kohl, and distinguished members of the committee, thank you for the opportunity to testify on the role of State Health Insurance and Assistance Programs (SHIPs) in the education and assistance of Medicare beneficiaries on the Medicare Part D prescription drug benefit. My name is Jack Vogelsong and I am the director of the APPRISE program, Pennsylvania's SHIP, within the Pennsylvania Department of Aging. I am also a member of the national SHIP organization's steering committee. Today, I will focus on how Pennsylvania prepared for Medicare Part D, the challenges we have faced, and our response to these challenges throughout the implementation of this new benefit.

The SHIP Network

Congress created the SHIP network in 1990 as part of Medigap reform. The program is available in all 50 States, DC, Puerto Rico, Guam, and the Virgin Islands, and serves 2.7 million Medicare beneficiaries annually. In most states, SHIP is administered by state agencies and departments of aging, and about one-third fall within their state insurance departments. Nationally, there are 12,000 volunteers that assist vulnerable populations, such as older Americans and those with low incomes or poor health status, with health insurance and public benefit programs.

In Pennsylvania, our network of staff in the 52 Area Agencies on Aging (AAAs) and nearly 600 volunteers have been trained to educate, assist and advocate for our Medicare beneficiaries through the APPRISE program. Volunteers are required to participate in a 24-hour training program and six months of mentoring by experienced volunteer counselors and paid coordinators on the intricacies of the Medicare Program and other insurance products, such as long-term care insurance and Medicaid. In addition, staff from the Pennsylvania Department of Aging and full time regional coordinators provide support to APPRISE counselors.

Pennsylvania's Preparation for Medicare Part D

SHIP Programs across the country began planning well over a year before the Medicare Part D Program was introduced to the public. In anticipation of the new benefit, Pennsylvania implemented an educational campaign to inform and assist the 2.2 million Medicare beneficiaries in our state. A 2004, Penn State study found that 57 percent of Medicare beneficiaries would turn to APPRISE and the state for assistance when faced with the decision about their Medicare

Prescription coverage, 10 percent more people than those who would contact 1-800 Medicare. The Penn State survey also indicated that less than 30 percent of our Medicare population would utilize the Internet to gain access to the Centers for Medicare and Medicaid Services (CMS) for the Medicare Prescription Drug Plan Finder.

Our past experience with Medicare beneficiaries indicated that any change to health care benefits, even when positive, would create a level of anxiety that would further complicate the educational process. That anxiety would result in a search for information that would have older Pennsylvanians turning to trusted resources, whether or not those trusted resources possessed the latest and most accurate information.

APPRISE Partner Training Program

Since many beneficiaries would turn to health care providers, pharmacists, and medical staff for information on the prescription drug benefit, we needed to help these potential educators become knowledgeable about the program and the local resources available for assistance.

To this end, the APPRISE program conducted an ambitious schedule of daylong partner trainings in the summer of 2005. The morning sessions were devoted to the details of the Medicare Prescription Drug Benefit and the impact it would have on special populations such as those residing in long term care facilities, those on Medicaid and waiver programs, and those who receive coverage through our state pharmaceutical assistance program (SPAP), the Pharmaceutical Assistance Contract for the Elderly (PACE). The afternoon sessions provided an opportunity for attendees to discuss partnerships with their local APPRISE office, to plan outreach events, and develop ideas on how to best serve beneficiaries within their own communities. APPRISE trained more than 1,800 partners at these sessions.

We were aware that the Medicare Part D benefit would affect different segments of the Medicare population in different ways. To simplify our educational campaign, we tailored our message for each target audience. By creating a personalized message, we were able to minimize the potential confusion stemming from parts of the law that may not affect every consumer. Each messages was largely based on the type of prescription drug coverage the beneficiary had before the implementation of Medicare Part D.

In addition, we partnered with grassroots organizations to reach populations that could be potentially missed by the national campaign. Grassroots partnerships with various diverse organizations resulted in over 40 informational sessions directed towards culturally diverse groups and faith based organizations around Pennsylvania. We also conducted sessions, provided marketing materials, and placed materials on our website translated into the preferred languages of our partners.

We conducted statewide legislative training sessions, partnered with the Pennsylvania Society for the Advancement of the Deaf, the Pennsylvania Nursing Association, personal care home providers, and the AAA Meals on Wheels program to reach the homebound population.

APPRISE Consumer Education

In addition to partner education, we initiated a two-phase consumer education program. The first phase focused on preparing Pennsylvanians for the Medicare prescription drug benefit. The second phase was directed at plan selection once plans became available in mid-November.

During phase one, the APPRISE program sponsored over 2,400 Medicare Part D informational sessions serving over 140,000 consumers since May 2005. For phase two, APPRISE established 124 Medicare Part D enrollment sites throughout Pennsylvania for people to receive individualized assistance with drug plan comparisons and enrollment into a Medicare prescription plan. Since mid-November, over 1,000 Medicare Part D enrollment events have occurred throughout the Commonwealth with approximately 38,000 seniors in attendance.

Challenges Before January

The time period to enroll in the Medicare benefit before the January 1, 2006 effective date was very short. Because the Medicare website became available on November 14, 2005, consumers were provided only a seven-week period to compare prescription drug plans. As a result, the demand for personalized assistance was extremely high. The APPRISE program responded by increasing the manpower available to assist beneficiaries in online comparisons of the prescription drug plans. Local APPRISE offices had to pull existing AAA staff from other duties to help consumers with online plan comparisons. While the relationships that APPRISE built with community and civic organizations resulted in large donations of staff and resources, additional

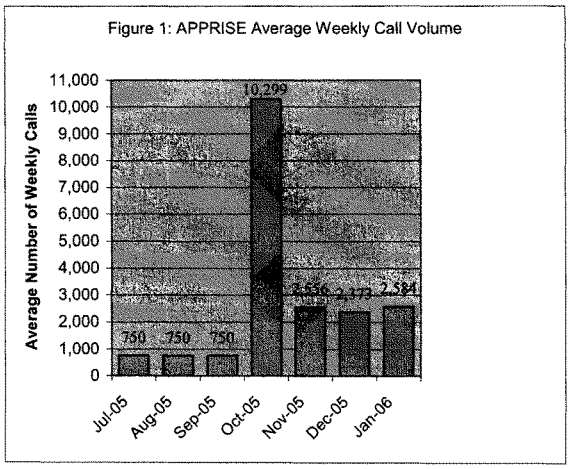
limited term volunteers had to be recruited and trained, although not as extensively as the existing APPRISE counselors. Colleges and high schools students were trained to enter data in the Medicare comparison tool while the APPRISE counselors verified the accuracy of information and the results of plan finders. Counselors verified existing health insurance coverage and counseled beneficiaries to ensure they actually understood the plan prescription benefit before any enrollment activity took place.

APPRISE Program Expansion

The APPRISE program operates a toll-free help line five days a week that is staffed by four volunteer counselors. This well-known program has been a resource to our legislators, state and federal agencies, health care providers, and businesses, all of which, in some way, had a vested interest in how this new benefit would impact Pennsylvania's Medicare population.

In 2004, prior to Medicare Part D, the center averaged 625 calls a week. As a result of the distribution of the Medicare & You 2006 Handbook and dual eligible consumers enrolling in Part D plans, call volumes surged last October, with a peak volume of 12,000 in a single week. To alleviate the dramatic increase in call volume to the help line, the Pennsylvania Department of Aging explored ways to of expanding our call capacity through an existing state contract with a call center. This contractor submitted a $600,000 proposal to supplement the existing help line for a period of 11 weeks. As this was not a financially viable option, Pennsylvania took extraordinary measures to serve Medicare beneficiaries.

The APPRISE program increased its capacity by adding eight additional volunteer counselors for a total of from four to twelve counselors a day, five days a week. This also included designating full-time Department of Aging staff to also answer calls five days a week and to expand capacity by more that 700 calls. With our increased capacity, our volunteer counselors are now answering 2,700 calls a week (see Figure 1).



Although in January need for enrollment assistance diminished, we experienced an increased demand for services to assist beneficiaries in receiving prescription drug benefits, specifically for dual eligible and special populations. Because the needs of these consumers were much more complex, it increased the time required for counseling. More importantly, many consumers were not able to fill their prescriptions when they went to their pharmacies. We also experienced a surge of calls from pharmacists and physicians requesting assistance on how to help consumers who were enrolled in plans, but were not recognized as eligible in the database.

Increased Program Costs

The additional cost to our AAA network for November through January is estimated at $400,000 over and above Pennsylvania's $1.4 million SHIP appropriation. This figure includes the costs incurred by local AAAs to hire temporary help in addition to existing staff to assist with the designated Part D initiative. Also, it includes the costs of additional town meetings, computer rentals, and Internet access not already covered by the AAA planning grants made available through the Pennsylvania Department of Aging. We anticipate these costs will continue to rise as consumers continue to experience problems.

In addition, for the past three months, Pennsylvania Department of Aging staff has been answering three APPRISE phone lines. The estimated staff cost for the Department of Aging is a minimum of $40,000 and increasing each day, not to mention the loss of staff time on other valuable projects.

Partnering with Other State Agencies

In addition the efforts the APPRISE program has undertaken to manage the transition of seniors and dual eligibles into Medicare Part D, Pennsylvania's Department of Public Welfare (DPW) conducted training sessions throughout the state focused on issues of interest to dual eligibles to prepare for Part D's implementation. In addition, the DPW established a website and created training materials, including Pennsylvania-specific frequently asked questions to ensure consumers and providers had the information they needed prior to January 1, 2006. Since January 1, the DPW has engaged around 50 staff members in easing the transition.

Due to early challenges with dual eligibles being denied drugs, the state Medicaid program implemented two stopgap measures. The first is in response to a glitch in the Medicare system that has not identified all individuals eligible for Part D's low income subsidy. As a result, Medicaid will pay for cost sharing over the nominal co-pay levels dual eligibles are required to pay. The second measure is for dual eligible consumers unable to secure a drug through Medicare Part D. Medicaid will provide a 5-day emergency fill of drugs. These stopgap measures have helped provide a temporary fix but problems still remain. Approximately 200 to 300 claims are paid daily for each of these stopgap measures. The Medicaid program continues to receive about 1,000 calls daily from consumers and pharmacists who need assistance navigating the Medicare program. The Department has spent approximately $2 million during the month of January in unanticipated staff time to manage the transition to Part D for dual eligible consumers.

Additional Concerns

In Pennsylvania 115,000 dual eligible individuals were passively enrolled into a Medicare Advantage Plan. Many of these individuals lost access to their existing healthcare providers, including hospitals, medical specialists, and mental health services. Because these individuals are currently enrolled in a Medicare controlled health plans and prescription drug plans, we are finding that

many of them are turning to the APPRISE and Medical Assistance programs to get assistance in accessing needed healthcare services and the full range of prescription drug coverage. The vast majority of consumers enrolled in these plans have complex medical problems requiring a broad range of health care providers and prescription drugs.

The Medicare Advantage plans did not seem to anticipate the need to "hand hold" these clients during the transition, nor do they seem to be proactive in getting the consumers existing providers into their networks to ensure continuity of care. Furthermore, the Medicare Advantage plans are not making certain that their network providers are willing to take Medical Assistance clients for whom they will need to bill Medical Assistance for cost sharing.

Previous to this change, this care management was the responsibility of caseworkers within the state Medicaid agency. This shift will have far reaching implications for the SHIP programs. Those dual eligible individuals who contact Medicare's 1-800 number are being referred back to the state health insurance assistance program for plan selections, location of health care providers, and filing appeals and grievances to obtain these benefits.

Conclusion

Over the next ten years, $174 billion will be spent on the Medicare Part D benefit by the federal government with addition billions of dollars being paid by Medicare beneficiaries in premiums. When constituents do not receive the valuable assistance they need to make informed decisions about this valuable coverage their perception of its value will be tainted. Despite CMS' efforts to provide support and assistance through their 1-800 call center and Medicare.gov there is a significant need to for face-to-face assistance to our constituents to ensure they receive the value that this legislation intended to provide.

I know of no more cost effective way to provide this service than the national SHIP network. We would like your support to enhance the services that we provide and expand our capacity to service more of our constituents. In Pennsylvania, we receive $1.4 million to perform this function for 2.2 million beneficiaries or about 64 cents per person. It is difficult to provide high levels of customer service at this rate.

I would like to take this opportunity to thank you the Committee, for inviting us to address the committee on Medicare Part D and SHIP, and I trust that my testimony informs your efforts in understanding how this program has affected so many Americans.

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Meeting The Challenges of Medicare Drug Benefit Implementation

Testimony of

Kenneth E. Goodman, Chief Operating Officer
Forest Laboratories

Submitted to the Senate Special Committee on Aging

Mr. Chairman, Ranking Member Kohl, and distinguished members of the Special Committee on Aging, as President and Chief Operating Officer of Forest Laboratories, Inc., I welcome the opportunity to submit a formal statement for the record regarding challenges to implementation of the Medicare Part D prescription drug benefit.

Forest Laboratories, Inc. is a pharmaceutical manufacturer that is headquartered in New York City with major research facilities in Jersey City, New Jersey and on Long Island, New York. Our major distribution center is located in St. Louis, Missouri. We were founded in 1956. Howard Solomon, our Chief Executive Officer since 1977, is a man whose personal life and family have been profoundly affected by severe depression. As a result, this is a company that truly is dedicated to finding effective treatments for diseases of the central nervous system and in particular, mental illness. During my tenure as President and Chief Operating Officer, I have helped grow the company from $10 million in sales to $3 billion. Our major products include Lexapro®, (escitalopram oxalate) an anti-depressant in the SSRI class that is the most widely prescribed treatment for depression in the elderly and Namenda®, (memantine) an anti-dementia medication and the only FDA approved treatment for moderate to severe Alzheimer's disease. Forest's success as a company has come through hard work, dedication to science and education. At Forest, we do not and will not engage in any direct to consumer advertising. We believe that such advertising is ill-advised and leads to inappropriate, over-utilization of medications.

My testimony today focuses solely on access to mental health treatments under Medicare Part D and in particular, access to Lexapro®. Among psychiatrists and particularly among those who treat geriatric patients, Lexapro® is considered to be among the safest anti-depressants. This is because Lexapro® is very potent; treatment can be initiated and maintained at very low doses. It is also very clean, causes few side effects and is unlikely to react with other drugs, again making it an ideal choice for treatment of depression in the elderly who take multiple medications. Among long term care residents who are being treating for depression, 40 percent are on Lexapro®. In 2005, approximately 1.7 million people over age 65 will have taken Lexapro®. Of these, approximately 500,000 are in long term care facilities, including approximately 200,000 in nursing homes. Prior to implementation of Part D, Lexapro® was the preferred anti-depressant on the formularies of all major long term care pharmacies.

As you are aware, last year, the Center for Medicare and Medicaid Services (CMS) issued formulary guidance that called upon the new Medicare Part D prescription drug plans to cover "all or substantially all" medications in six classes. The guidance was originally issued in

draft and was finalized after a short period for public comment. Like many advocates for mental health treatment, Forest Laboratories applauded CMS' efforts to ensure access to critically necessary drugs for vulnerable Medicare beneficiaries, a large percentage of whom are dual eligibles who would be auto-assigned into plans on a random basis.

Forest Laboratories also supported Congress' endorsement of free markets, believing that competition among plans and manufacturers was the best way to control prices. Like other manufacturers, by mid-summer, we had entered into many contracts with plans, but also had many offers outstanding. Then on June 10, 2005, without any notice to our company, and without any public process, CMS revised its formulary guidance. This guidance document reiterated the earlier document but included a very short list of exceptions. Much to our surprise, among available anti-depressants, CMS singled out Lexapro®, advising plans that if the plan formulary covered citalopram (the generic version of Celexa®), Lexapro® need not be covered.

Effectively, the guidance directs Part D plans to treat Lexapro® and citalopram as interchangeable. However, while it is true that Lexapro® is an enantiomer that is also found in citalopram, Lexapro® and citalopram are not therapeutically equivalent drugs. The scientific and clinical evidence to support this is substantial. For example:

- Citalopram is composed of two enantiomers, R-citalopram and S-citalopram. Clinical studies have demonstrated that the R-enantiomer found in citalopram, but not in Lexapro®, inhibits the therapeutic effect of the S-enantiomer and also is responsible for additional side effects.
- Several studies have shown that patients not achieving a good response to citalopram have been able to respond to Lexapro® – fulfilling a medically accepted criterion by which antidepressants are demonstrated to not be interchangeable.
- A recent prospective, randomized, double-blind, head-to-head trial in major depressive disorder demonstrated that Lexapro® 20 mg/day is significantly superior to citalopram 40 mg/day in both response and remission outcomes.
- FDA has approved Lexapro® for treatment of depression and generalized anxiety disorder, whereas citalopram is only approved for treatment of depression.
- The FDA's Orange Book, which is used by pharmacists as a reference to determine therapeutic equivalence among pharmaceutical products does not list Lexapro® and citalopram as therapeutic equivalents.

Since the guidance was issued, the American Psychiatric Association (APA), the National Alliance of Persons with Mental Illness (NAMI), the National Association of State Mental Heath Program Directors (NASMHPD), the National Mental Health Association and nearly 900 practicing physicians and psychiatrist have written to Dr. Mark McClellan to ask that CMS rescind the exception for Lexapro®. Given the overwhelming clinical data demonstrating that Lexapro® and citalopram are not interchangeable, we assumed that CMS would respond positively to these letters. However, on Monday, August 29, 2005, CMS' Jeffrey Kelman, M.D., informed us that no further formulary policy guidance would issue this year. While Dr. Kelman did give his assurance that this issue would be revisited in 2006 for plan year 2007, Dr. Kelman was adamant that it was simply too late to correct the formulary guidance for 2006.

CMS' exception for Lexapro® had the immediate effect of interfering in our negotiations with Part D sponsors. Several of our customers stated explicitly that they made the determination not to contract with us based upon the CMS guidance. The guidance also affected other books of business. Further, while these sponsors pointed to the guidance as the reason for not keeping Lexapro® on their formulary, they also told us that they were directed by CMS to add another, specific branded product in the same class. CMS' actions directly conflict with the statute that prohibits the Secretary from interfering in negotiations with drug manufacturers and PDP sponsors and from requiring a particular formulary.

While CMS' direct interference in the contracting process contravenes the statute and Congress' intent, ultimately, our greater concern, shared by those who wrote to CMS, is the impact on patients. Absent a correction, Medicare beneficiaries currently stable on Lexapro®, including approximately one-half million in long term care facilities, will either have to seek an exception, pay out-of-pocket or agree to be switched to citalopram or another generic product. Many could be switched even without prescriber authorization. Such switching practices are contrary to all established clinical guidelines and predictably, will result in patient harm and higher health care costs. Importantly, under Part D, PDP plans make more money by switching patients to generics, and are not accountable for increased health care costs that are associated with adverse drug events that can lead to increased physician time and even hospitalization.

As has already been reported in Drug Topics (November 21, 2005), the Chicago Tribune (January 24, 2005) and the Washington Post (February 6, 2006), access to Lexapro® is an identifiable problem under Part D. Pharmacists are having to provide the medication or spend hours on the telephone obtaining prior authorization approvals. Some plans are imposing step edits, meaning that the patient, currently stable on Lexapro®, has to switch to a generic and fail, before they can switch back. We believe that the vast majority of patients have been able to stay on Lexapro® because many plans are honoring CMS' transition guidance and providing a thirty day or longer fill. One long term care pharmacy that serves a large share of the market estimates that 30 percent of patients could lose access to Lexapro® once the transition period is phased out.

Based on the clinical data and past experiences, it can be anticipated that between 30 to 50 percent of patients who are switched from an anti-depressant that works for them, may fail on citalopram or whatever other anti-depressant is tried next. We are already beginning to receive reports from doctors about formerly stable patients who decompensated after being switched. Although some of these stories predate the implementation of Part D and do not involve Medicare beneficiaries, they nevertheless show the detrimental impact of switching which is solely dictated by financial and not clinical considerations. For example:

- The American Society of Consultant Pharmacists reported to CMS that after citalopram became a multi-source drug, a nursing home in upstate New York attempted to convert Lexapro® patients to citalopram. Of those who were switched to citalopram, one-third failed the conversion. Two residents were sent out for acute psychiatric evaluation and numerous others received psychiatric consultations within the facility.

- A psychiatrist from Minnesota reported that her patient was required by his health plan to switch from Lexapro® to citalopram. The patient decompensated and became severely depressed, even while on citalopram. He began drinking, was charged with DUI and eventually lost his job. He has now been restabilized on Lexapro.

- A psychiatrist from Missouri reported that he authorized a switch from Lexapro® to citalopram after receiving a call from a pharmacist indicating the patient had requested the change to save money. Within less than three months, the patient destabilized and became depressed, affecting both her marriage and job performance. The psychiatrist later learned that the patient had not requested the change.

- A physician in Ohio reported that his patient was switched from Lexapro® to citalopram by the pharmacy benefit management company that managed the patient's employer-sponsored drug benefit. The pharmacy benefit management company told the patient that the physician had authorized the switch. The physician states this is untrue: he never authorized the switch. While on citalopram, the patient decompensated. The physician complained about the substitution and requested that his original prescription be "dispensed as written," so that the patient could again receive Lexapro® .

Despite our best efforts and multiple written requests to CMS, CMS has never identified what or whom it relied upon when it issued its guidance excepting Lexapro® from the requirement that substantially all anti-depressants be covered. We understand that CMS currently is in the process of revising its formulary guidance and is committed to a public process. We hope that CMS will take this opportunity to correct the guidance issued last year. We are not even asking CMS to direct all plans to cover Lexapro® on their formularies. All we are asking is that CMS treat Lexapro® no differently than any other anti-depressant and rescind statements that suggest that citalopram is an appropriate therapeutic substitute. (This can be done easily, it only requires CMS to send an email and post a revised document on their website). Rescinding such statements will help curtail some of the most insidious switching practices where neither patient nor physician are given complete or accurate information about who is initiating the request, the differences in the drugs or the risks of changing medications. We are confident that as long as dual eligibles are protected with appropriate safeguards as they transition to Part D and other beneficiaries are able to exercise choice, access to Lexapro® will be preserved for those who would benefit from treatment, without unduly burdening plans.

We appreciate your consideration and hope that as you consider necessary fixes to Part D you will look carefully at the need to ensure that CMS' decision-making process is transparent, and that formulary access to approved, effective medications such as Lexapro® are not arbitrarily curtailed to the detriment of Medicare beneficiaries who suffer from severe depression and anxiety.

I welcome the opportunity to respond to your questions or provide you with further data.

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