S. HRG. 109–726

IMPLEMENTATION OF THE MEDICARE PRESCRIPTION DRUG BENEFIT

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

FEBRUARY 8, 2006

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE

31–519—PDF WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON FINANCE

CHARLES E. GRASSLEY, Iowa, *Chairman*

ORRIN G. HATCH, Utah
TRENT LOTT, Mississippi
OLYMPIA J. SNOWE, Maine
JON KYL, Arizona
CRAIG THOMAS, Wyoming
RICK SANTORUM, Pennsylvania
BILL FRIST, Tennessee
GORDON SMITH, Oregon
JIM BUNNING, Kentucky
MIKE CRAPO, Idaho

MAX BAUCUS, Montana
JOHN D. ROCKEFELLER IV, West Virginia
KENT CONRAD, North Dakota
JAMES M. JEFFORDS (I), Vermont
JEFF BINGAMAN, New Mexico
JOHN F. KERRY, Massachusetts
BLANCHE L. LINCOLN, Arkansas
RON WYDEN, Oregon
CHARLES E. SCHUMER, New York

KOLAN DAVIS, *Staff Director and Chief Counsel*
RUSSELL SULLIVAN, *Democratic Staff Director*

CONTENTS

OPENING STATEMENTS

ADMINISTRATION WITNESS

WITNESSES

ALPHABETICAL LISTING AND APPENDIX MATERIAL

COMMUNICATIONS

IMPLEMENTATION OF THE MEDICARE PRESCRIPTION DRUG BENEFIT

WEDNESDAY, FEBRUARY 8, 2006

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:05 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Charles E. Grassley (chairman of the committee) presiding.

Also present: Senators Hatch, Snowe, Kyl, Thomas, Santorum, Smith, Bunning, Crapo, Baucus, Conrad, Bingaman, Lincoln, Wyden, and Schumer.

The CHAIRMAN. The Administrator has asked if he could have 12 minutes instead of the usual 5 minutes for his testimony, and unilaterally I said so. I need to check that with Senator Baucus now. Is that all right?

Senator BAUCUS. Maybe 11, if you would.

The CHAIRMAN. All right. Maybe 11. All right.

Anyway, Senator Baucus and I will have opening statements before we go to the director.

OPENING STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Obviously, today's hearing is about the oversight of our committee on the implementation of legislation that we passed and have responsibility for, the Medicare prescription drug benefit.

I wish I could say that implementation has gone smoothly, but, as we all know, it has not, especially for some of our Nation's neediest beneficiaries, also referred to as dual eligibles. They are now being transitioned from Medicaid to Medicare for prescription drug coverage, and that has not gone so smoothly.

Computer and information problems resulted in some beneficiaries being charged much higher cost-sharing, some beneficiaries could not get their drugs under the new plans, and pharmacists have had difficulty in getting through to the plans for information about specific individuals.

As a result, many pharmacists have filled prescriptions or given emergency supplies, and that was out of their pocket, advancing the prescriptions. They are now waiting for payment.

Some plan representatives have been unable to answer important questions, like which plan someone is enrolled in. We have had instances where some beneficiaries did not receive their cards, some instances where people actually got two cards.

Now, we have had States stepping up to pay for prescription drugs in these problem areas for specific individuals. All of these situations, we all agree, are unacceptable, and we need to fix those problems, and fix them fast.

I have confidence that we are going to hear how some of those are being handled today, and handled successfully. But we are also going to probably be told about some problems that are just now coming to light, because, when you are dealing with 44 million people, you tend to have some start-up issues. By all accounts, CMS, the plans, the pharmacists, and others are working to fix these problems.

On the problems faced by dual beneficiaries, we knew the transition to Medicare would not be easy. During the development of the bill, the Finance Committee thought long and hard about switching Medicaid coverage to Medicare. We considered the challenges that these beneficiaries face, being frail, older, having impairments. Change, for populations like that, can be disruptive under the best of circumstances.

Frankly, in the end, the Finance Committee bill, in 2003, called for these beneficiaries, after we had given all this thought to it, to continue their prescription drug coverage under Medicaid, under the program that they knew and was working.

But there were many members of Congress, on the other side of the aisle and in the House of Representatives—and in the House I suppose there are both Republicans and Democrats—who wanted to convert prescription drug coverage of these beneficiaries from Medicaid to Medicare.

Now, I appreciate that view of having one national program, but we were concerned about the transition. We knew it was bound to be problematic. The Senate happened to debate this issue long and hard in June of 2003.

There was an amendment on the Senate floor to have dual eligibles' prescriptions covered by Medicare. That amendment failed by a vote of 47 to 51, so this committee's position held tight going into conference. But as we all know, that conference agreement that came out called for the transitioning of the dual-eligible beneficiaries to Medicare.

So in the end, the House position won over the Senate position, and the 47 Senators who thought that we ought to only have one program instead of the dual eligibles being handled as they historically had, won out, and I guess won out over what I believe should have been, and what the administration thought should have been.

Now, that is all history. I am not happy that things have not gone as well as they should have with the legislation that was finally signed.

But I would like to remind my colleagues that it is a little disingenuous that people who seemingly got what they wanted—to have dual eligibles covered under Medicare—are now upset about it. Everyone knew full well that transitioning the duals could not be perfect, and problems would be inevitable. I know what the response will be. It will be, yes, we wanted the duals in Medicare, but we would have handled the transition differently.

I will not even try to respond to that. There is no response. It is very easy to sit up and say, well, I would have done a better job.

If those 47 Senators who thought they knew best, if they want to know who they are, I will be glad to tell them who they are. I am not one of them.

We are not here to assign blame or point fingers, but I do think it is important that the record reflect the events that led to this point. The history is part of that record. But it is time to move on. Now is not the time to make excuses. We need to have productive conversations and decisive actions to correct recent shortcomings.

I am very satisfied that Senator Baucus and I have led off with this in the meeting that members of the Finance Committee had with Secretary Leavitt and Dr. McClellan 2 or 3 weeks ago, and our staffs have been cooperating very much in that intervening time, between Senator Baucus's staff and mine, and trying to listen to the staff members of everybody on this committee, and then in turn working with the people at CMS.

Dr. McClellan's testimony will follow up on some of the questions raised by members during that meeting. In fact, we gave him notice at that meeting that we would have this hearing. We did not say exactly when, but here we are, and we asked him to be ready to respond to some of those questions.

The administration has ramped up call center capacity, created a dedicated phone line for pharmacists, and they required plans to extend their transition fill policies to 90 days. They also created a process for States to be reimbursed for costs incurred during the transition.

I might add that all of these actions were taken administratively, no legislation was needed. We have specifically asked the administration when legislation is needed, because we need to act on that very quickly if any is ever needed.

As I said, this is good progress, but we cannot, as a committee of oversight with responsibility in this area, let up on this until it is crystal clear that the executive branch of government has gotten the start-up issues under control.

This committee has tremendous responsibility, both to the beneficiaries and to the taxpayers, and I think we demonstrate that we take those responsibilities with utmost seriousness.

I will do whatever else we need to do to make sure that the problems are resolved. We need to become better-informed about the true nature of the problems. That has been happening, as I indicated, at several levels here, but most frequently between Senator Baucus's staff and my staff.

Today's hearing, I hope, will help us continue to carry on where we started 3 or 4 weeks ago. We have people besides Dr. McClellan testifying who are on the front lines of implementing the benefit and helping beneficiaries to enroll.

In addition to Dr. McClellan, we have representatives of two prescription drug plans, William Fleming and Susan Rawlings, representing Humana and Wellpoint, respectively. We have Mr. Bernauer and Mr. Schule, who represent chain and independent pharmacists.

Then we have Ms. Paeth and Mrs. Willoughby, people that have been helping beneficiaries learn about the drug benefits and helping with enrollment. So, I think we are going to have a very productive meeting.

I would like to now go to Senator Baucus, and then we will go immediately to Dr. McClellan.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA

Senator BAUCUS. Thank you, Mr. Chairman. I appreciate you holding this hearing. It is, undoubtedly, very important, certainly to a lot of seniors in our country, pharmacists and States, and many others trying to make this drug benefit work.

Just a reminder, the Finance Committee played a very key role in enacting this provision. Therefore, I think we have to be very diligent to make sure that we oversee it and that the program is well-run.

In 2003, after years of debate, as just a reminder, we passed this bill. I was very proud to be part of that. I felt we needed to have provisions in the law to provide a drug benefit for seniors. Nothing is perfect. It is extremely complicated and expensive, but I thought it was the right thing to do, and I am very proud to have worked to help make that happen.

We know the law was not perfect, it was new, but I thought the law had the potential to do some real good to an awful lot of people, and that is why I supported it. It has the potential to make prescription drugs available to millions who could not otherwise afford them. It has the potential to make drugs available that will lessen pain. It has the potential to save lives.

Unfortunately, the administration, in my judgment, has implemented the new law poorly. After Congress passed the law, the Centers for Medicare and Medicaid Services, otherwise known as CMS, had the duty to ensure that Medicare drug benefits were up and running by January 1, 2006.

Clearly, it was a huge task, very difficult. I think CMS worked at it, worked hard. Regrettably, their efforts came up short, I think, in two major areas. First, the government made the new drug benefit needlessly confusing.

As part of the new law, Congress passed a temporary drug discount card, available in 2004, which was supposed to give temporary relief from high drug costs. Seniors of modest means were eligible for a $1,200 Federal subsidy for their drug purchases.

But most Medicare beneficiaries did not sign up for the drug card. Why? Because they were paralyzed, paralyzed by choices. CMS approved 40 Medicare drug cards in my State of Montana alone. Far from celebrating the array of choices, most Montana seniors found it so confusing, they gave up. They did not sign up.

Less than a year later, CMS was approving drug plans for the new drug benefit. I then urged CMS not to repeat the mistakes they made with the drug card. I urged CMS to approve only plans meeting the highest standards.

But CMS repeated the mistakes of the drug card. CMS approved dozens of plans for participation in the new drug program. CMS approved more than 40 drug plans in my State of Montana.

I support choice. I support competition and a free market. We all do. It is great that Americans can choose, for example, from hundreds of different models when buying a new car. But when people

do not know what they are buying, choice can lead to confusion, and that is particularly true in health care.

Ask elderly Americans whether they prefer a four-speed automatic or a five-speed manual, and they will probably choose the automatic. But ask them whether they prefer a drug plan with a four-tiered formulary to a plan with five, they will probably look at you with a mixture of confusion and anger.

My second concern relates to the warnings that CMS ignored. Last year, I asked the independent Government Accountability Office to report on CMS's plans for seniors eligible for both Medicaid and Medicare. I asked, what were CMS's plans for seniors whose drug coverage was moving from Medicaid to Medicare?

In December of 2005, the GAO reported that CMS's plans were insufficient to avoid big disruptions in coverage. CMS disagreed. CMS said, "We have worked diligently on the transition from Medicaid to Medicare drug coverage and these individuals will get effective, comprehensive prescription drug coverage on January 1, 2006."

Well, that did not happen. GAO was right. Data systems failed. Pharmacists and States were stuck with the bill for co-payments that should never have been charged. Some vulnerable seniors left the pharmacy without the medicines they needed.

We are going to hear later today about some of these issues, including from Tobey Schule, an independent pharmacist from Kalispell, MT. Mr. Schule is one of thousands of pharmacists who have been burdened with the flawed transition from Medicaid to Medicare.

Last month, Secretary Leavitt and Dr. McClellan briefed members of this committee on problems implementing the new drug program. They outlined seven specific problems, and they outlined plans to fix them.

I very much appreciate CMS's attempts to fix the problems, but some problems remain unsolved. Dr. McClellan, I look forward to hearing from you on how and when CMS plans to finally fix them.

In addition to ensuring that the implementation flaws are fixed, Congress should also address the problem of confusion. We can do that by learning the lessons of Medigap, that is, the supplemental health insurance program for seniors with Medicare covering Part A and Part B.

In 1980, Congress enacted Medigap amendments that they offered to fix marketing abuses and consumer confusion with Medigap. The reforms required Medigap insurers to meet minimum standards and have minimum loss ratios. I will never forget, that was a huge battle. A huge battle, but very much needed.

Ten years later, Congress again took up Medigap reform, passing legislation to standardize Medigap policies. Ten different Medigap options would be offered, each with a basic set of benefits. This gave consumers an apples-to-apples comparison of Medigap coverage.

I think we should do the same with the new drug program. We should standardize the drug plans. We should make it easier for people to make good choices about which plan is best for them. I intend to introduce legislation to do just that.

I understand that the drug benefit is young, but I want this benefit to work. We simply cannot afford another round of confusion. We need broad participation, and that is not going to happen unless we make the program more accessible and more understandable.

I supported enactment of the Medicare drug benefit in 2003. I still support it. Health insurance needs to cover prescription drugs, but we need to work to make it work.

I look forward to hearing from our witnesses on how they can make that happen.

The CHAIRMAN. Thank you very much, Senator Baucus.

Before Dr. McClellan starts out, because we do have six people on the second panel, we want to make sure that all the questions get asked that members want to ask of Dr. McClellan.

But I would ask that members follow the red light. This is the way I would like to have it, because sometimes you never know exactly when the red light goes on. But if you start your last question before the red light goes on, finish your question, and then the witnesses can answer your question.

Senator BAUCUS. Briefly.

The CHAIRMAN. Yes. Briefly. Then we move on.

Now, I think Senator Baucus and I have watched our red light very closely. At least, I compliment Senator Baucus for doing that. So I ask you to do that.

This is my frustration. When he goes, all of you guys are going to go. Senator Baucus and I have to listen to the last panel and you guys go eat lunch on time and we never get lunch. So this is kind of a "share the burden" sort of thing. We all get paid the same salary, so we ought to do the same work.

Dr. McClellan?

STATEMENT OF MARK McCLELLAN, M.D., PhD, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Dr. MCCLELLAN. Thank you, Mr. Chairman, Senator Baucus, members of the committee. I appreciate the opportunity for this status report, and especially to talk about the steps we are taking to fix transition problems, following up on our earlier meeting. That is why I really appreciate the extra time to explain those steps in sufficient detail.

As the vast majority of the millions of beneficiaries who have enrolled are using their new drug coverage successfully, plans are now filling more than a million prescriptions a day. Because of competition, this coverage is costing much less for beneficiaries, taxpayers, and the States than people expected.

Back in 2003, Mr. Chairman, you will remember there was a lot of discussion about whether there would be any plans available at all. Now they are here, they are lower in cost, and offering better coverage options.

We believe that we can make competition work even better by simplifying the presentation of comparable information on plans, which will assist beneficiaries in choosing a plan and further harness market forces to improve beneficiary satisfaction and hold down costs.

A change this big, in this short a period of time, is bound to have some problems. I am very concerned about anyone who has experienced problems in getting their medicines. We make no excuses for the problems. They are important, they are ours to solve, and we are finding and fixing them.

So I would like to describe the specific steps we are taking to address implementation issues, as we outlined in HHS's first-month report on the drug benefit last week. We have worked to address these problems.

We have heard from many pharmacists and others that there are still plenty of bumps, but things are getting better. New enrollees and people who have switched plans for February have had significantly less difficulty starting to use their coverage this month.

Certain beneficiaries who enrolled or switched plans late in a month, particularly dual-eligible beneficiaries, have experienced real problems when attempting to fill prescriptions, especially early the next month.

The information system did not have sufficient time to reflect this change, and hundreds of thousands of beneficiaries switched plans in the last half of December, contributing to our early January problems.

Our goal is to encourage beneficiaries to make decisions earlier in the month so that only 20 to 25 percent of those switching would do so in the last week.

To meet this goal, we have been sharing an educational message. We encourage beneficiaries to enroll or switch by the 15th of the month, and try to enroll several weeks before they need to start using their coverage.

We have updated our on-line enrollment center messages and modified scripts in our call centers. We are communicating this information to pharmacists, States, and advocacy organizations.

We will continue these educational activities this month, and they may already be having an effect. In the last week of January, only about 24,000 beneficiaries switched plans, reducing the problems of incomplete information at the beginning of February.

Although smooth and timely data transfers among Medicare, our drug plans, Medicare Advantage plans, and retiree plans in 57 States and territories have occurred for most beneficiaries, we have been working intensively to smooth these data hand-offs.

When information is not exchanged smoothly, the lag time increases between when a beneficiary enrolls and when full information, particularly on dual status and co-pay status, becomes current for both the plan and the CMS systems.

To address this, we are working on systems enhancements and smoother transfers with our partners. In mid-January, we contracted with Electronic Data Systems, EDS, to help CMS work together with the plans, the States, and pharmacies to resolve challenging data translation issues.

We expect them to complete a preliminary systems review with key initial recommendations by the end of February and further review with additional recommendations by the end of March.

We expect to work with plans, States, and our other partners on a continuing basis to implement their recommendations, achieving

the goals that I am going to talk about in a second by mid-April, and we may retain EDS's services through the year.

Many plans send CMS daily files reflecting their enrollment transactions. CMS compares these data to our own files to confirm Medicare status. Our goal is that plans covering 90 percent of our enrollee population complete daily data transfers successfully to reduce lags in obtaining up-to-date beneficiary information. Currently, 7 out of the 10 largest drug plans use daily transfers.

To check and further assure the accuracy of the information exchange between plans and CMS, we sent a special updated set of data files, including full co-pay information, on dual and low-income subsidy eligibility to plans on January 13th, 18th, and 30th, and we will do so again as part of a full enrollment file later this week.

Our goal is to achieve, by 10 days before a new coverage month begins, at least a 95-percent match rate for enrollment and co-pay information on the dual-eligible beneficiaries who have been the biggest challenge between Medicare and the plans.

As a result, additional adjustments and batch data processing by plans near the end of the month can be limited, while addressing the needs of late-enrolling beneficiaries. We have already seen the match rate for plan enrollment and co-pay information increase from mid-January, exceeding 90 to 95 percent before the end of the month.

CMS continues to work on matching data files with the States, and our goal is to continue accurate transfers to ensure that appropriate information for dual-eligible beneficiaries is available.

We obtained a match rate of greater than 99 percent for duals submitted by the States in the fall of 2005, and we expect to maintain this high match rate.

To provide responsive customer service to beneficiaries through the CMS call centers prior to January 1, we increased our customer service representatives up to around 7,800. Since then, we have updated the scripts used by our CSRs, including information on questions that need to be asked to properly assist callers.

Although wait times spiked in early January, in the last 2 weeks they have fallen to under 2 minutes. We are continuing to track that. Our goal is to keep the average wait time well under 5 minutes.

We have instructed the drug plans to provide sufficient CSRs and to support quality service by phone. CMS has been monitoring the status of the plans' customer service lines to ensure that wait times are reasonable and response is appropriate.

Plans must provide numbers for both pharmacy technical contacts and for exceptions and appeals requests. Plan performance has improved. For example, in the beginning of January, wait times for beneficiaries contacting call centers for nine major plans averaged close to 12 minutes, dropping to just over 6 minutes by the end of the month. For pharmacists, the average wait time has fallen to 3.5 minutes in these plans.

While many plans are now providing timely phone access, some have not responded adequately, so we are increasing monitoring of plans' call center activities to help assure a high level of performance. We are surveying all prescription drug plans to assess wheth-

er they provide correct information to beneficiaries and pharmacists within a reasonable time.

We expect continuing improvements as we address systems and data transfer issues. We expect plans to generally answer calls within 5 minutes by early April, and our goal is to ensure that 80 percent of customer calls are answered within 30 seconds.

To help pharmacists identify what plan a beneficiary is in and how to bill, CMS collaborated with pharmacists, starting in 2004, to create an electronic eligibility and enrollment query system that operates as part of the pharmacist's existing computer systems.

Response times since January 2nd have consistently been less than 1 second. In addition, the number of queries to this system is decreasing because more individuals have their plan cards with their plan information.

For example, on January 4th, the system received nearly 1.5 million inquiries. On January 31st, it had dropped to around 300,000, and it has since declined further. CMS has increased its call handling capacity at the pharmacist help line 30-fold, and made it available 24 hours a day, reducing wait times for pharmacists to under a minute.

We also worked with Wellpoint to establish a point-of-sale mechanism, whereby pharmacists could obtain payment for medications dispensed to beneficiaries who demonstrate coverage under Medicare and Medicaid, but for whom plan information could not be obtained.

CMS is providing technical assistance and using the point-of-sale system through our pharmacy help line, and we have also worked with pharmacy software vendors to provide software-specific support for point-of-sale and eligibility checks.

We are working with health plans and pharmacies to identify business processes and procedures, such as coverage determinations, exceptions, and beneficiary reimbursement, where there is an opportunity to create uniform approaches to reduce confusion and red tape for pharmacists, physicians, and patients. We expect this effort to proceed quickly over the coming weeks, and we will fully support it.

CMS continues to engage in rigorous outreach to the pharmacy community through national, State, and local pharmacy organizations and their newsletter and e-mail lists, as well as their standards organization and technical societies.

Outreach efforts have also included hundreds of town hall and State Pharmacy Association meetings around the country, including dozens of such events in Montana and Iowa.

We have held numerous national conference calls, distributed over 25 Rx Updates to the pharmacy community on a wide range of benefit topics, and posted extensive information on a portion of our website dedicated to pharmacists.

Specifically promoting the new pharmacy tools, we produced a CD-rom that was distributed by all national associations, and held special training sessions around the country conducted by pharmacists from our 10 regions. We are going to continue these outreach activities fully in the coming weeks.

CMS also worked closely with the States, beginning in 2004, on auto-enrollment in the low-income subsidy eligibility application,

calculation of the State phase-down contributions, training those who assist beneficiaries, and exchanging information on State beneficiaries with Medicare and Medicaid.

We appreciate that States have supported pharmacists who have faced difficulties in serving certain dual-eligible beneficiaries, and we have established a demonstration project to reimburse States for costs they incur by covering drugs that should be covered by the appropriate drug plan.

We will also reimburse States for appropriate administrative costs for providing these services, and for connecting beneficiaries who are having difficulty to their Medicare drug plan. We expect the vast majority of States to participate in this program.

Upon receipt of claims data from a State, we plan to provide estimated payment within 4 weeks. By February 15th, we expect to have a contractor in place to process and reconcile those payments with plan and State records, as well as guidelines on the submission of drug claims and administrative costs.

We are asking States to implement steps to help assure that pharmacists have checked enrollment status through a card, plan letter, or eligibility query, attempted to contact the plan or the Medicare line in case of incorrect co-pays or coverage information, and, in the presence of evidence of Medicaid eligibility, billed through the Wellpoint system.

States that work with us to implement best practices like these to support pharmacists in using the new Medicare systems have already limited billing to their State systems, often to just a very small fraction of their dual-eligible beneficiaries.

For example, Pennsylvania, a State with a large Medicare population, which has engaged in vigorous pharmacy outreach and collaborative work with our regional office, has paid only 5,500 total prescription drug claims through February 5th in their State billing systems.

We expect that most States will implement these steps to minimize State billing by February 15, and, if some billing continues to be necessary in a State, we will extend the demonstration program to early March.

To ensure adequate plan performance, we are monitoring trends and tracking complaints. This has already led to changes in how we operate, and I would like to illustrate this by talking about drug coverage requirements.

We set up specific checks to ensure plans provide robust formulary coverage for all needed medications. In particular, plans must cover all, or substantially all, anti-depressants, anti-psychotics, anti-convulsants, cancer drugs, immuno-suppressants, and anti-retrovirals for HIV-AIDS. Patients with mental illnesses can continue essentially all of their current medications through the year.

We review each deletion from a plan's formulary to ensure continued access to a broad range of drugs. Plans cannot remove a drug from their formulary without first going through an extensive process with CMS and providing extensive advance notice to their enrollees.

CMS developed specific procedures for timely exceptions and appeals. Using these proceedings, a Medicare beneficiary can get cov-

erage for a drug not on a plan's established formulary. We are collecting information on the use of a plan's appeals and grievance process.

We required plans to have a transition policy for dual-eligible individuals to get a temporary supply of their current drugs while they determine whether similar on-formulary medicines will work for them. We have recently extended this transition period to 90 days.

When we hear of specific complaints regarding the transition policy, we have worked with plans to ensure their timely resolution. We are enforcing compliance with plan contracts, including call center responsiveness, formulary requirements, appeals processes, and pharmacy contracting.

We are addressing issues on a case-by-case basis. It is too soon to see patterns, but while we are responding to complaints we are also closely monitoring trends. This tracking information can lead to corrective action or sanctions, if needed, which we will take, and they will be considered in our contracting decisions for future years.

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

[The prepared statement of Dr. McClellan appears in the appendix.]

The CHAIRMAN. Thank you, Dr. McClellan.

The first question is, I think I heard you clearly, so it is somewhat repetitive of your statement, but one of the key things that came out of our first closed-door session 3 weeks ago was a request by our committee members that you give us a time-line for when and how these problems will be fixed.

Would you again lay out the key milestones and the goals on that time line? Because I want to make sure that we have a clear response to the committee's request of 3 weeks ago.

Dr. MCCLELLAN. That is exactly what we tried to respond to with the steps that I outlined in my expanded opening statement.

The key areas include reducing the cases where late enrollment and switching occurs, because, when people enroll or switch plans at the end of the month, there is a time lag that is unavoidable between when they enroll in a plan and when all their information is available in the plan systems and the pharmacy systems. So we can avoid some of the problems that happened in early January with a large number of late enrollees and plan switchers by limiting that occurrence.

We have some specific goals set out in terms of reducing the rate at which those late enrollments occur and an extensive education program to back that up.

Second, in the area of data hand-off and systems issues, I outlined a series of steps that we are taking right now, and with the dates included, over the next few months to get to a very high level of matching between the information in the plan systems and in our systems.

I focused on dual eligibles, because those are the most complex data transfers. They involve a lot of additional information from States, on co-pay status with the different co-pay levels. So, if the systems work for the dual eligibles, it will be even more straightforward for the systems to work for beneficiaries who enroll in a plan on their own.

In fact, right now we are seeing a very high rate of successful use of coverage by people who sign up, wait a few weeks until they get their acknowledgement letter or their drug plan card, and then go to the pharmacy and get their prescriptions filled smoothly.

Well over 90 percent of those individuals who sign up on their own are getting their coverage working just fine, and we are going to keep driving that up as well.

So, we laid out the specific timetable for making those steps happen, keeping in mind that, as long as we have late enrollees who are trying to use their coverage early the next month, we are going to have some built-in difficulties in making sure everyone can get covered smoothly the first time they use their coverage.

We talked about improvements, specific improvements in customer service, and a time line for achieving those improvements in the plan. We are already at a high level of response time performance within the CMS 1–800–MEDICARE systems.

We talked about some specific further steps for education and outreach with pharmacists to make sure all community pharmacists are aware of the tools that they have available to use the Medicare systems effectively.

I outlined a specific set of steps and time-frames for States to work with us for prompt reimbursement of their costs and for making sure that they are transitioning the remaining minority of dual-eligible beneficiaries.

In many States, it is just a few hundred or a very low rate of beneficiaries who are still using the State systems. When States use these best practices, we can get just about everyone into Medicare coverage right away.

I talked about our compliance steps, particularly in areas like formulary requirements and transition requirements, and exceptions and appeals, and how we are going to be tracking those. So, these were intended to cover the specific topics that we raised at the discussion with you all 2 weeks ago.

The CHAIRMAN. All right. Then I would ask, not a follow-up question, but this for you to do in writing. If you would provide the outline of that time-line to us in writing, and also how you are going to keep us, as a committee, informed weekly on the progress.

Dr. MCCLELLAN. We absolutely would be glad to do that. These points are covered in the oral testimony that I just presented, which I think we have provided to you in writing.

I want to thank your staff and Senator Baucus's staff for meeting with us to make sure that we are responsive to the issues that you have raised, and for being willing to continue to work closely with us on tracking the progress of the benefit implementation.

The CHAIRMAN. All right.

In regard to the Agency's 90-day first-fill policy, there is some confusion about the Agency authority to require plans to do that and to enforce the requirement. Is there any question about the

ability to do that legally, the enforcement of the policy, and what action it will take if it is determined that the plans are not complying with it?

Dr. MCCLELLAN. We have the authority to assure effective transition coverage for beneficiaries. For reasons that we have detailed in promulgating this policy, we have laid out why this is necessary for effective coverage.

I am very pleased that many drug plans had already implemented longer transition periods before we took this action, so many plans were already in compliance with it. We are going to be monitoring any specific complaints that come up to make sure that people do get the required medications under this policy.

Many plans are going ahead and starting to educate beneficiaries about how they can save money by switching to another drug that works very similarly. That is fine right now, as long as it is done on a voluntary basis.

And this extended time period, as we have heard from many pharmacists, can be very helpful in educating beneficiaries about how they can save even more money while meeting their prescription drug needs by using a low-cost on-formulary drug.

The CHAIRMAN. All right. In this order, the next four would be: Baucus, Hatch, Conrad, and Santorum.

Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman.

Dr. McClellan, could you give me the dates by which you plan to reach those goals in each of the six areas you just mentioned?

Dr. MCCLELLAN. We did.

Senator BAUCUS. Would you do that right now, please? Just give me a date. Number one?

Dr. MCCLELLAN. For the late enrollment, pushing duals.

Senator BAUCUS. Yes. When are we going to get that problem solved? Give me a date. I have lots of questions to ask, so just give me a date.

Dr. MCCLELLAN. By the end of February we are going to have——

Senator BAUCUS. By the end of February. All right.

The next one. Systems hand-off. When are you getting that solved?

Dr. MCCLELLAN. Two steps we laid out.

Senator BAUCUS. Give me a date.

Dr. MCCLELLAN. There is an end of February goal——

Senator BAUCUS. I want a date. Just give me a date.

Dr. MCCLELLAN. [Continuing.] And then there is a mid-April set of goals.

Senator BAUCUS. So you are saying by mid-April, they will be all solved, mostly? Mostly solved?

Dr. MCCLELLAN. Except for the late enrollees. Senator, I do not want to be difficult here, but when——

Senator BAUCUS. We will work with you. I just want to know what your goals are. We will work with you. I just want to know what they are.

Dr. MCCLELLAN. All right.

Senator BAUCUS. All right.

Customer service delays.

Dr. MCCLELLAN. We have some goals that we are putting in place right now.

Senator BAUCUS. Which are, and what date? When are we going to solve the problem?

Dr. MCCLELLAN. Right now, for Medicare.

Senator BAUCUS. When are we not going to hear of problems?

Dr. MCCLELLAN. By April and May.

Senator BAUCUS. April. All right. April.

Education and outreach to pharmacists?

Dr. MCCLELLAN. Ongoing. We have a set of education——

Senator BAUCUS. Date? Date?

Dr. MCCLELLAN. February.

Senator BAUCUS. February. You'll get that solved in February.

Dr. MCCLELLAN. And then ongoing in February and March to make sure that every pharmacist gets what they need.

Senator BAUCUS. And States reimbursed?

Dr. MCCLELLAN. We are intending to get States into this demonstration program right away so that they can ramp down the use of State systems.

Senator BAUCUS. Date?

Dr. MCCLELLAN. Mid-February.

Senator BAUCUS. Mid-February.

Dr. MCCLELLAN. If we need to extend the demonstrations to early March, we will do that.

Senator BAUCUS. All right.

Then you had compliance, the formularies.

Dr. MCCLELLAN. We are tracking complaints right now. We should have patterns available in time for us to use in our determinations for plan participation next year, and that will be by April.

Senator BAUCUS. All right.

I am not being critical, I am just asking the question. So you think by March/April you will have all this pretty much well in hand?

Dr. MCCLELLAN. Well, we are making a lot of progress right now. We have seen that in the much smoother early February period compared to January.

Senator BAUCUS. I will think about those dates. But in the meantime, I appreciate you giving us dates.

Dr. MCCLELLAN. Yes.

Senator BAUCUS. Obviously you are going to try to work to improve upon those dates, to move them up earlier.

Dr. MCCLELLAN. Yes. I do want to highlight the problem with late enrollments. When people enroll late in the month and try to use their coverage early the next month, there is no technical way to make sure that the data fully catch up in just a matter of a few days.

Senator BAUCUS. Yes.

Dr. MCCLELLAN. So we are trying to limit that problem by limiting the number of enrollees——

Senator BAUCUS. Late enrollees complicate this. I very much appreciate that. You are right.

Let me read you a quote here. The quote is, "Imposing some standardization on any additional benefits that are offered, analo-

gous to standardization in the individual Medigap market, would make it easier for beneficiaries to shop for plans."

That was a quote with respect to how to design a Medicare drug benefit and was made by a very, very wise, intelligent, smart person. Can you guess who that might be?

Dr. MCCLELLAN. Go ahead.

Senator BAUCUS. No. Can you guess who that might be?

Dr. MCCLELLAN. No, not offhand. I have seen a lot of quotes lately.

Senator BAUCUS. Well, it was by you. [Laughter.]

Dr. MCCLELLAN. All right.

Senator BAUCUS. It was by you, a very wise, intelligent, smart person.

Dr. MCCLELLAN. You threw me off by that introduction. [Laughter.]

Senator BAUCUS. It was the year 2000. That is when you made that statement.

So if you made that statement in the year 2000, why is that not a good, wise, smart, intelligent idea today?

Dr. MCCLELLAN. I think it is a good idea. We have heard a lot of further ideas from many people. Senator Wyden has been doing some work on this area.

Senator BAUCUS. But basically standardizing the plans, just like Medigap.

Dr. MCCLELLAN. Giving people apples-to-apples information that they can understand and use to get the plan that they want. We have seen that most people did not want the standard coverage that was included in the law. I know that there was a lot of discussion that went into designing that plan with a deductible, a donut hole, and 75 percent coverage.

But what we have seen is that the vast majority of the millions of people who have enrolled have enrolled in plans that are different than that, that do not have a deductible or that do not have as much of a donut hole.

So we are seeing that there are other, better designs that people want, and we need to give them better information to find those plans quickly.

Senator BAUCUS. I am not going to argue with you, but obviously there is a trade-off. There is a trade-off between choice and competition on the one hand, and ease of use and understanding on the other. There is no science in this. You just have to make a judgment here as to which makes the most sense in that spectrum.

We all know it is not a perfect analogy, but back in the Medigap days it was just chaos for seniors trying to decide what Medigap coverage to purchase.

We standardized it. We improved upon it in 1980, then standardized later. It seems to have worked pretty well. We all hear constantly from seniors, there are way, way too many choices, way, way too many plans. I have a chart here that reflects that. I mean, I cannot understand it, it is so complex.

So does it not make sense to figure out some wise, smart way to kind of standardize this to try to draw the line somewhere between the extremes? One extreme now is just total complexity. It is a

wild, wild west free-for-all, essentially. The other would be just one standard plan.

Does it not make more sense to maybe have some group figure out, say, 10 plans, and standardize them along the lines I mentioned, along the lines that you suggested in that *Health Affairs* article in the year 2000? Does that not make sense to try to get some order out of all this chaos?

Dr. MCCLELLAN. I think, in a way, as Chairman Grassley has mentioned, if there are things that we can do administratively, right now, we can help with these issues right away.

Senator BAUCUS. Yes. But let us just not get too wrapped around the axle, ideology, and so forth. Let us just get something solved here that works.

Dr. MCCLELLAN. Well, I definitely want to work together.

Senator BAUCUS. Thank you.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Well, if there is anybody who has not gotten around the axle and who is willing to work with us and do what needs to be done, it is you.

Dr. MCCLELLAN. Thank you.

Senator HATCH. You have been there from the beginning. I remember when we had the tripartisan discussions. You were there every day. You were there every time we needed you as we did this bill. You are there now. We are all amazed at how many companies want to participate. I happen to think that is a pretty good thing.

Now, it makes the selections difficult, but it is a wonderful thing to be able to have a large number of suggested plans. In some cases, they have been better than what we designed in the bill.

Now, I just want to personally express my gratitude to you for how hard you have worked on this program. I mean, this is a monumental change.

I am going to praise Senator Grassley and Senator Baucus, who led the conference committee, along with Chairman Thomas and others. I mean, they really did a very good job. But it is still a tough, hard, complicated, very big program.

I have seen great public servants in my time here, in both parties, in both administrations, but I do not know that I have ever seen anybody who has worked as hard or done as proficient and good a job as you and your staff have done with regard to this very, very difficult-to-implement bill.

And, frankly, I think we did the best we could do, and there are millions of people who are pleased with what we have done. Some are frustrated. Pharmacists are frustrated.

Let me just ask one question to you. Do you have any thoughts on when CMS will not be relying as much on the States to fill in the gaps for the Medicare Part D program?

I know in my home State of Utah, it took staff away from other essential Medicaid duties to implement the prescription drug program, and they were only reimbursed for part of their costs through the Federal participation dollars.

State legislatures did not appropriate matching State funds to have a State Medicaid staff work on implementing the Medicare drug program. Now, people in my State believe that they should have 100-percent reimbursement of their administrative costs by

the Federal Government. Now, any insight you might have on that would be greatly appreciated.

Dr. MCCLELLAN. Yes, Senator. We agree that the States should be 100 percent reimbursed for any costs they have incurred in connecting people with their coverage and helping pharmacists to use the new Medicare systems.

In fact, in the States that have been able to limit the use of their billing systems already, these steps are very important, so we want to fully reimburse those costs.

We think that if all States adopt some of the same kinds of practices that are now being used in States like Pennsylvania, we can quickly get to a very low level of reliance on the State billing systems, then move forward as we take these other steps, and then turn those off entirely in the coming days and weeks.

I would like to also thank you for your earlier comments. The people who really deserve the credit at the Agency are the staff and our information systems offices, and our beneficiary choices offices, and the offices that work with the States and the regional offices all over the country who have been working really hard so that everyone can take advantage of this benefit.

Senator HATCH. Well, back to my original point. I remember when we did this bill, we were concerned that there be at least two companies that would compete in these areas.

Dr. MCCLELLAN. Right.

Senator HATCH. Now, personally, I believe, having this plethora of companies in most States is a very, very good thing, because it puts a lot of pressure on everybody to get the very best plan they possibly can.

I personally would not like to see it narrowed down to 5 or 10 and not allow the open-ended competition that really is giving us some pretty good choices, as far as I am concerned.

Dr. MCCLELLAN. Right.

Senator HATCH. I have other questions, but I will submit them for the record. Thank you.

Dr. MCCLELLAN. Thank you, Senator.

[The questions appear in the appendix.]

The CHAIRMAN. Senator Conrad?

Senator CONRAD. Thank you, Mr. Chairman.

Thank you, Dr. McClellan. Let me just start by saying I respect you, I like you, I like and respect the Secretary. I have just done meetings all across my State, and I wish I could share the anger that I have experienced at those meetings, because people are furious at your Agency.

All this talk that I have heard from some of my colleagues is so disconnected from what I am hearing. I will tell you what I am hearing. And I supported this bill, as you know. I was proud to have supported this bill. But this has been a fiasco. This has been botched and bungled every step of the way. I have never seen a bigger failure of government since Katrina.

Everywhere I go in my State there is an endless stream of complaints. I got calls this morning from people, irate. In fact, I just got a call from a pharmacist in Bartino, ND who said he is ready to quit providing coverage to Medicare patients because this has been so badly handled.

Let me just tell you what I have heard at meeting after meeting. Widespread confusion and growing anger. Too many plans. People cannot get through on the 1-800 number. When they do get through, the information is no good.

I heard you say the response time on the CMS line has dropped. You know why? Because people say calling CMS is worthless. That is what they tell me. Now, maybe you are getting a lot fewer calls because they are not getting any good service when they call.

Cannot access the website. When they could get through, the information was either wrong or not available. The first week, pharmacists across my State were livid. They said there was absolute chaos. They could not get through to plans, could not get through to your Agency.

People did not have plan cards. Those eligible for Medicaid and Medicare that would come to the drug store were told they were not covered. This became such a problem in my State, the Governor had to step in to solve the problems created by the failure to implement this legislation in any kind of competent way.

Pharmacists were livid over what they told me was the complete incompetence of your Department. I have been told repeatedly that there is no way to compare the plans accurately, that some drugs are not covered by any plans, that the plans are not responsive, that nursing home residents are not getting the drugs that they need, that pharmacists are working 15- to 17-hour days, that they are not being paid by the plans, even according to their own contracts with those plans.

These computer systems do not work. Already, formularies are changing. I will tell you, honestly, in my time here, I have never had a worse evaluation of what we have done here than in this program.

Now, you have given us a series of time-lines here. Let me just ask you this. We have 103,000 people eligible in North Dakota. So far, only 8,700 have signed up in stand-alone drug plans.

We have had 10,000 dual eligibles. They were just assigned. Unfortunately, in many cases they were assigned incorrectly, because they went to their pharmacy and they were told their drugs were not covered. That is why the Governor had to step in to rescue what was a fiasco.

Medicare Advantage. That is 750 people. Those, I think we could say, had signed up, so that would get us to 9,400 signed up. Retiree subsidy, 4,600. Those were assigned by their employers. TriCare. They were automatic, 9,700. So that is a total of 34,000. But only 9,470 out of 103,000. What are we going to do to improve this situation?

Dr. MCCLELLAN. Well, Senator, you raised a number of important issues, and I know our regional office has been working with specific pharmacies and with beneficiaries to make sure their concerns get addressed. We have seen, by all the metrics that I talked about in my testimony, a substantial reduction from those early weeks in January and the rate of problems.

We have been working closely with the State of North Dakota, like other States, to make sure they are reimbursed for those costs and that they are helping to transition everyone into their coverage as quickly as possible.

People who have enrolled in the program already are getting real help with their drug costs. And while many people have signed up on their own and more are signing up every day in North Dakota, the people who are getting better coverage through Medicare Advantage, more secure coverage through new help from Medicare for their——

Senator CONRAD. Well, let me just stop you. Medicare Advantage. Medicare Advantage. Before we get very enthusiastic about that, 750 people out of 103,000 possible.

Dr. McClellan, I've just got to tell you, this is botched, and botched on a grand scale. Somehow, together, we have got to get this thing fixed, and fixed fast. It is not fixed. I mean, I got complaints pouring in to my office because they knew this hearing was coming. I mean, I have never seen people so angry. I just have these people tell me, you have got chaos out there.

The CHAIRMAN. Senator, your time has expired.

Senator CONRAD. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Santorum?

Senator SANTORUM. Thank you, Mr. Chairman. Mr. Chairman, I appreciate the opportunity to question.

Can you give me the percentage of people who are in the program who have not had a problem?

Dr. MCCLELLAN. The vast majority of beneficiaries are getting their prescriptions filled every day.

Senator SANTORUM. Can you give me a number? Do you have any idea what percentage of folks are having problems versus folks who are not?

Dr. MCCLELLAN. Yes. For people who signed up on their own and signed up ahead of time so that there was time to wait to get their information into the systems, and they got a letter back or a card back from their drug plan, well over 90 percent of those beneficiaries had no difficulty in getting their prescriptions the first time, and that number continues to go up.

And I say "no difficulty." Some people may have had to make a phone call or something like that, but because the wait times for getting connected with their coverage have gone down by calling a plan or by calling us, that is now much faster.

So, there are millions of Medicare beneficiaries in that category, including, again, well over 90 percent of people who have signed up for coverage on their own, who are getting new, better coverage through a Medicare Advantage plan, and also the vast majority of our dual eligibles.

Senator SANTORUM. You said the biggest problem is folks who sign up late in the month.

Dr. MCCLELLAN. Yes.

Senator SANTORUM. It seems to me like there is a rather common-sense answer to that. That is, why do you not just put a cut-off date at some point in time in the month, and say that, if you sign up after that cut-off date, your coverage does not start until the following month?

Dr. MCCLELLAN. That is a very good question. The way the law was designed was based on an enrollment process that does allow people to sign up until the end of the month.

Senator SANTORUM. Oh. So you are suggesting that Congress made a mistake by allowing people to sign up. So we drafted a bill that allowed people to sign up until the very last day of the month and then made benefits available the following day.

Dr. MCCLELLAN. We are trying to——

Senator SANTORUM. Is that what Congress did?

Dr. MCCLELLAN. We are trying to address this problem administratively.

Senator SANTORUM. I do not want to badger the witness here, but please answer my question. Is that what Congress did?

Dr. MCCLELLAN. That was the basic model in the law.

Senator SANTORUM. So Congress put together a model that said you could sign up the 31st of January and be eligible for your benefit the following day, and expected there not to be any problems. I see.

So some could say that it was a botched job on the part of CMS. Some might suggest that Congress may not have been thinking quite clearly when it put together a statute that is almost administratively impossible to accomplish by setting up a turn-around time, as such.

So what you are telling me is, to fix the problem that I think everyone here agrees is a problem, which is allowing people to sign up until the day before the end of the month and then making that benefit available the following day, is there anything you can do to fix that or is Congress going to have to change that?

Dr. MCCLELLAN. We have definitely taken some steps to address that. I talked about the education work we are doing.

Senator SANTORUM. I understand. But you cannot arbitrarily put a cut-off date.

Dr. MCCLELLAN. We are investigating whether we really do have the statutory authority to make this change, and whether making this change now would carry its own disruptions that we want to try to keep in mind as well.

Senator BAUCUS. Would the Senator yield just for a point of information? Just very briefly, 15 seconds.

The CHAIRMAN. I will give you additional time.

Senator SANTORUM. Thank you.

Senator BAUCUS. Namely, we modeled this after the plan in Medicare Advantage, so there is nothing new here. That is, the date is not new. It is a procedure that was followed previously in the law under the Medicare Advantage drug program, so it is not a new procedure.

Senator SANTORUM. I thought in Medicare Advantage there was a cut-off. Is there not a cut-off in Medicare Advantage?

Dr. MCCLELLAN. There is not a cut-off. But Medicare Advantage is a different situation. It is, as you know, coverage that has not affected so many millions of people at the same time. We have seen gradual and steady enrollment and continue to see gradual increases in enrollment in Medicare Advantage.

In contrast, what we had at the end of December and in early January was, literally, hundreds of thousands of people joining a plan late or switching a plan late, which is not a situation that we had ever had happen in the Medicare Advantage program.

The CHAIRMAN. Senator, proceed.

Senator SANTORUM. Thank you, Mr. Chairman.

Another question just on how the program is doing. You say 24 million people have signed up. How does that fit with what you had projected by this date that would have signed up?

Dr. MCCLELLAN. Well, most people who enroll in a program wait until close to the end of the enrollment period before making a decision. If you look at the way people make choices in the Federal employees' plan or in retiree plans, there generally is a delay when people make a decision.

So the fact that we have had, by early January, close to 4 million people sign up on their own who did not have coverage before, the fact that we have had much greater participation in the retiree programs—a lot of people were worried not only that there would not be any drug plans, but that retiree coverage would get dropped.

Overwhelmingly, we have not seen that happen. Retiree coverage is stronger. The decline that had been taking place for the last 15 years has essentially stopped.

Senator SANTORUM. So let me make that point. One of the big concerns we had here was that there would be an abandonment of drug coverage by private employers to their retirees.

Dr. MCCLELLAN. Right.

Senator SANTORUM. In fact, we have been seeing that over time. One of the provisions that was put in the bill was to actually subsidize those plans to make sure that did not happen. That has worked, is what you are telling me.

Dr. MCCLELLAN. There has been much more take-up of that than expected, so that 11 million-plus retirees are continuing their coverage, with more support from the Medicare program to keep it in place. That saves money for us compared to having them be in the Medicare drug coverage, and it is better for them because it is coverage that people like and want to continue.

Senator SANTORUM. And the final point I would like to make, is to talk about the savings that have occurred vis-à-vis what we thought would be the cost of this program.

Again, there are a lot of complaints about this program, but what we are seeing is the competition between plans and competition in pricing has actually brought down the cost that we projected in this bill. Can you explain how that happened?

Dr. MCCLELLAN. Well, the President's budget, released this week, showed costs of the drug benefit being $130 billion lower than had previously been projected.

A primary reason is the strong competition we have seen among the drug plans. That has led to much lower premiums than expected. Premiums that seniors are going to pay this year are now expected to be around $25 a month.

When the bill was being discussed and before we had actual information on these competitive bid prices, the cost for a beneficiary was expected to be around $37 a month. So, that is much lower.

Not only that, because we have had strong competition, there are plans available that fill in the deductible, that fill in the donut hole, that get people predictable flat co-payment amounts, things that seniors really want, more than what was in that standard plan designed in the legislation.

So we have seen real savings for beneficiaries, real savings for taxpayers, and, I might add, savings for States as well. In talking to the State of Pennsylvania recently, they are going to have millions of dollars of savings.

Senator SANTORUM. Our Governor just told us, $180 million in savings to the Commonwealth of Pennsylvania.

Dr. MCCLELLAN. That is right, because of these lower costs.

Senator SANTORUM. Thanks.

The CHAIRMAN. Senator Bingaman?

Senator BINGAMAN. Thank you very much. Thank you for being here. Thank you for your hard work on trying to make this system work.

This bill was signed by the President in December of 2003, so it has been on the books now for a couple of years. We are into the third year of the law. It is clear to me that there is a big disagreement between the administration and some of us here in Congress, at least, about whether or not some changes in this law should be enacted before this Congress adjourns sometime this year.

I gather the administration's position is that we should not change the law. There was a sense of the Senate resolution that was voted on last Friday that I was not here to vote on—I think Senator Grassley offered it—essentially saying that legislation is not needed at this time.

I believe 42 Senators voted to say that no legislation is needed at this time; 54 voted the other way. So, a majority of the Senate did not want to go on record as saying we did not need to change the law.

Now, why can we not work together with the administration and craft a bill that will fix some of the problems that we are talking about here? This issue that Senator Santorum just raised, he says, Congress made a mistake when we wrote the law and said you could sign up on the 31st of the month and expect to get your drugs the next day. That was a mistake, so we should change it.

But every effort that I have been involved in to try to get a change has resulted in a stone wall: we can do this administratively, we do not want to change. Why can we not work together to make the obvious changes that we all agree ought to be made?

Dr. MCCLELLAN. Well, Senator, I appreciate your interest in making sure we get this right and get it right for everyone as quickly as possible. I hope you will not mistake our focus on the administrative actions that we can take right now to make the program work better, and that we are taking to make improvements every day, and to make further improvements in the month or 2 months ahead.

That does not mean we do not want to keep reporting closely to you all and to make sure that we are addressing all the problems that arise. There is a lot of time left in the legislative session. There is a lot of time left——

Senator BINGAMAN. So you are open to the possibility of changing the law before this session is over?

Dr. MCCLELLAN. Our first focus, right now, is on solving the problems that exist right now. We think we can do those administratively. We will stay in close touch with you about that.

Senator BINGAMAN. Let me cite one of those to you. The low-income subsidy that is in the bill, the report I have gotten is that 60 percent of the people who have applied for that are turned down, and primarily they are turned down because they violate the assets test, which means, for example, a widow who has combined assets of $10,000, including the cash value of a life insurance policy, is turned down because she cannot meet the assets test.

Do you not think that it would make some sense for us to go back and revisit that and either repeal the assets test or modify it so that this low-income benefit is not denied to so many people? In my State, I am told that there are 100,000 people eligible for it. Fewer than 10,000 of them are signed up because they keep getting turned down.

Dr. MCCLELLAN. As you know, because you feel so passionately about this assets test, the assets test in the law is a result of a compromise with a limited amount of taxpayer resources that are available to help make sure they go to provide the best coverage possible for as many people as possible who really need it. We have been focused on making sure that more people who are eligible for this assets test can sign up for it.

Social Security has been doing a tremendous amount of outreach work, and we keep learning from our experiences about best practices for doing this as we go along. We are now 1 month into the benefit.

Social Security has almost 1.4 million people enrolled in the low-income subsidy, which, if you look back on prior programs that have had assets tests or other means tests, is a very good number for the first month of the benefit.

For Medicaid, 40 years later we are still only at 50-percent enrollment. So again, I think our first focus needs to be on making sure that people who do have the least means to pay for their drugs can take advantage of this program.

Senator BINGAMAN. Let me ask about one other issue, which is a little unrelated. There is a provision in the bill, the prescription drug bill, that allows Indian Health Service and Indian providers to get Medicare pricing for their contract health service dollars. That requires some implementation by you folks. It was supposed to be implemented over a year ago. Nothing has been done on it. This means a lot of money to the Indian Health Service. It this something you could get people working on and get that implemented?

Dr. MCCLELLAN. Absolutely. I will follow up with you on that. We have been doing a tremendous amount of outreach and interaction with tribal pharmacies and with other leaders in Indian country to make sure they can take advantage of the important new benefits in Medicare.

[The information appears in the appendix.]

That includes free preventive benefits for diabetes and other conditions that are very common in the Native American population, as well as making sure that their pharmacies and the people in Indian country take full advantage of the drug benefit. But I do want to follow up with you on that.

Senator BINGAMAN. Thank you very much.

The CHAIRMAN. Some members have stepped out, so I am going now to Senator Wyden. Then of the members that are here, Senator Thomas would be next.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Going back to my Grey Panther days, Dr. McClellan, my sense has always been that with seniors, the first impression is just critical. So if we do not get done the kinds of things Senator Baucus is talking about, it will be uphill for a long, long time to come. I urge you to move quickly on that.

Now, for the first time you have opened the door to making it easier for seniors to compare these policies. I think that is constructive, and I want to follow up with you on it. I have been in contact with the National Association of Insurance Commissioners.

It seems to me we could start moving voluntarily, your Agency and theirs, to begin to make this information more understandable to them, then we could move ahead with the kind of excellent legislation Senator Baucus is talking about.

Would you be willing to have your folks call the National Association of Insurance Commissioners, do it right away and begin to work with them on trying to simplify these policies?

Dr. MCCLELLAN. We would definitely like to hear the perspectives quickly from NAIC on this. I would just let you know, Senator, because I know how important this issue is to you, we have also had discussions with the health plans about this.

I think you have been hearing from some health plan executives, too, about ideas that they have, as well as from some of our experts in the field who are counseling beneficiaries, who are using the tools that we have now and who are helping us find ways to make those even more effective for beneficiaries than they are now, because there are, as you say, some gaps and some opportunities that are apples-to-apples comparisons.

Senator WYDEN. Are you at all open to changing the enrollment period before there is a penalty? We have had several votes on this. Here is what I am concerned about. There is so much confusion out there, that a lot of people will not sign up because they cannot do these comparisons. Then, of course, they start racking up the penalties.

If we eliminate the confusion, a lot more people are going to sign up, and we will not even face these enrollment penalty issues. Senator Snowe, I, and others have been very interested in this.

Will you—like you have done on comparisons—say, today, that you all will take another look at this question of the enrollment period? Because I think there is a way we can get this solved, but you all need to be flexible on this.

Dr. MCCLELLAN. Senator, let me say right now we would like to keep talking and reporting to the committee, and all of you, about the status of our ongoing enrollment efforts. Our focus right now really is on the steps that we can take administratively, now, to address and solve problems.

As part of that effort, we are tracking enrollment support. We are still seeing steady enrollment in the program, people using the tools that are available and help that is available to make deci-

sions, people hearing more about plans that their friends and colleagues have used that are getting them assistance now.

So that is really what we are focused on in the short term. I think your suggestions about ways to improve the apples-to-apples comparison are things that we can do right away. So, let us talk.

Senator WYDEN. I think Congress is going to change the enrollment period issue for you, is my own kind of judgment. But we can talk about that again.

One other matter that Senator Snowe and I have been very interested in is, we think a lot of folks are not signing up because the government is not doing enough to hold down the costs.

Senator Snowe and I have now got a majority of the Senate behind our bipartisan proposal to hold down these costs. Of course, we have had a lot of discussions with you about this.

How do you think you can hold down costs, for example, with single-source drugs without something like the Snowe-Wyden legislation? There is no capacity of the government to hold down the costs when you have single-source drugs unless the government is able to bargain. Senator Snowe and I have been trying to get that passed.

Tell me how you would see the government, at this point, with the government's hands tied behind the government's back, hold down the cost of single-source drugs?

Dr. MCCLELLAN. Well, Senator, I think what we have seen is tremendous efforts to negotiate lower prices and get drug costs down by the prescription drug plans. That is why the cost of this benefit is turning out to be vastly lower than people had expected. I, again, have asked our actuaries, our independent actuaries, about whether we are taking the most effective steps to hold costs down, based on all the information that we are seeing now.

That includes a lot of new information showing that these plans have costs coming in much lower than expected, for better benefits than expected, and they continue to tell us that they do not think that their additional steps through further negotiation, on top of all the negotiation that is going on, would further lower costs without compromising quality of care.

Senator WYDEN. Mr. Chairman, my time is up. I would only say that the witness did not respond to my question about single-source drugs. We will have some more discussions about it.

Dr. MCCLELLAN. Let us keep it up. Thank you.

Senator WYDEN. Thank you, Mr. Chairman.

The CHAIRMAN. All right.

Now, since Senator Schumer came back, I am going to go to Senator Schumer. Then it will be Senator Thomas, then Smith, Lincoln, Kyl, then Snowe.

Senator Schumer?

Senator SCHUMER. Thank you, Mr. Chairman.

I would like to address two issues here today that are deeply affecting my State of New York. The EPIC program—that is one of the State SPAPs, Prescription Assistance Programs—and then formulary switching by drug plans.

As you know, Dr. McClellan, there was a lot of concern when the Act was written about seniors who already had drug coverage, and that they would be pushed onto the Medicare program to shift the

cost to the Federal Government. To adjust for this, obviously, employers who continued to provide coverage were given a 28 percent subsidy for their expenses.

But this is not a problem just for companies, it is a problem for certain States as well, States like New York who have generous drug programs for their seniors who are at too high an income for Medicaid but still need help affording prescription drugs.

Governor Pataki recently announced his intention to shift 25 percent of the members of New York's program, called EPIC, onto the Medicare drug benefit. That is 91,000 people of the 367,000 currently enrolled in EPIC. Right now, he is only looking at EPIC enrollees who are eligible for the Federal low-income subsidy.

But I am concerned. We have a very tight State budget. They are cutting back health care costs. EPIC coverage might be phased out for the rest. That would leave them much worse off than they are now, just like we were worried about with the employers.

So, first, I want to ask you, how are things going for the employers with the 28-percent subsidy? Second, I am hoping we can expand this 28-percent subsidy to State prescription plans, because that is not working out.

In the Senate bill we had dealt with that, in the House bill we did not. If it has worked well for private companies, would you work with me to try to extend this subsidy to State non-Medicaid plans?

Dr. MCCLELLAN. Senator, we have exactly the same goal that you and Governor Pataki do, which is making sure that people who count on EPIC can continue to do so, get the same or better benefits than they have had before.

Senator SCHUMER. Great.

Dr. MCCLELLAN. We would like to do it in a way that saves the State the most money possible. The State of New York is expecting hundreds of millions of dollars in savings as a result of the new Medicare drug benefit.

Senator SCHUMER. Right.

Dr. MCCLELLAN. One way for EPIC to work would be to get the employer subsidy directly. The disadvantage of that from a State standpoint is that the employer subsidy is more modest than the comprehensive financial help that Medicare can provide through the drug benefit itself and the low-income subsidy, with EPIC adding onto the drug benefit.

That is exactly what the Governor wants to do, so it provides more savings for the State, it ensures that beneficiaries continue to get the high-quality EPIC coverage that they have counted on, and we will be working very closely with the State to make sure that is done carefully.

Senator SCHUMER. Good. So I urge you to do two things. One, try to make sure that all the EPIC beneficiaries are made whole, they are not worse off after this action. Second, make sure at least that the State is made whole.

Dr. MCCLELLAN. Right. And we expect the State to be able to save a lot of money.

Senator SCHUMER. Good.

Dr. MCCLELLAN. We will work very closely with the State.

Senator SCHUMER. All right. That is helpful. That is good news. I am going to keep pushing you on this because this is really important to New York, and to these 367,000 people. EPIC has been an extremely successful program, as you know. I do not think you would disagree with that.

Dr. MCCLELLAN. No.

Senator SCHUMER. We've just got to keep it at that level. I am just worried, as things work their way through, things might fall through the cracks. So I am glad that you have a positive attitude like this, and expect to be hearing from me regularly on it. All right.

Next, on formularies. I would like to touch on something several of my colleagues mentioned to you and Secretary Leavitt last month. Since drug plans are allowed to change their formularies, seniors may choose a plan because it has a drug they need, then they find out a few months later that the drug plan has dropped that drug. There are a lot of people who need one particular drug; the elasticity is not the same. So then they are stuck with the plan for the rest of the year that does not have the drug that they want, and it is the whole reason they picked that plan.

So I think that does not make any sense. Today, Senator Snowe, Senator Bingaman—I think there are others on the committee—we are introducing a bill—it is called the Medicare Drug Formulary Protection Act—that would prohibit plans from changing their formularies until the next open enrollment period, so then the person could leave.

It would be wonderful if this legislation were not necessary. Do you recognize this is a problem? How will you work with us to resolve it?

Dr. MCCLELLAN. Well, Senator, I want to be very clear that drug plans cannot change their formularies willy-nilly, and we have not seen this happen yet, except in cases where it is important to change the formulary, like if a new generic drug becomes available that can save people in the program a lot of money without compromising safety or without requiring them to change the medication they use, or if there is new information from the FDA that may influence the way——

Senator SCHUMER. So you are not going to let them change their formularies?

Dr. MCCLELLAN. But there is a process for making formulary changes that requires a lot of steps before any change can occur to make sure that beneficiaries are fully protected.

First of all, the change has to be reviewed by the prescription drug plans' P&T Committee. It is an expert committee with independent representation. Second, the proposed change has to be submitted to us, where we make a decision about whether it is——

Senator SCHUMER. And you are going to be tough on those changes?

Dr. MCCLELLAN. We are going to do it in the interest of beneficiaries.

Third, if there is an approval, the beneficiaries need advance notice, an opportunity to continue on their drug. We have seen a few of these requests come in, but we will be very——

Senator SCHUMER. I am glad to hear that you are not just going to allow it randomly. That is a big relief to us, and we would like to work with you on it to make it as narrow as possible.

Dr. MCCLELLAN. Absolutely.

Senator SCHUMER. Or only as necessary as possible.

Dr. MCCLELLAN. We will keep in close contact.

Senator SCHUMER. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Thomas?

Senator THOMAS. Thank you, Mr. Chairman.

Thank you, Doctor, for being here. Let me say that maybe it is because of our smaller State, and so on, but we have had pretty good luck with the program, as a matter of fact.

I met with the pharmacists, I have met with AARP, which has been very involved in it, and by and large it has gone reasonably well. We do have some unique, I think, issues because we do have rural areas, one pharmacy in town, that sort of thing.

With regard to the pre-approval process, each plan has its own process. Some of the pharmacists and physicians are concerned about the medications for the pre-approval process. Have you been concerned about that? Has there been difficulty?

Dr. MCCLELLAN. Well, if there are any specific complaints, we are investigating them and will track them if there is a pattern. We have not seen any widespread problems with a particular plan, but we do want to hear about any concerns that any of your pharmacists or beneficiaries are having so we can follow up on those promptly. We have been doing that through our regional office, working with people in Wyoming and your office already, and I want to thank you for that.

Also, I think there are some opportunities for simplifying how this benefit works for pharmacists. Right now, when they go through a preauthorization process, they may get one code back from one plan, a different code back from a different plan, and that adds to the red tape and the administrative burden in the pharmacy.

Senator THOMAS. Right.

Dr. MCCLELLAN. I am very pleased that there is now a group that involves a number of plan representatives and pharmacy representatives, senior levels working together to simplify those administrative steps.

We are going to push that process along and support it fully to make this exceptions process, or the prior authorization process, work as simply as possible for our pharmacies.

Senator THOMAS. Good. I think that is helpful. There is confusion, of course, because there are lots of formularies out there, and so on. But in a small town, there is one pharmacy and they carry a relatively small number. So do you have any plans to help people understand, in communities of that kind, what might be available so it makes it a little easier?

Dr. MCCLELLAN. When beneficiaries call us, or go to our website, or have someone who works with them go to our website at *medicare.gov,* or when they go to an enrollment event—we have a lot of enrollment and counseling sessions going on around the State of Wyoming—they can get information on plans that serve a particular pharmacy.

So if someone in one of these rural communities, absolutely, wants to have convenient access to their pharmacy, they can ask, is such and such pharmacy in this plan, or I want a plan that gives me the best deal on my medications that includes this particular pharmacy, and we will find them a plan that gets them the pharmacy service they need.

Senator THOMAS. One of your other persons to testify, and from a small town, has indicated that there is some question about the preparation of pharmacists to be able to deal with the questions that they have. Have you focused on that at all, assisting pharmacists?

Dr. MCCLELLAN. Senator, that has been a huge priority for us. That is why we have had our regional staff and the pharmacist staff of our Agency do events around the country, all over the country, literally, over the past year. For example, we have had an event in Kalispell, MT for training and information about the drug benefit.

Senator THOMAS. The bottom line, finally, I know pharmacists are limited as to what they can do, but they are the people you go to when you want some information.

Dr. MCCLELLAN. They have been tremendous in this process.

Senator THOMAS. Right.

Dr. MCCLELLAN. We are improving the information available to them every day.

Senator THOMAS. You are helping them. Thank you for all you are doing. Thank you.

Dr. MCCLELLAN. Thank you.

The CHAIRMAN. Senator Smith, then Lincoln, then Kyl, then Snowe.

Senator SMITH. Thank you, Mr. Chairman.

Welcome back, Doctor.

Dr. MCCLELLAN. Thank you.

Senator SMITH. Thank you for going another round of this after last week.

Dr. MCCLELLAN. I am glad to.

Senator SMITH. Last year, it was either to you or to Secretary Leavitt I expressed concern that the formularies used not discriminate against mental health medications.

So I was very pleased when CMS indicated to plans that they would be expected to cover all, or substantially all, medications in six therapeutic classes, including anti-depressants, anti-psychotics, and anti-convulsants.

Plans are expected to forego using strict management utilization techniques that might prevent beneficiary access to these medications. I really appreciated your doing that.

But I have heard, nevertheless, that many plans are not abiding by CMS's guidance, and beneficiaries are now having trouble getting these types of prescriptions filled. It is of enormous concern to me, and I wonder if you can discuss what you are doing in response to plans not covering this category of medication.

Dr. MCCLELLAN. Well, Senator, I know how important this is to you. It was your attention to this issue that helped us focus on making sure we had effective coverage rules in place, last year, and I share the same concern. I have seen some of the specific reports.

What we have done is, when we hear a specific complaint about a beneficiary not getting a drug for a mental illness that should be covered, and if they are on an existing therapy, essentially all of the mental illness drugs are covered under the benefit and they can continue that coverage through the year.

So if we hear about specific complaints like that, we will follow up with the specific plan and make sure that it is addressed. We are keeping track of these problems. If a pattern does emerge, we have further enforcement actions that we can take against the plan.

We are working very closely with the APA and many of the advocacy groups on this, but as you hear about specific cases, we want to know about that, too.

Senator SMITH. Well, it was good to include it in the requirements, the formulary guidance in 2006. My question to you is, are you going to require it in 2007?

Dr. MCCLELLAN. We are going to have a public comment process soon on the formulary guidance for 2007, and I will look forward to discussing the best way forward with that guidance with you as it comes out.

Senator SMITH. I would appreciate it. I think you do not have a complete prescription drug plan if you do not cover these categories of medicines. They have had them in the past through other means, but now the government is involved in it, and the government needs to give equal weight to mental health as it does to physical health. So, I would appreciate your attention to that.

After you left the Aging Committee last week, I had a constituent from Tillamook, OR named Robert J. Kenny, who gave testimony you would have liked. It was very favorable to the prescription drug plan.

But he had a few recommendations. He is retired. He spends a lot of time as a volunteer at the State Health Insurance Program, or SHIP, in his community. This is what he said: "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."

He said, "We could nationally provide local TV and radio advertisements giving the telephone number of the closest SHIP office, or its equivalent, which can be called to get real help to those that need it in a timely manner."

He indicated that he enjoyed it, he had great success, and people left by enrolling with him. He was very pleased with the program, but I think what he is asking, and what I am urging, is that perhaps we ought to consider some very inexpensive local advertising that would give out a number of one of these senior centers where they are anxious to be helpful. When they help, people leave happy with you, CMS, and the prescription drug Medicare Part D.

Dr. MCCLELLAN. I think that is a great idea. We hear the best ideas from people who are out there on the ground, people like him who have done this counseling, know the program and are really putting their efforts into helping seniors. So we have heard a lot of good ideas, and I will definitely take this one back.

Senator SMITH. Thank you.

The CHAIRMAN. I visited the Marshalltown, IA hospital and sat in on SHIP volunteers doing that. It is a wonderful resource. I even heard of instances where, on further information, they get a hold of people and get them back and say, we advised you this plan, but we found out this plan is yet better for you, and it just seemed to me a great enthusiasm among the SHIP volunteers.

Dr. MCCLELLAN. These local volunteers have been very helpful. We had an event in Jonesboro, AR at an elementary school, where sixth graders did some of the counseling, advising, and helped some of the seniors on the Internet, too. So there are lots of sources of help.

The CHAIRMAN. I did not know you had time to go outside the city. I would have had you come to Iowa.

Dr. MCCLELLAN. We are getting a lot of local help.

The CHAIRMAN. Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman.

I have kept him pretty busy in Arkansas. He has been to Jonesboro, Ft. Smith, and your regional office in Dallas has been enormously helpful.

We started, back in September and October, getting the word out about our SHIP offices and what they could do in being helpful. I want to echo what Senator Smith and the Chairman have said, that we can do more in terms of allowing those local folks to be helpful. I think we have tried very hard in Arkansas, and we appreciate your supporting that and hope you will continue to do that.

I would also like to echo the other comments from Senator Smith about mental illness. We have definitely had some concerns in Arkansas. Many folks saw the heartbreaking article in the *Washington Post* on Monday.

But I know that in some of our local communities in that instance, the community health center was the one that reimbursed for their extra costs that the private plan for Part D should have covered.

Did CMS do anything special as far as outreach and education for persons with mental illness, and what are they going to do about reimbursing those centers?

Dr. MCCLELLAN. Senator, we have done extensive outreach on mental illness issues. This has been a high priority for many Senators, particularly Senator Smith and you.

Senator LINCOLN. Right.

Dr. MCCLELLAN. As a result, we worked very closely with many organizations and advocacy groups, like the National Association for the Mentally Ill, NAMI, and many others to help people find out about this coverage.

And, as you know, many people with mental illness who have not been able to qualify for Medicaid, or even some people on Medicaid with mental illnesses who need multiple medications, have, until now, not been able to get the drugs that they need.

Senator LINCOLN. Right.

Dr. MCCLELLAN. I have been very pleased, in hearing from NAMI and other groups, about so many people with mental illnesses who are now getting much better coverage.

But we need to make sure to continue those outreach efforts. If you do hear of any specific cases of a beneficiary inappropriately being denied a medication that they were on before, the drug that they need to keep their mental illness in good clinical control, we want to act on those promptly.

Senator LINCOLN. We have seen an awful lot of closure in terms of our mental health centers. I do not know. Will the community health centers be reimbursed for those costs?

Dr. MCCLELLAN. If beneficiaries were to have been paid by the prescription drug plan, we will work with them on reconciling those payments.

Senator LINCOLN. Right.

There was another article in the *Washington Post* on Saturday about the report of FDA's backlog of over 800 generic drug applications. In the administration's budget that has come out, looking for ways to cut Medicare programs, it certainly jumped out at me from the budget in terms of the volume and the amount of cuts that they are looking at.

How are we going to do that? How are we going to provide the most cost-effective way to provide the volume of drugs that are needed by Medicare beneficiaries if the administration continues to allow a backlog of generic drug applications to balloon to 800 or more?

Dr. MCCLELLAN. Well, Senator, I know a bit about this issue from my previous job as well——

Senator LINCOLN. Right.

Dr. MCCLELLAN. [Continuing.] Where we launched a new initiative to do two things. One, was to speed up the approval of generics. We have seen a big increase in the number of applications.

One way to do that is to improve the quality of the applications coming in. In many cases—you would not think this would be true—it takes a second round or a third round for the generic application to be approved.

So, there have been more generic approvals over time, and we are seeing the benefits of that right now, not only in Medicare and Medicaid, but in our whole health care system.

We have the lowest rate of drug spending growth in more than a decade this past year, in good part as a result of greater availability and lower prices from strong competition in generic drugs.

Senator LINCOLN. So you are saying that that 800 backlog should not be alarming because you have approved more?

Dr. MCCLELLAN. Well, I can tell you what we are seeing, which is that when generics can come on the market, they are coming on quickly and they are coming on at a lower cost than before because of strong competition.

Senator LINCOLN. Is that not an incentive for us to eliminate some of that backlog?

Dr. MCCLELLAN. Well, I am sure. I mean, I think that is a better question for you to direct to FDA, but I know it is a very high priority for them to make sure generics are available quickly when a brand-name patent ends.

Senator LINCOLN. We had one other question from our nursing homes. Actually, two questions from our nursing homes at home.

The auto-enrolling of dual eligibles. CMS relied on the data from the Social Security Administration, like the resident's home of record. They used that data to randomly assign beneficiaries to plans.

In some cases, the long-term care residents were assigned to a plan that was outside their region because their home of record was different, a different State from their long-term care facility.

Do you have any plans to address that problem, or how you might?

Dr. MCCLELLAN. Yes, it is a problem. In the initial phases, even if they were outside the State, the plans can provide drug coverage. In most cases, most of the plans have broad national networks, and so, temporarily, even if they were in an out-of-State plan, they could get the drugs that they need.

But we have been working to identify those specific cases. When we find out about it, we will assign that beneficiary or work with that beneficiary to choose a plan that is in their coverage area going forward.

Senator LINCOLN. All right.

And we are still waiting on guidance from you. Our attorney general came out with a ruling yesterday about being able to choose our State law. So do you have any idea when we can expect that guidance from you?

Dr. MCCLELLAN. I am glad you asked about that.

The CHAIRMAN. Give a short answer.

Dr. MCCLELLAN. Yes. We took a look at their answer that came out just last night. I am not the lawyer, but it looks consistent with what we had been saying to community pharmacists in Arkansas, and around the country. We are reviewing that attorney general opinion right now, and we will get back to you with a fuller response.

Senator LINCOLN. Maybe this week?

Dr. MCCLELLAN. Yes.

Senator LINCOLN. All right. Thank you.

[The information appears in the appendix.]

The CHAIRMAN. I visited two nursing homes in my State during January on this very issue, and I never had any of my nursing homes give any complaints about the transition.

Senator Snowe?

Senator SNOWE. Thank you, Mr. Chairman. Thank you for holding this hearing, because I think it is one of the most critical oversight hearings that we could have this year on this significant benefit.

Welcome, Dr. McClellan. I know that you are certainly attempting to address many of the issues that have been associated with the implementation. I think it is not a surprise that it would be fraught with difficulties, but I think that the implementation has been more than just mere growing pains.

I hope that you will adopt the operative word of being flexible in grappling with some of the key questions that have been raised here today, and in the future.

I think it is going to be very important in order to encourage other seniors to enroll in this benefit program. So, I appreciate what is being done to resolve many of these difficulties.

I hope we can get beyond that, because it ultimately could enshrine the concern among seniors about how they view the program, and ultimately they will not sign up in the final analysis. That also could be to the detriment of the benefit.

Senator Wyden and I, as he mentioned, are concerned about negotiations and being able to pass legislation to vest the Secretary with that authority and prerogative. You were mentioning that the savings are accomplished in the current benefit. But, as Senator Wyden indicated, and I think correctly, most of the savings come from the subsidy.

So is it not in the Federal Government's interest to have the ability to negotiate in those circumstances where the plans might request it or their sole source drugs, which GAO has indicated is where we could derive savings?

Is it not in the Federal Government's interests, since this program is costing upwards of $700 billion, to make sure that we have the very best price, if it is necessary, for the Secretary to use that authority?

Dr. MCCLELLAN. Well, it is certainly in the Federal Government's interest, in fact, its responsibility, to get the most effective cost, the lowest possible cost of the drug coverage while providing up-to-date access to the medications that people need, and we should keep talking about this.

But I have not seen any proposals on government negotiation that would save money, and especially that would save money without driving people to narrower formularies or restricting access to medications.

You will remember, when we were having debates about this legislation several years ago, there were some proposals made that would have relied on government negotiation, but the only way they kept their costs in the ballpark was by limiting the number of drugs that could be covered in a class to no more than two. So, nothing like what we——

Senator SNOWE. That was not our proposal, though.

Dr. MCCLELLAN. No, I know it was not your proposal.

Senator SNOWE. Right. No. That was a fixed——

Dr. MCCLELLAN. The goal is the lowest possible cost without preventing access to needed drugs.

Senator SNOWE. It just seems to me that the singular interest of the Federal Government is to save money and to have that leverage. It is not requiring the Secretary to negotiate, it is allowing him to, if necessary, under certain circumstances. That is all.

I cannot understand, when we are spending $700 billion-plus, that we would not be interested in maximizing our ability to get the best price, not just relying on the subsidy.

The subsidy does accomplish that in making it better, but that is the Federal Government's money. So why are we not trying to make sure we are also getting the best prices? That is what I am saying. I do not understand why there is a resistance on this question, I really do not.

Dr. MCCLELLAN. We are seeing much lower costs for the taxpayers as well. The cost of the drug benefit this year is 20 percent lower.

Senator SNOWE. I understand that. But it is all still taxpayers' money. So the idea is to make sure that we are getting the best price incorporated in that, in addition to the taxpayers' subsidy, which is what this is all about. That is what this is all about.

I just do not understand. It is not requiring, it is allowing. It is leverage, like you do in the marketplace. It is the same idea, having the same leverage. The Federal Government should have that ability as well, and certainly, we will continue to try on that score.

In terms of eligibility and participation, it concerns me that only 1 in 10 seniors have enrolled in this program on their own. Are you concerned about that, that only 3.6 million have really self-enrolled, all the others have been automatically enrolled? Is that a concern? Because that means that there is not broad-based participation.

People are concerned—rightfully—because of all the confusion, concerns, complexities, and they have decided not to sign up for the program. Now, does that concern you?

Dr. MCCLELLAN. We are continuing to see hundreds of thousands of people, every week, enrolling on their own. One reason that more people did not have to enroll on their own is because employers did not drop coverage, also because the Medicare Advantage health plans are offering stronger benefits.

So, we are seeing most Medicare beneficiaries now taking advantage of this program, and we are seeing hundreds of thousands more signing up every week. We are very much on track with our enrollment expectations for this program.

I do share your goal of making sure that anybody who has questions can get those questions answered. They know they can call 1–800–MEDICARE or get help at local events that we are having all over the country, including in Maine.

Senator SNOWE. Well, it gets back to the question of flexibility, because on the question of the enrollment period and extending it to the end of the year, I hope you do not wait until the end on that issue, because I think it would encourage more people, if they knew that there was latitude, to think about it and to get help, to think through whether or not they should participate. That would benefit seniors.

Also, for formulary protection, as Senator Schumer indicated, that clearly is important, because that is also another impediment and barrier for our people signing up. I really do think you do not want to wait until the end on the question of enrollment, and that is why so many of us are pushing that question as well.

We ought to extend it so we can get this right, so we get this program off on the right foot. I know that has been difficult, but I think we really have to send the right signal so that we can encourage people to sign up, because they will benefit from the savings. Thank you.

The CHAIRMAN. Thank you, Senator Snowe.

Senator SNOWE. Thank you.

The CHAIRMAN. We will start a second round now of 5 minutes. I hope that we can keep it within 5 minutes.

The Agency has contacted EDS to assess the causes of some of the start-up issues with prescription drugs. So what is EDS doing,

and what have they found to date? What recommendations has EDS made?

Dr. MCCLELLAN. Well, first, they reviewed the overall picture of our systems, how the different pieces that needed to work together for data hand-offs were actually set up, and to make sure that those were fundamentally sound.

I think they may give us some recommendations on simplifying a few steps in the overall processes, but overall they have provided us with an overview that looks like we have the right basic structure in place.

The challenge that we have is in hand-offs between each of the different parties in making these prescription drug benefit information systems flow, making those work as smoothly and quickly as possible.

So a big part of the EDS effort is about bringing together representatives from health plan perspectives, pharmacy perspectives, and State perspectives to make sure we have a shared, consistent understanding of what needs to happen to resolve the remaining data transfer issues, and that we are then all working together to make those transactions go smoothly and quickly.

Every day, we see progress in addressing some of these hand-off issues. For example, we are seeing more plans successfully use daily batch processing. We are seeing more transaction questions being resolved.

I would expect that, as they continue to work with us and hear from all of these different parties—from Medicare, from the States, from the plans, from the pharmacists, as they come together—we will continue to make progress like that. That led to the specific dates and time-frame that we put in the information that we gave to you earlier.

The CHAIRMAN. I have a question on another contract. I do not ask that to assign fault or blame, because I know your staff has been working very hard.

A number of people are interested in knowing about the genesis of the contract with Wellpoint. We have not heard from them yet, but Wellpoint's testimony states that they were approached in November. After signing the contract, it seems there was not much time for Wellpoint to get ready, let alone inform pharmacists.

So could you tell us why the Agency did not take that action sooner of contracting with Wellpoint?

Dr. MCCLELLAN. Well, we took the action based on the availability of a national plan that could serve as a fall-back for providing prescriptions for beneficiaries who did not show up fully in our information systems. That reflected some discussions and work done inside the Agency before we put the contract in place.

Over the course of the summer, that is when we heard about which plans were going to be able to serve beneficiaries. Those contracts were accepted and then finalized in September.

After that, we worked on the best way to provide this sort of fall-back service for filling prescriptions. Having a national plan that could do it, that could serve all areas, was a very important consideration, and then that led to the contract in November.

The CHAIRMAN. All right.

Senator Baucus, I have asked my last question, so I will turn to you, now.

Senator BAUCUS. Thank you, Mr. Chairman.

A couple of points here, Dr. McClellan. I think Senator Snowe touched on it. From the statistics that CMS has given us, in the country, about 55 percent of Medicare beneficiaries have coverage. In my State of Montana, it is only 35 percent.

In the country, the beneficiaries who have signed up in the stand-alone PDPs are about 8 percent nationwide. Eight percent voluntary sign-up. Eight percent. In my State of Montana, it is 7 percent.

Beneficiaries in Medicare Advantage programs who are getting a drug benefit, 12 percent in the U.S., 1 percent in Montana. Then the dual eligibles is 13 and 10. Beneficiaries in employer plans taking retiree drug subsidies, 15 and 8. Federal retirees, it is 7 and 9.

So the point I am making, or just want to confirm, frankly, is the number of beneficiaries who have signed up in the United States voluntarily, not already automatically into some other plan, is about 8 percent nationwide. As I said, in my State of Montana, it is about 7 percent.

So my question is, is that not pretty low in terms of voluntary sign-up? One Senator here said 24 million Americans signed up. Well, that is not accurate. We are talking about the voluntary end of this thing, and Senator Snowe said it was really 3.6 million, which is a pretty low percentage.

Why is it so low?

Dr. MCCLELLAN. Well, one of our goals was to minimize the number of people who would need to sign up by making sure this drug coverage worked well with coverage that people already had.

So we have been very pleased that so many people with retiree coverage are continuing it and taking advantage of the new Medicare subsidies. Also, Medicare Advantage, as you know, Senator, was not much of an option in Montana before this bill was enacted.

Senator BAUCUS. Right. That is correct.

Dr. MCCLELLAN. Now you have Medicare Advantage plans covering the whole State.

Senator BAUCUS. That is correct. Well, not much. As I said, this shows about 1 percent.

Dr. MCCLELLAN. Well, the plans are there, but it takes a little bit of time for people to find out about them and sign up.

Senator BAUCUS. Yes.

Dr. MCCLELLAN. We still have more than 3 months left in the open enrollment period.

Senator BAUCUS. Good.

Dr. MCCLELLAN. We are still seeing very steady enrollment in the plans.

Senator BAUCUS. Right.

Dr. MCCLELLAN. And as we mentioned before, a lot of people tend to wait until later on in a sign-up period to enroll and make a decision.

Senator BAUCUS. Right. I just want to point out that we have a long ways to go; nationwide, 35 percent have no credible drug cov-

erage today for seniors, and in my State of Montana, about 65 percent do not.

I am just concerned about the lower sign-up in more rural States. I have a hunch that CMS generally, in other efforts to educate people, is more vigorous in urban areas where there are a lot more people, and not quite as vigorous in rural areas where there are fewer people and where distances are much greater.

I am just asking you to look at the problem that rural States have and be much more vigorous in rural States as well.

Dr. MCCLELLAN. I will. And we would like to follow up with you and your staff on that. For the people who did not have coverage before in Montana, I believe it is about 21 percent who have signed up for a prescription drug plan. So if you take the people who kept their coverage now, we are well on our way.

Senator BAUCUS. Thank you.

If you would also give us a little more breakdown on who the beneficiaries are. For example, what about Native Americans? We have a sizeable Indian population in Montana.

Dr. MCCLELLAN. Yes.

Senator BAUCUS. We are a little concerned that they are not getting the same treatment, the same access as others.

[The information appears in the appendix.]

Senator BAUCUS. Turning a little bit to education, or lack thereof, of pharmacists, you have stated you vigorously reached out to pharmacists. I must say, some of the independent pharmacists that I have talked to have not heard from you—not from you, personally, but not heard from CMS—at all.

The concern we have is that the treatment of pharmacists by CMS is substandard compared to, say, the treatment that CMS gives to doctors. That is, you educate doctors directly on Medicare benefits and all that is involved in Medicare. You do not go out and directly reach out to the pharmacists. Rather, it seems that you are relying on trade associations to get the information out to pharmacists.

You would not do that with doctors. You would not reach out to the AMA and have the AMA educate doctors. Rather, you do it directly. Fifty percent of doctors do not belong to the AMA.

Is that somewhat true with pharmacy trade associations, too? We have a very strong impression in my State that there has been virtually no CMS education and outreach, at least to independent pharmacists.

[The information appears in the appendix.]

Senator BAUCUS. On our next panel, we are going to hear from a pharmacist from Kalispell, MT. He was told, well, go to the trade association meeting. It is in Billings. That is about a 500-mile drive. That is the only opportunity he has had to try to figure out what is going on here.

So could you kind of help get your efforts at your Agency to deal more directly with pharmacists on a much more solid basis?

Dr. MCCLELLAN. We will do that. I would also like to provide your staff with the outreach that we have already undertaken in Montana. And you are right. We worked with RxM, with the Montana Pharmacy Association, and with other national groups that reach many Montana pharmacists, but that by no means is the

only outreach we are doing. We have 18 pharmacists on staff at CMS, doing primarily outreach activities with pharmacists. That is a lot more than we have doctors.

Senator BAUCUS. Well, get out to Montana a little bit, will you? Do not just stay in this area. Get out to the rural States.

Dr. MCCLELLAN. They have been enjoying the State. We had 60 events, I believe, in Montana last year, including in Kalispell.

Senator BAUCUS. I participated in a couple, myself.

Dr. MCCLELLAN. Right. And we know we need to do more of that, so we will keep it up. We want to reach everyone.

Senator BAUCUS. But just so you know, the impression—not impression, the fact—is that independent pharmacists in Montana have not been contacted. They are at sea. They do not know what to do.

Dr. MCCLELLAN. Well, we will keep up not only the work with the associations, but also the events, also the direct mailings, also the work with their software vendors, and other steps to reach all of them. We will keep talking with you about that.

Senator BAUCUS. All right. I think you understand. Thank you.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

I want to follow up on Senator Baucus' question, Dr. McClellan, because I think, in addition to the education issue, the small, independent pharmacists seem to be saying they do not have any leverage with the plans. They are saying, when it comes to getting paid and getting promptly reimbursed, that they do not have much clout.

Is there anything you can do to give them a hand in that regard?

Dr. MCCLELLAN. Absolutely. If any pharmacist has concerns about the contract terms that they are getting, that they agreed to, not being followed, they can come to us with a complaint.

I know there is also other monitoring and oversight of these contracting issues from other government agencies that are involved in making sure the competition is working the right way, like the FDC and others. We stay in touch with them about the drug benefit.

But we do expect contract terms to be enforced, to be in play so that pharmacists are paid according to the schedule that they agreed to, and that there are not undue delays or improper claims denials. I think there are a lot of other things we can do to help pharmacists, who have been tremendous in this effort.

I talked earlier about some steps for simplifying administrative processes to reduce their workload, and I talked about the progress that we have made in making more comprehensive information available to them on the beneficiary so they can fill the prescription.

Senator WYDEN. A lot of these small independents have really put themselves on the line here.

Dr. MCCLELLAN. Yes.

Senator WYDEN. And I think we need to give them more leverage with the plans.

Now, by your count, Dr. McClellan, how many seniors were wrongly denied drug coverage since January 1?

Dr. MCCLELLAN. Well, we have worked to make sure that any seniors we hear about get the drugs that they need.

Senator WYDEN. But what is the number? How many seniors, by your count, were wrongly denied drug coverage? Blumberg, for example, says that there are complaints that hundreds of thousands of seniors were wrongly denied drug coverage. Your Agency, of course, is the one we look to for the numbers. By your count, how many seniors were wrongly denied coverage?

Dr. MCCLELLAN. I would like to make a distinction between the potential universe of people who could be denied coverage because their data did not catch up with them, these late switchers that we have talked about, and people who were affected by some problems with the data hand-offs. That number looks to us to be in the range of several hundred thousand beneficiaries. That does not mean that all of those beneficiaries did not get their drugs.

In fact, whenever we hear about one of these cases, either through 1–800–MEDICARE or our toll-free pharmacy help line, or the work that our regional offices are doing with your office, with local groups, we make sure that those beneficiaries get their coverage.

Senator WYDEN. Would you get back to me with an Agency report on how many seniors were wrongly denied? I want to know, for example, the kind of context you are talking about.

For example, they may have been subjected to co-payments that, for a lot of low-income seniors, would be a hardship. So, if you would get me that, I would like to know—at this point the program began January 1—how many seniors have been wrongly denied coverage.

[The information appears in the appendix.]

Senator WYDEN. The last point I would make, I think you know I voted for this legislation. I have the welts on my back to show for it. As the former director of Grey Panthers, I took a lot of flack for this. I want to make this work.

I do not think anybody wants CMS to be known as the Center for Medicare Snafus. Nobody wants that. But there is some real work that has to be done, and I would urge you to follow up on Senator Baucus' suggestions.

I think he gave us a good set of goals and a framework for us to proceed. Please contact the National Association of Insurance Commissioners, as you indicated, right away. We have got a lot of work to do, and I appreciate the chance to continue working with you on it.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Lincoln, for 5 minutes.

Senator LINCOLN. Can I take his minute he left?

The CHAIRMAN. If that is all you will take, gladly.

Senator LINCOLN. Thank you, Mr. Chairman. I will try to be brief.

I would like to echo Senator Baucus as well on educating pharmacists. Many of our pharmacists in Arkansas did not even know about Wellpoint or the E–1 queries and the processes that they needed to do their job. And it was not just our rural pharmacists. We had them in the major groups, too, Wal-Mart, who did not even know what the E–1 was.

So our hope is that we can rectify that problem, because, without educating our pharmacists, it is not going to happen.

The State reimbursement. Last week, our office received a copy of the template for the State reimbursement costs from CMS. In addition, I think the CMS representative indicated that the Agency will contract with the reconciliation intermediaries to calculate and process the reimbursement.

Dr. MCCLELLAN. Right.

Senator LINCOLN. And I have been in and out. I hope this has not already been dealt with. But it seems that the implementation of the reimbursement process is still in a lot of early phases. We are one of those States with about 17,000 beneficiaries who have been dealt with by the State, to the tune of about $4 million.

As of Friday, your staff indicated that CMS had yet to have contact with these so-called reconciliation intermediaries. Is that correct? Can you give us an update on the time-line for that reimbursement process? Will you have to extend the February 15th deadline, considering today is the 8th?

Dr. MCCLELLAN. Yes, Senator, I talked about that a little bit earlier.

Senator LINCOLN. All right. I am sorry.

Dr. MCCLELLAN. I will get you some updated information. We have the template out already which describes what States need to do.

[The information appears in the appendix.]

Senator LINCOLN. Right.

Dr. MCCLELLAN. And it makes clear what kind of information we are expecting, so we are already getting some of the claims information in. The contractor is there to process the claim so that the States do not have to worry about interacting with the specific drug plans. We have taken a little bit of time to make sure that gets done right, that it is not going to end up——

Senator LINCOLN. This is what the intermediary is going to do?

Dr. MCCLELLAN. That is right, so that the States——

Senator LINCOLN. And you obviously, hopefully, had contact with them since Friday, which is when we heard you had not.

Dr. MCCLELLAN. To get this contract in place, the State will send in the claims information to us. We expect the intermediary to be in place, doing this process.

Senator LINCOLN. Are they in place now?

Dr. MCCLELLAN. We expect them by February 15th. We expect that States are going to get estimated payments based on the costs they have incurred by a month after they submit the information.

Senator LINCOLN. And you do not think that you are going to have to move that deadline on the 15th?

Dr. MCCLELLAN. In terms of the 15th deadline, we are expecting the vast majority of States to take us up on this reimbursement plan and get in place some steps that can limit the amount of billing to the State system by the 15th. If we need to extend beyond that, we will.

Senator LINCOLN. What about the administrative costs that the States have incurred over the past month and a half?

Dr. MCCLELLAN. Administrative costs for providing the drugs and for getting people connected with their Medicare plans would be fully reimbursed in this program as well.

Senator LINCOLN. Will you extend that?

Dr. MCCLELLAN. Yes.

Senator LINCOLN. If it is incurred after February 15th, will you extend that?

Dr. MCCLELLAN. If necessary. In fact, we have seen some of the best results in States that have been able to identify staff who can work with us and the plans to get people fully enrolled, and we want to fully reimburse those costs.

Senator LINCOLN. What happens if there is a difference of opinion between what the State comes up with as a figure regarding reimbursement and the reconciliation intermediary does? I mean, if there is a discrepancy there, are you going to establish an appeals process? How will they reconcile that?

Dr. MCCLELLAN. Well, we will work directly with the State to make sure that all reasonable costs are reimbursed. We have developed this framework. One reason it took a few days is, we wanted to get input from the States.

We have been working with a set of representatives, the National Association of State Medicaid Directors, to make sure we set this up right. I am sure we will——

Senator LINCOLN. I just have 1 more minute, and I have one more question to get on your mind.

The Inspector General at the Department of Health and Human Services recently issued a report to determine the extent to which Medicare prescription drug formularies included drugs commonly used by dual eligibles under Medicaid.

In the report, they found that only 8 percent of the dual eligibles in Arkansas were randomly assigned to prescription drug plans that covered all of the most common drugs used by dual-eligible populations.

It was the lowest percentage of any State in the country. Compare that with our neighboring regional State Missouri, where 25 percent of their dual eligibles had access as they were randomly assigned to PDPs.

Do you think there is any answer to why that discrepancy happened? How can we be sure that the 61,000 residents of Arkansas who are dual eligibles are going to get the access to the drugs that they need through their PDPs?

Dr. MCCLELLAN. Senator, we did a further analysis. All the OIG did was to look at a list of drugs that were covered. We did a further analysis that looked at the actual Medicaid dual-eligible population, which drugs they actually take, and how well that matched up with the plans that they were assigned to for a whole set of States around the country.

What we found was that 93 percent of the drugs that beneficiaries used were covered by the plans they were on. This is because people tend to be in plans that cover the most common drugs.

The drug plans have very robust formularies, typically covering 80 or more out of the top 100 drugs used by seniors. There are not

a lot of seniors who are on two or three different medicines for their stomach acid or their hay fever.

Senator LINCOLN. Right.

Dr. MCCLELLAN. So we can get you that information.

Senator LINCOLN. Please do. If you will share that with me, that would be most helpful.

[The information appears in the appendix.]

Dr. MCCLELLAN. And then I also want you to know that our transition policies, our coverage, and our other requirements for enabling beneficiaries to continue drugs that they are on now that they need, especially drugs for mental illness, HIV-AIDS, other conditions, those are very broad as well. So, there may be some switches down the road for a hay fever medicine or something like that, and these can actually save beneficiaries and the program money.

Senator LINCOLN. Right.

Dr. MCCLELLAN. We want to implement those.

Senator LINCOLN. Well, I apologize that we are having to go step by step with you on so many of these specific issues.

Dr. MCCLELLAN. It is all right.

Senator LINCOLN. But, quite frankly, we are getting them step by step in our offices. So, I would just encourage you to please keep up the educational process of pharmacists and seniors, States, and the SHIP offices, which we have talked about here.

As you know, we started early in Arkansas trying to get as many of the organizations, the Area Agency on Aging, the SHIP, the local community folks, involved in that educational process.

Thank you, Dr. McClellan.

The CHAIRMAN. Thank you. We are done with you for today. [Laughter.] For today.

Dr. MCCLELLAN. I am sure I will see you again, Senator.

The CHAIRMAN. I think the hearings are very important. Of course, Senator Baucus and I will decide on future hearings. But I think the extent to which you have this communication, as you can, weekly with our staffs and give us updates on how you are coming on meeting the time-lines, I think that we will not have to take as much time in an open hearing. But I will be responsive to members that want to have you back for another hearing. Thank you very much.

Dr. MCCLELLAN. Thank you very much, Mr. Chairman.

The CHAIRMAN. Yes.

Would the next panel come, even as I read your names? Dr. William Fleming, vice president of pharmacy management, Humana; Ms. Susan Rawlings, president, senior services, Wellpoint; Mr. David Bernauer, chairman and CEO of Walgreen; Mr. Tobey Schule, who is a pharmacist from Montana that Senator Baucus will introduce; Ms. Joy Paeth, CEO of the Area Agency on Aging of Southwestern Illinois; and Ms. Pamela Willoughby, faith community nurse, Bedford, VA.

So we are going to hear from people who are dispensing drugs directly to patients, and we are going to hear from people who are going to be speaking about the issues of informing the public about the programs so that they can sign up.

I am going to ask Senator Baucus to speak about Mr. Schule before we start with Mr. Fleming.

Senator BAUCUS. Thank you, Mr. Chairman.

I am really proud to have Tobey Schule here. Tobey Schule is from Kalispell, MT. He got his degree in pharmacy from the University of Montana. He has practiced for about 30 years, maybe even longer than that, throughout the State, including Kalispell, where he is the co-owner of Sykes Pharmacy.

Mr. Chairman, Sykes is a real institution in Kalispell, MT in the Flathead Valley. I go there often. It is a wonderful place to kind of find out what is going on in the valley.

His son Travis is here with him as a pharmacist at Sykes. He has been joined by his family. His daughter Jenice is also here. I just want to tell you that the people he serves, there are a lot of elderly, a lot of mental health patients, a lot of walk-ins, a lot of patients at assisted living facilities, nursing homes, mental health centers.

He is also a member of the Montana Pharmacy Association. It is my great pleasure to have Tobey come all the way from Kalispell, MT to come to Washington, DC.

Now, we talked earlier this morning. He says he is a little nervous, but I think by now he has kind of gotten the swing of things. I said to him, Tobey, just do not worry. Just tell it like it is. Have a good time and just say what you think and feel.

But Tobey, we are very happy to have you here.

Mr. SCHULE. Thank you.

The CHAIRMAN. And we welcome all of you, of course.

It is standard procedure for us to accept from you a very long statement for the record, and then of course we have asked you to summarize in 5 minutes. So, everything that you give us will be printed in the record. We will go through all, then we will ask questions.

Dr. Fleming?

STATEMENT OF WILLIAM FLEMING, PharmD, VICE PRESIDENT, PHARMACY MANAGEMENT, HUMANA, INC., LOUISVILLE, KY

Dr. FLEMING. Thank you.

Mr. Secretary, Senator Baucus, and other members of the committee, thank you for allowing me to testify about the important new outpatient prescription drug benefit. I am William Fleming, a pharmacist and vice president of Pharmacy for Humana, headquartered in Kentucky.

For 20 years, Humana has been serving Medicare beneficiaries through health plans that offer affordable, comprehensive health care coverage. Today, we provide health insurance to nearly 9 million members.

Humana has launched stand-alone Medicare prescription drug plans in 46 States that offer low premiums, a broad formulary, and comprehensive health education programs. Today, over 2 million members belong to our plans, including over 600,000 dual eligibles.

We have three basic plan designs: a standard plan, an enhanced plan, and a complete coverage plan. Humana offers plans with premiums below $20, and as low as $1.87 in seven rural States. Each

of these plans has the same formulary, covering all Part D medications.

Humana has more than 53,000 pharmacies in our network, including thousands of independent and long-term care pharmacies. Since January 1, we have processed nearly 8 million prescriptions.

I have included some success stories in my written testimony. For many enrollees, this new benefit is important to them. I want to share our experiences, including the challenges and opportunities for improvement.

Humana began preparing for implementation when the final regulations were published. Here is what we did. We created a dedicated Part D operation. We enhanced our systems and processes. We increased our customer service staff 5-fold, and we developed contingency plans for potential problems.

CMS converted to a new information management system in November. While CMS tested our ability to connect with this system, there was not an opportunity to test end-to-end processing. In our partnership with CMS, we have worked diligently to identify and resolve many system issues, but there is still a lot of work to be done.

The Part D program is the first time a new benefit offers varied levels of subsidies. CMS has had to rely on States' information, information from Social Security, and internal information.

Because of the data translation issues between CMS, PDPs, and pharmacies, many dual-eligible and low-income beneficiaries have experienced access-to-care issues.

In January, we experienced 50 percent higher call volume and 30 percent longer call times than predicted. Over the next few weeks, our customer service staff will grow by more than 50 percent.

Our beneficiary and pharmacy help desk call center statistics have improved dramatically over the past month. At the end of January, over 6 of 10 beneficiary calls related to access of care were answered in less than 30 seconds, and 96 percent of beneficiary calls related to enrollment were answered in 30 seconds or less. Moreover, for our pharmacy help desk, two-thirds of the calls are now answered in 30 seconds or less.

Humana believes, and it is our policy, that our enrollees, especially the poorest, need 60 days to transition into this new benefit, 90 days for the one-one effectiveness, as dictated by the CMS policy, and our policy is more than is required. From the very beginning, Humana reached out to pharmacists, beneficiaries, community leaders, and others to address implementation issues.

While there are many lessons learned, I offer the following suggestions as to where policy improvements can be made. Part B versus Part D drug coverage. This is an enormous source of confusion for all involved.

The same drug may be covered under Part B or Part D, depending on the place of treatment or diagnosis, meaning that each potential Part B-coverable drug must be evaluated. I provide examples in my written testimony.

Enrollment time-frames. Regulation or legislation permits beneficiaries to enroll or change enrollment up to the last day of the month. If a beneficiary enrolls in a plan on January 31, it is difficult, even with the most efficient systems, to have that election

effective on February 1. Through our trade association, we are working with CMS on alternatives.

In conclusion, we have heard good stories about beneficiaries saving money. While there are operational challenges, I encourage you to be vigilant in monitoring issues and evaluating which of those need system-wide regulatory changes versus case-by-case improvements.

We commend Congress for establishing this program, and we urge the committee to support the program and ensure consistency while recognizing the tremendous value it is providing to millions of beneficiaries across the Nation.

Thank you.

The CHAIRMAN. Thank you very much for being on time. We appreciate that.

[The prepared statement of Dr. Fleming appears in the appendix.]

The CHAIRMAN. Ms. Rawlings?

STATEMENT OF SUSAN E. RAWLINGS, PRESIDENT, SENIOR SERVICES, WELLPOINT, NEWBURY PARK, CA

Ms. RAWLINGS. Chairman Grassley, Senator Baucus, thank you for the invitation to address the committee today. My name is Susan Rawlings, and I am the president in charge of senior services for Wellpoint, Inc.

The majority of my career experience has focused on Medicare programs and retiree health plans that deliver products, programs and services that meet the needs of our senior and disabled populations.

I am here today to talk to you about Part D implementation, of course, but first let me start off by saying that for those Wellpoint customers and pharmacists whom we have not been able to serve up to our own internal standards, we apologize. We are not discouraged, though. We are working day and night and we are making progress, and that, I will share with you today.

Prior to the launch of Part D, we provided access to care for over 1 million Medicare members, and we continue this tradition with the new Medicare Part D program.

We offer the new Medicare prescription drug benefit through our Medicare Advantage prescription drug plans, or MAPDs, which also include three new regional PPO programs around the country, and we also offer the stand-alone prescription drug plans in all 34 regions that span the Nation.

We contract with 51,000 rural, urban, and suburban pharmacies across the country, and our network continues to grow. We currently have an estimated 1.2 million Part D members, and approximately 60 percent of those are auto-assigned dual eligibles. We have already processed 3.5 million claims through our system as of the end of January.

Wellpoint is fully committed to supporting effective implementation for Part D for all Medicare beneficiaries, together with our partners at CMS. Our highest priority is to make sure seniors and disabled Americans are getting their prescriptions filled on a timely basis and are paying no more than they should.

We are paying special attention to the transition to Part D for dual eligibles, and especially those missed in the auto-enrollment process. The facilitated enrollment program was created just for that purpose, to be a safety net for those dual-eligible beneficiaries who were somehow missed during the open enrollment and auto-enrollment. Wellpoint is a CMS contractor for this program.

The process that was created allows the pharmacist to submit a claim for a prescription for a non-enrolled dual eligible and enables the beneficiary to leave the pharmacy with their prescription.

Everything the pharmacist needs to know about the process is written on a standard instruction sheet that has been provided to independent pharmacies, chains, and pharmacy associations in our contracted network.

If a pharmacy follows the steps described on the sheet, the dual eligible will be enrolled into a Wellpoint plan and can immediately access their new drug benefits.

The pharmacy is, however, a very key partner in making this program work efficiently and effectively. For example, the pharmacy is responsible for verifying the individual's Medicare and Medicaid eligibility, and that means really just looking at their cards. It also is required to enter appropriate minimal information into our system, such as name, address, birth date, and the valid Medicare number.

These modest requirements promote faster prescription processing and act as important safeguards that protect pharmacists, plans, and CMS from potential abuse of the program.

This process is, in fact, little different than the process a pharmacist would use to bill any public or private plan.

Now I would like to highlight a number of proactive steps we have taken to help all Medicare beneficiaries. We have increased staffing and the hours of operation at our call centers for both beneficiaries and pharmacists. We have added additional technological capacity and capability.

We have voluntarily extended our formulary transition from 30 days to 90 days, beginning January 1, and we have extended the facilitated enrollment prescription quantities allowed from 14 days to 30. For the pharmacy community, we have enhanced our communications efforts using multiple strategies.

So what positive results have we seen? Our customer service is improving. For example, our average speed to answer on our customer service lines has improved over 30 percent from the first week to the last week of January, and, in fact, in our facilitated enrollment process we have already processed, through the end of January, 575,000 claims, which we estimate has enabled 120,000 beneficiaries to receive their drugs.

I would like to take this opportunity to recommend some additional strategies that CMS might consider to further improve the Part D implementation process. We very much appreciate CMS's efforts to work with us collaboratively on these recommendations, and we do recognize that many of these are already in progress or under consideration.

First, continue to intensify efforts to provide correct, accurate eligibility information. Resolving this single issue will accelerate the pace at which the overall program is functioning smoothly.

Second, clarify that beneficiaries who choose to switch plans and enroll after the 15th of the month may not have their enrollment materials before the first day of the month. That would help alleviate confusion among beneficiaries, including those for whom the data files may not yet correctly indicate their eligibility.

Third, increase pharmacy outreach to create one-stop shopping for help. Because CMS's outreach has been very effective, CMS could also train their call centers to handle additional pharmacy-related calls, particularly calls about the facilitated enrollment process.

The Part D program is already making a big difference in the quality of life for many Medicare beneficiaries. We share the concern for the beneficiaries expressed by many stakeholders, including this committee.

I also want to acknowledge, though, that this unprecedented public/private partnership between our industry, pharmacies, beneficiaries, and CMS brings together the talent and determination that can solve these problems.

Thank you. I would be happy to answer your questions.

The CHAIRMAN. Thank you.

[The prepared statement of Ms. Rawlings appears in the appendix.]

The CHAIRMAN. Mr. Bernauer?

STATEMENT OF DAVID W. BERNAUER, CHAIRMAN AND CEO, WALGREEN CO., DEERFIELD, IL

Mr. BERNAUER. Thank you, Mr. Chairman, and thank you, Ranking Member Baucus. It is a great pleasure to be here.

My name is Dave Bernauer. I am the chairman and CEO of the Walgreen Company. Walgreens is the largest retail pharmacy in America, employing over 20,000 pharmacists, myself included, albeit a very rusty pharmacist. But we filled over 500 million prescriptions in the last year, and have already filled millions of prescriptions in the Medicare Part D benefit, so I think we can talk about that.

There is no question in my mind that, over the long term, this Medicare Part D benefit is going to improve the health care and quality of life for tens of millions of Americans. There are some short-term issues, for sure.

We recognized early on at Walgreens that, given this zero to 60, or zero to 20 million 1-day start of this program, there were going to be enormous problems. We have been educating our pharmacists for well over a year through regular bulletins and updates on what is going on.

We also knew it was going to be a problem for the patients, so we really had several approaches. One is, we got volunteers. Over 1,400 of our pharmacists went out and had multiple visits, in the hundreds and even thousands, in senior centers, assisted living centers, and so on with seniors, helping them make decisions.

We had 2 weeks last fall where we had Medicare days where we had people available to sit down with seniors in the stores and talk to them about their problems and challenges with signing up for a program.

But probably what I am most proud of is a collaboration between our IT people and our pharmacists to come up with what we call a Medicare Savings Advisor, where we can drop into a special program the drugs that that individual is taking, whether they are a Walgreens customer, and we can just drop it in from our system or actually key them in, and then give them a customized, printed report that shows them what the top three or four plans are for them to sign up for.

This has been greatly appreciated. We have printed more than 500,000 of these reports, and well over half of those were just in January alone. So we think the word is getting out, and we are seeing more and more people come in. It has been a terrific benefit for those people who are looking for a plan.

I would like to address, though, what has happened over the last 40 days and put some perspective to that. As I was driving this morning—and it took us nearly an hour to drive 6 miles—I could not help thinking about the parallel of rush-hour traffic.

What this plan was like, dropping 20 million people into something new all on the same day, was the equivalent of asking a million new commuters to come into Washington, DC this morning at 8 o'clock. We just absolutely flooded the systems, whether you were talking about the pharmacy, the phone system, the help centers, the computer systems, we just put tremendous strain on them.

Over the years, we have learned that any time an employer of 100,000 people or more changed, our pharmacists shuddered because of the extra burden that that causes.

In this case, we had tremendous pressure over that period. I think that it is very important to keep that perspective as we look at the problems that happened. The good news is, that rush hour is pretty well over.

Eighty percent of the prescriptions are taken by 20 percent of the people. Those 80 percent, for the most part, have already had prescriptions filled. Once they have prescriptions filled, we have IDed them.

We know who they are, we know what their benefits are, and from that point on they are going to be fine. So it is really the new people that are coming in to the program that are the biggest challenge.

So I want to talk about all the current data problems. I am convinced those are getting fixed. I think there are three things, some of which have been talked about quite a bit already this morning that need to be fixed. The first one is this lag period. If we cannot fix it through regulation, then I think legislation is absolutely the right way to go.

Senator Baucus, you made the point that we modeled it after the Medicare Advantage program. The difference is, that has basically been a paper claim system, or certainly was when it started. Pharmacy is an immediate electronic adjudication that happens today, so prescriptions are a much different animal, and that is the reason for the problem there.

Second, the standardization of messaging from the plans could have a huge impact on the efficiency of this system, so that when our pharmacist gets a message back from the plan, it just does not say "drug not covered," but tells us whether the drug is not covered

because it is a Medicare issue, not covered under Medicare, or it is a plan issue. Then also, it should tell us what drugs are covered in that class of drugs so that we can have an intelligent discussion with the doctor.

Then, third, CMS really needs to encourage doctors, physicians, and the patients themselves to get transitioned from the drugs that they have been on to the drugs that are covered within the formulary they are on.

If we do not do that soon, when April 1 comes up and that runs out in this transition period, we are going to have another rush hour on April 1 like we had January 1. So, we really need to work on that issue, and that has not been brought out previously.

Finally, as a taxpayer, I would really like to make just a quick statement about the unintended consequences that we risk if we do not look at generics as being the real driver in lowering costs.

Under Medicaid plans, for example, States pay more than $120 for each prescription. Even after rebates for branded prescriptions, it gets to about $110. A generic costs them about $20 in total.

So getting that generic mix is much more important than getting the rebates from the branded manufacturers. As Dr. McClellan said, the plans have really done a good job of getting rebates, pretty close to what Medicaid has got. But, much more importantly, is the fact that they are getting a much higher mix of generics versus brands than what is being experienced in Medicaid today.

Along with that, I am very concerned that, with the reconciliation bill, we are reducing the reimbursement to pharmacies on generics, when there is only about a $2 spread with the Medicaid plans today on the average generic reimbursement versus the brand, and the profitability for the pharmacies.

Private pay has a difference of about $6.50 today between those, because they recognize they want to incent pharmacists to increase generic utilization. What we did with the reconciliation bill is just absolutely reverse that, and I am afraid it is going to end up costing me as a taxpayer, and all of us as taxpayers, a lot more money because we are shifting the incentives the wrong way.

Thank you very much for the opportunity to speak. I would like to invite you, and all the members of the Senate Finance Committee, to come out to a Walgreens store or another pharmacy and talk to pharmacists in the store. Many of the people in the CMS group did that over the last month. It was very helpful for them.

[The prepared statement of Mr. Bernauer appears in the appendix.]

The CHAIRMAN. Mr. Schule?

STATEMENT OF TOBEY SCHULE, R.Ph., OWNER, SYKES PHARMACY, KALISPELL, MT

Mr. SCHULE. Chairman Grassley, Senator Baucus, I appreciate the privilege and opportunity to speak to you about Medicare Part D and how it is affecting my patients and pharmacy.

I am the co-owner of an independent pharmacy in Kalispell, MT. Over 90 percent of my walk-ins are elderly. We also provide weekly medication exchanges for three assisted living facilities and the mental health center in our community.

Medicare Part D has become a major factor in my pharmacy. I contracted with every company offering plans in Montana, and I would like to address my concerns with this new benefit.

The implementation of Part D has caused confusion and frustration for my patients. With over 40 plans to choose from, my patients said that they were scared and intimidated by all of the options.

This program does not need to be so complicated. Many were baffled by the information they received from the insurance companies and the Medicare handbook. Patients who could make sense of the material were instructed to check the Internet and to see what coverage was appropriate for their individual situation. I question this approach, since the vast majority of my elderly patients do not have computers.

Access through 1–800–MEDICARE was not much better. The phone systems are automated, and many of my elderly patients are unable to navigate through them.

There were a few meetings in Kalispell where my patients could seek answers, but after attending these sessions, many patients came back to the pharmacy even more confused.

Education for pharmacists was not much better. I heard of one event sponsored by CMS to educate pharmacists, and that was in Billings, MT, which is 500 miles from my store.

I relied most heavily on my drug wholesaler for information. In mid-December, I asked how to determine Part D coverage. Through this call, I learned about the E–1 transaction, which showed eligibility. I now use this system many times a day.

Many of my patients have both Medicaid and Medicare, but the billing system did not recognize them as dually eligible. They could not afford the high co-pays that the system said that they should be charged. I handled each patient in a case-by-case basis.

Fortunately, we are a small pharmacy and we know all our patients, so we gave them the medications on the spot. I cannot help but think how many patients across the country must have gone without their medication. We are now working through billing issues, trying to determine how we will be reimbursed.

I am very concerned for my patients because we must change their medications to match formularies for plan. I expect to see increases in physician visits, labs, hospitalizations. Medicare should have a plan to track the costs associated with medication changes.

Some plans are offering the mail-order pharmacy, and I do not think that mail-order should even be an option for Medicare Part D. If patients are getting some medications through mail-order and others from their local pharmacy, there is no continuity of care.

We have spent a tremendous amount of time on the phones with different companies getting billing information or prior authorizations to fill. We have been on hold as long as 4 hours. In other cases, we were simply disconnected. This is unacceptable.

I think it is unacceptable to show co-branding on insurance cards. It is confusing the patients, leading them to think that they can only go to certain pharmacies. There was no negotiation between pharmacists and insurance companies on reimbursement rates. To continue serving my patients, I am forced to accept the low rates offered.

Also, insurance companies are slow to pay claims. My pharmacy has over $45,000 in unpaid claims from Medicare Part D. I am not sure how long independent pharmacists will be able to stay in business with the low reimbursement rates.

Thank you again for inviting me to appear today. I will now answer questions.

The CHAIRMAN. You did very well. You did not act nervous. [Laughter.]

Mr. SCHULE. Thank you.

[The prepared statement of Mr. Schule appears in the appendix.]

The CHAIRMAN. Ms. Paeth?

STATEMENT OF JOY PAETH, CHIEF EXECUTIVE OFFICER, AREA AGENCY ON AGING OF SOUTHWESTERN ILLINOIS, BELLEVILLE, IL

Ms. PAETH. Thank you for the opportunity to speak about our experiences with the Medicare prescription drug benefit.

I am from an Area Agency in Southwestern Illinois. We are located just east of St. Louis, Missouri and serve 115,000 older persons in a 7-county region in Illinois. Our primary purpose as an Area Agency is to build systems, coordinate services, and above all, provide answers on aging.

It was natural for us to go full speed ahead to assist with the Medicare prescription drug coverage. We began by assisting older adults with the prescription drug cards in 2004. This led us to learn about the Access to Benefits Coalition, ABC, and some of their tools, such as Benefits Check-Up.

We believe the resources, training, tools, and new collaborators are what helped us to successfully assist older adults, caregivers, and persons with disabilities with the Medicare prescription drug coverage.

In building our coalition, we began with our traditional aging network and continued to expand from there. As an Area Agency, we were always strong collaborators, but now we were communicating with organizations that were never part of our traditional network.

Recognizing that media played a large role in that process and that we shared the same media market with two Missouri Area Agencies on Aging, it was critical that we provide the same message to all of our communities. With the three AAAs and the ABC coalition locally, we were set.

Our coalition had the ability to reach out to approximately 3,600 older adults with the assistance of the financial resources from the national ABC for the region. These resources helped to do things that may seem simple to many, but were critical to the aging networks being able to accomplish this task.

The coalition's members added high-speed Internet access, additional phone lines, temporary workers, laptops, and wireless Internet connections. Our strategy was to simplify the message, not an easy one. We provided one phone number. They never have to make another phone call; we transfer them directly to their community. We, whenever possible, had a live person answer the call.

The real challenge was to assure that the person on the line could correctly answer the caller's questions. CMS was instru-

mental in providing training for the coalition. CMS's embrace of the existing aging network made this daunting task doable.

We also placed a great emphasis on training the small local pharmacies, as well as the larger ones, and, along with the training, each pharmacy was given materials they could include with their customers' prescriptions, noting the appropriate AAA's phone number so they could call should they have questions about the Medicare prescription drug coverage.

Outreach and education became more and more challenging as we approached the fall. A typical event would bring in approximately 30 to 40 people before the Medicare prescription drug coverage, and now an event like that would bring over 200 people.

There was a definite point in time, however, when we knew that the education and outreach was done and it was time to help people enroll. However, this happened prior to the plans being available.

Whenever possible, we handed out the Plan Finder worksheets and then we continued to work closely with our Social Security Administration. This proved to be an effective strategy when assisting people with the low-income subsidy.

At that point, we were able to access resources from the National Association of Area Agencies on Aging through the Administration on Aging and CMS to focus on areas that had a high population of persons with low incomes. There is also a focus on low-density and hard-to-reach areas with this same grant.

At the same time, a team from NCOA's My Medicare Matters campaign was deployed to assist with the entire ABC region. This helped us eliminate backlog and keep up with incoming calls. Our challenge, as was mentioned earlier, was that 300,000 older adults and persons with disabilities were using the State's plan, which is now a wrap-around plan.

They were required to apply for Medicare prescription drug coverage, which required three steps: applying for the low-income subsidy, making sure the plan was appropriate that they were auto-enrolled in, and once again applying for the Illinois coverage.

January 1, this is where we hit most of our challenges with the Illinois coverage. The software was not always working from the PDP, and to be able to switch to the plan required the State to do the switch; the network could not help the individual.

There were also regions in the State that had no coordinating PPOs or HMOs. We have some more now, and that has been helpful.

The numbers of questions we are now getting have decreased; however, the ones we are getting are more complicated. Some of the challenges we have today are, customer service lines for some of the plans have long waits, and the network of AAAs and SHIPs have no dedicated line to these plans.

There has also been a delay in entering the person's data in the system, so we cannot access that. Our Medicaid problems have revolved around the individual not being automatically enrolled or knowing if they are LIS-eligible. These are the most frustrating challenges, because there is nothing we can do to help the person, and we are the entity with whom they have built trust.

Insurance brokers also have been enrolling people in plans that are not appropriate, sometimes using their only switch, so they are in a plan that does not have any of their drugs for the remainder of the year. This is not all right.

Pharmacies have not been getting the appropriate information from the E–1 queries, and we are helping them struggle to find that kind of information. All of these challenges, however, are really minor for a new program, and the majority are being addressed.

I have to say, though, having the financial resources in the aging network dedicated to supporting Medicare prescription drug outreach and enrollment activities has been the only way we have stayed educated and able to assist.

As May 15th approaches, our resources go away, but the need to help seniors, particularly those with low incomes and concerns regarding Medicare prescription drug coverage, will remain.

We want to continue to hear stories, such as, I used to pay $2,800 a month for my prescriptions and now I am paying $1,400 for the entire year. That is why we do what we do. Thank you very much.

The CHAIRMAN. Thank you, Ms. Paeth.

[The prepared statement of Ms. Paeth appears in the appendix.]

The CHAIRMAN. Now, Ms. Willoughby?

STATEMENT OF PAMELA WILLOUGHBY, R.N., FAITH COMMUNITY NURSE, ST. JOHN'S EPISCOPAL CHURCH AND BEDFORD PRESBYTERIAN CHURCH, BEDFORD, VA

Ms. WILLOUGHBY. Mr. Chairman, Senator Baucus, it is my privilege to speak here today. I am the Parish nurse at St. John's Episcopal Church and Bedford Presbyterian Church in Bedford, VA.

Because of this unique position, I was called by David Edwards of the Central Virginia Area Agency on Aging. Would I be interested in becoming a tier-one partner, since there was no one in Bedford City or County to sign up those eligible?

Nine volunteers met at St. John's with Margaret Moon, a health insurance specialist from Philadelphia. She explained the program in general and referred us to *medicare.gov* on the web. We knew the big picture but none of the how-to details.

I made a Medicare Part D flyer for the weekly newspaper and the Bedford County Ministerial Association to reach the target population through the church bulletins and newsletters.

The volunteers work every Thursday, 3 or 4 hours, and I work an additional 15 hours a week. Clients call my cell, appointments are made. It is important to match the volunteer's expertise with the individual client. Each appointment requires at least an hour, more or less, to enter the prescription data and compare the top three plans.

It is not unusual for clients to take upwards of 17 prescriptions, and we have to refer to the Epocrates software in my Palm Pilot and/or call the pharmacists on many occasions. The drugs are not always easy to find.

Oftentimes, the clients take the print-outs home to study them and then come back the following week to sign up. Approximately 252 clients have been signed up in the computer lab as of February 9th. We learn something new about the program every week, and

this is shared among us and makes it easier to answer the many questions.

The program is not easy. It requires study, dedication, and commitment by the volunteers who make our program possible. But we absolutely think it is a worthwhile program. The feedback is very positive, and people are most grateful.

I try to give each client my business card so they will have a contact person for positive and negative feedback in the upcoming open season if their health should change or they need to choose a different plan. Many of the now seven volunteers sign up clients at their home.

According to the 2000 census for Bedford City/County, there were 9,160 eligible clients, and we have only signed up about 3 percent as of February 6th. Some have come on crutches, in wheelchairs, been mentally challenged, blind, or deaf.

It is a broad spectrum of people, well-educated with doctorates and computer literate to those who are educated or not, and with or without computer skills. Children come for their parents, neighbors bring friends.

The common denominator is, "It is so confusing, can you help me?" There is a website in Virginia for questions or to identify problems, but with no feedback it has not been useful.

There are a few problem areas I feel should be addressed. Lagging data entry. The client must activate their own letter of confirmation if they qualify for additional assistance. Clients have the annual cost, but need to know the monthly cost for their prescriptions.

Designers must look critically at the May 15th deadline. It is not that the people do not want the coverage, it is just that it is terribly complicated and many do not know where to turn for help.

A major effort must be made by Federal, State, and local groups to assist those eligible, and it must be done one-to-one. We have basically communicated this is an issue for the elderly; it is in fact a societal issue. The donut hole needs to be filled. Many of those eligible cannot afford the increased monthly premiums for gap insurance.

In conclusion, this plan is a compassionate idea, written by career politicians, insurance, and pharmaceutical executives, implemented by bureaucrats, administered by special interests, with enrollment designed by the computer savvy, aimed at folks who are largely technologically challenged. This is the definition of Medicare Part D from an elderly woman who was being helped to sign up.

Thank you.

[The prepared statement of Ms. Willoughby appears in the appendix.]

The CHAIRMAN. Yes. Thank you, Ms. Willoughby. I appreciate that very much. You bring us opinions right from the grassroots. That is very good. You did as well, Ms. Paeth, Mr. Schule. Thank you very much.

My first question is something I am going to want each one of you to answer, but I think in terms of a very short answer, because each one of you could probably speak the whole 5 minutes on this issue.

I am trying to get at if there is a trend here. One of the goals of today's hearing was to talk about people on the front lines implementing the benefit.

I know your written testimony refers to this, but I would like to have a summation. In your opinions, has the situation improved from what it was like in the first few days of the benefit becoming available?

Now, I think I want to rephrase that, not that it has improved just a little bit, reached a plateau and has not improved any better. But have you seen some gradual improvement? I will start with you, Dr. Fleming, and go across there.

Dr. FLEMING. Yes, Mr. Chairman. There is a lot of work left to be done. We have seen the system improve dramatically since the implementation on January 1st. The fundamental problem that we have seen with this implementation is the lack of end-to-end testing that we were are able to do before the benefit was implemented.

We certainly did a lot of work in trying to make sure we could connect with CMS with all the systems. But one of the challenges that we had was the end-to-end of CMS to the plans, the plans to pharmacies, CMS to Social Security, and making sure those things worked end to end, such that, when the member went to the pharmacy, they got their medication. It is improving.

The CHAIRMAN. Thank you.

Ms. Rawlings?

Ms. RAWLINGS. Thank you. Actually, I feel it is improving as well. I think we have seen a number of different specific improvements. One, the electronic transmissions, as he is speaking of, have gotten much quicker and much more accurate and improved, and our customer service lines have improved as well.

The CHAIRMAN. Mr. Bernauer?

Mr. BERNAUER. Yes, as I said. But I would not want to say that it is going to the degree that we should say, all right, this is going to be all right, and kind of go on to something else. I think there are some big opportunities to improve this.

It is such an immense plan and it is going to have such impact on the country going forward, that we need to get it right. The three things I mentioned about standardization, the lag time, all those are very important to still fix for us.

The CHAIRMAN. Mr. Schule?

Mr. SCHULE. I am not convinced that it is actually getting any better. I think where it is better for us is the fact that we have more people that we have gotten previous claims for. I am not getting the response times that I am hearing today.

I had a situation Monday that took 2 hours before I could get a patient covered. I think, on an individual basis, no, I do not think it is really improving. But maybe because we have not got the numbers right now, it seems better.

The CHAIRMAN. All right.

Ms. Paeth?

Ms. PAETH. Well, we are delighted with the changes in the Plan Finder, the website. That has been greatly improved since December, so that has been helpful. Our questions, as I said, are more challenging now.

We are still having to find the answers because no one in the network has gotten that challenge yet, and they have not had that question come up. So, having to find the answers. But the coalitions that we have built with the local pharmacies have been helpful, so the network has pulled together to find those answers to questions.

The CHAIRMAN. Ms. Willoughby?

Ms. WILLOUGHBY. From November to today, I have seen a gradual improvement, especially with the computer program.

The CHAIRMAN. All right. Thank you.

I am going to go to Dr. Fleming. My question is not criticism of your company, but to use your expertise. When people call in to somebody, they find that they are not talking to a person very knowledgeable to answer their questions. That has been particularly true about transition fill policies. We know that the policy is changing at 90 days.

I think I will ask three questions instead of going back so we will not take a lot of time. How does Humana keep its representatives up to date? How do you monitor call center representatives to make sure they are giving the right information? What happens if you find a representative is not doing a job very well?

Dr. FLEMING. All great questions. We have a 6-week training program for our call center specialists. The training includes communication training, senior sensitivity training; product training about the different levels of benefits and the offerings that are there; training on Medicare and the different things that happened within the Medicare world; systems training, training on how to use our technology, systems, and tools to identify members, document stuff, and get them information; and other Humana administrative processes.

We do monitor our representatives for taking calls. Each of our representatives are monitored, I believe it is 10 calls per month. We monitor what is happening with their calls. We look at, and want to continually improve, how they respond, the information they give, and make sure they are answering the question right the first time for all of our members who are calling in.

At the same time, we do have a system and a tool called Mentor, which is our internal product for when we make a change. For example, let us say we change the transition policy and a question is coming up about transition policy. It will flash up on their screen and remind them of what the policy is.

Certainly, training is a big deal. How we educate our associates, how we train them, and how we discipline them. We take it very seriously, and Humana has done that, really, we think very well over the years.

The CHAIRMAN. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman.

Tobey, you did a great job. I think you were outstanding. I mean it. I am not just blowing smoke here. I mean, you were direct and to the point. You gave a good summary of the reaction you have and the seniors that come to you have, and what they are facing.

So it is direct. You are just telling it like it is, and I think everybody appreciated it. I know I did, and I think I can speak for everybody. I might tell you that Senator Blanche Lincoln walked over to

me as she was walking out and said, boy, you have a great man in Tobey Schule. I was reading his statement. I underlined everything. It is so good. So, thanks for what you are doing.

Could you maybe flesh out just a little bit where, still, the greatest problem is? You said you did not see a lot of improvement. But if you had to put your finger on something that really has to be addressed, maybe it is the immediacy, maybe it is the urgency, what would you have us really focus in on and fix first?

Mr. SCHULE. The thing that I would like to fix first is probably our dual-eligible patients. We are seeing several patients whom we are not able to get on this plan without making medication changes. They are not fitting the formulary.

We had spent the last few years with the Montana Medicaid system, we got people stabilized on formularies, the restricted formularies we were using there. I guess I really question why we did not just have an automatic Medicaid-type formula, pretty much the same as it was. I know with Montana Medicaid, they had drugs of preference based on money coming back, reimbursement from the drug companies.

So I think the biggest thing, to me, right now, is I am really concerned about the patients and their health care. I think we have missed the boat for our elderly.

Senator BAUCUS. I appreciate that. This is such an important issue, clearly, for so many people in our country. I brought back to Washington one of the main persons in Montana who is on the firing line, the front line. She is back here, sitting behind me. Her name is Gillian Morgan.

She hears all these complaints and concerns from seniors who come into her office, so I brought her back here for this hearing so I could talk to her directly to get an even better sense of what is going on.

Here is what she picks up. A lot of it is the formularies, that seniors, for the first time, are confronted with the formulary. It is very confusing. Not to be critical to what Dr. McClellan said, her experience is that the formularies are being changed and it is causing more confusion.

There are so many times that she has to try to call CMS, and now she has developed this fax form and she is trying to get information to CMS to get them to talk to the doctors, to get the doctors to call either the pharmacists or the plan, or whatnot to work out what drug really is necessary or appropriate in this situation.

Either you, Tobey, or others, do you ever face the same kinds of formulary issues?

Mr. SCHULE. We do. On some medications, I can say we can easily change people from one thing to another. However, when I work with our mental health patients, you do not mess with their psychotropics or you end up with a hospitalization. We see this over and over. When patients do not have the money to get their medication, they end up in the hospital.

Senator BAUCUS. Do you see concerns there, that mental health patients are not getting the drugs they need?

Mr. SCHULE. Because we do the mental health center in Kalispell, we have roughly 120 patients that we fill weekly boxes on. We have probably 10 of those patients, because of the formularies,

we had looked at trying to change or were given a chance for a 30-day override.

But the problem is, it only goes 30 days. Now we are coming in to the next 30 days and they are not approved to stay on that medication. It is going to put them back into a facility to stabilize them again to get on the new medication. If there was a way to track this, I think it is going to cost us a lot of money versus by just paying for the medication.

Senator BAUCUS. You mentioned you are out, I think you said, about $45,000 and need to be reimbursed, just out of your pocket that you paid. I think it was $45,000. Let me ask Mr. Schule.

Mr. SCHULE. That was last Friday. We did a quick number.

The CHAIRMAN. But you have advanced that for people.

Mr. SCHULE. Yes. That we are waiting to get paid on.

Senator BAUCUS. So in your experience, what is your expectation of how quickly you get reimbursed, and the point where you do not have to be reimbursed for out-of-pocket?

Mr. SCHULE. Yes. I mean, I would like to see it get back to a point—I mean, we all have our businesses to run. We learned our business. We got it set so that, on our Medicaid, for example, that twice a month when we were being paid by our Montana Medicaid, our budgets we based on those things.

And I realize the whole system is overwhelmed. I just got some claims Friday, and it is a month since we saw anything, and it was not complete for the month. So I am beginning to wonder how that is going to transition. Are we going to finally get it back? Part of that money, the claims were submitted later after we sorted out that that patient was eligible.

Senator BAUCUS. Well, this has been very helpful. Thank you very much, Tobey, and all of you. Ms. Willoughby, I know you are a little nervous here, too, so thank you for what you are saying. We will keep working on this.

I know my time has expired, but just one very quick point. Your best advice as to what we in the committee can do to help straighten out some of the problems. We both agree, the Chairman and I, that this is a good program, it helps people. We all agree with that.

So what can we do? Do we just keep lighting a fire under CMS and have them come up here all the time? Is it legislation? Just your advice on how we kind of get from here to there so that you do not have these kinds of problems, just as quickly as possible. Anybody? Really, my time has expired.

But Ms. Willoughby, maybe you can respond.

Ms. WILLOUGHBY. More communication.

Senator BAUCUS. More communication. Between?

Ms. WILLOUGHBY. CMS and the people actually signing people up.

Senator BAUCUS. CMS and the people on the ground, the pharmacists, seniors, and all that. All right. Good. Thank you all very, very much. I know you have come great distances, and I appreciate it.

The CHAIRMAN. Yes. Thank you all very much, too.

The hearing is over.

Senator BAUCUS. Mr. Chairman, I forgot to mention, Senator Rockefeller wanted me to say he could not be here. He has other

commitments to make. He has a lot of questions he would ask of the witnesses and follow-up, too, but he regrets that he could not be here for this hearing.

The CHAIRMAN. I should have reminded you that you could get some questions for answer in writing. So would you please cooperate with us on answering the questions in writing, if there are some submitted to you? Thank you very much.

[Whereupon, at 1:02 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Committee On Finance

Max Baucus, Ranking Member

NEWS RELEASE **http://finance.senate.gov**

Statement of U.S. Senator Max Baucus (D-Mont.)
U.S. Senate Finance Committee Hearing
on Implementation of the New Medicare Drug Benefit

Thank you, Mr. Chairman. And thank you for calling this hearing.

The Finance Committee played a key role in enacting Medicare drug benefits. We must be diligent in overseeing their implementation.

In 2003, after years of debate, Congress added prescription drug coverage to Medicare. I was proud to help pass that law. The law was not perfect. But it has the potential to do some good.

It has the potential to make prescription drugs available to millions who could not otherwise afford them. It has the potential to make drugs available that will lessen pain. It has the potential to save lives.

Unfortunately, the administration has implemented the new law poorly. After Congress passed the law, the Centers for Medicare and Medicaid Services — CMS — had the duty to ensure that Medicare drug benefits were up and running by January 1, 2006.

I appreciate CMS's efforts to implement the new law. It's a huge task. CMS worked hard.

But CMS's efforts have come up short, in two major areas.

First, CMS made the new drug benefit needlessly confusing.

As part of the new law, Congress passed a temporary drug discount card, available in 2004. The card was supposed to give temporary relief from high drug costs. Seniors of modest means were eligible for a $1,200 federal subsidy for their drug purchases.

But most Medicare beneficiaries did not sign up for the drug card. Why? They were paralyzed by the choices. CMS approved 40 Medicare drug cards in my state of Montana alone.

-- more --

Far from celebrating the array of choices, most Montana seniors found them so confusing that they gave up, and did not sign up..

Less than a year later, CMS was approving drug plans for the new drug benefit. I urged CMS not to repeat the mistakes that they made with the drug card. I urged CMS to approve only plans meeting the highest standards.

But CMS repeated the mistakes of the drug card. CMS approved dozens of plans for participation in the new drug program. CMS approved more than 40 drug plans in Montana.

I support choice, competition, and the free market. It's great that Americans can choose from hundreds of different models when buying a new car.

But when people don't know what they're buying, choice can lead to confusion. That's particularly true of health care.

Ask elderly Americans whether they prefer a four-speed automatic or a five-speed manual, and they will probably choose the automatic. Ask them whether they prefer a drug plan with a four-tiered formulary to a plan with five, and they will probably look at you with a mixture of confusion and anger.

My second concern relates to the warnings that CMS ignored.

Last year, I asked the independent Government Accountability Office to report on CMS's plans for seniors eligible for both Medicaid and Medicare.

I asked: What were CMS's plans for seniors whose drug coverage was moving from Medicaid to Medicare? In December 2005, GAO reported that CMS's plans were insufficient to avoid big disruptions in coverage.

CMS disagreed. CMS said: "[We have] worked diligently on the transition from Medicaid to Medicare drug coverage ... and ... these individuals will get effective, comprehensive prescription drug coverage ... on January 1, 2006."

That did not happen. GAO was right. Data systems failed. Pharmacists and states were stuck with the bill for co-pays that should never have been charged. And some vulnerable seniors left the pharmacy without the medicines that they needed.

We're going to hear about some of these issues today, including from Tobey Schule, an independent pharmacist from Kalispell, Montana. Mr. Schule is one of thousands of pharmacists who have been burdened with the flawed transition from Medicaid to Medicare.

I appreciate CMS's attempts to fix the problems. But some problems remain unsolved. Dr. McClellan, I look forward to hearing how — and when — CMS plans to fix the problems.

In addition to ensuring that the implementation flaws are fixed, Congress should also address the problem of confusion. We can do that by learning the lessons of Medigap.

In 1980, Congress enacted amendments that I offered to fix marketing abuses and consumer confusion with Medigap. The reforms required Medigap issuers to meet minimum standards and have minimum loss ratios.

Ten years later, Congress again took up Medigap reform, passing legislation to standardize Medigap policies. Ten different Medigap options would be offered, each with a basic set of benefits.

This gave consumers an apples-to-apples comparison of Medigap coverage.

We should do the same with the new drug program. We should standardize the drug plans. We should make it easier for people to make good choices about which plan is best for them. I intend to introduce legislation to do just that.

I understand that the drug benefit is young. But I want this benefit to work. We simply cannot afford another round of confusion. We need broad participation. And that's not going to happen unless we make the program more accessible and understandable.

I supported enactment of the Medicare drug benefit in 2003. I still support it. Health insurance needs to cover prescription drugs.

But we need to make it work. And I look forward to hearing from our witnesses on how we can do so.

###

Testimony of

David W. Bernauer
Chairman and Chief Executive Officer

Walgreen Co.
Deerfield, Illinois

to

United States Senate
Committee on Finance

Wednesday, February 8th, 2006

Chairman Grassley, Ranking Member Baucus, and Members of the Senate Finance Committee, I am David W. Bernauer, Chairman and Chief Executive Officer of Walgreen Company, which is based in Deerfield, Illinois. I am pleased and honored to be here today to participate in this important hearing of the Senate Finance Committee on implementation of the Medicare Part D prescription drug benefit program.

Walgreens is the nation's largest pharmacy chain with sales of more than $42 billion last year. We have provided pharmacy service to patients for 105 years and have more experience meeting the prescription needs of patients than any other pharmacy in the country. Today, we operate more than 5,100 pharmacies in 45 states and Puerto Rico, employ nearly 20,000 pharmacists and will dispense more than 500 million prescriptions this year.

Preparing Walgreens for Medicare Part D

Walgreens and the chain drug industry in general recognize that Medicare Part D is the most significant expansion of Medicare since its inception. We are pleased that millions of additional seniors now have access to prescription drug coverage as a result of the new Part D benefit. However, there have been several important challenges for beneficiaries and pharmacists in transitioning to the new Part D benefit.

We appreciate all the steps that have been taken by CMS, states, and plans to work with us to ease this transition for beneficiaries and pharmacists. For example, we appreciate all the time and effort expended by CMS in working with our industry and the health plans in developing the "TrOOP facilitator". This tool allows pharmacies to electronically query a special database that is supposed to instantaneously return information to the pharmacist about the Part D plan in which a Medicare beneficiary has been enrolled, including the beneficiary's billing information. It will also facilitate coordination of benefits with other payers. The development of the TrOOP facilitator was a very important public-private partnership that should serve as the model for how current and future Medicare Part D implementation issues are addressed.

We appreciate the fact that many senior HHS and CMS officials have visited dozens of retail pharmacies across the nation over the past few weeks – including Walgreens' pharmacies – to see first hand the challenges that pharmacists and beneficiaries are having with Part D. We know from talking with them that these visits have been an eye-opening educational experience. We hope these visits have helped them better understand the environment in which we provide pharmacy services and result in practical ideas and solutions for addressing the issues that were brought to their attention.

At Walgreens, our pharmacies are committed to helping seniors understand the new Part D drug benefit. Like many other chain pharmacies, we developed an extensive education and outreach program to train our pharmacists, district pharmacy supervisors, and other senior personnel about Part D. We've had more than 1,400 pharmacy staff employees volunteer to speak in their communities to senior groups about Part D and educate them on the benefits and enrollment process. In fact, our pharmacists will continue these senior outreach efforts throughout the enrollment period. Twice last fall, we held week-long Medicare Part D information days at our pharmacies nationwide. We also developed our own Medicare prescription insurance plan report - called the Walgreens Rx Savings Advisor - which provides seniors with a free, personalized list of Part D plan options based on their current prescription drug needs. We have provided 500,000 individually, personalized reports to date, including 282,000 in January alone. Our patients have found this to be an important part of their decision process in selecting a Medicare Part D drug plan.

In addition, many of our pharmacists have taken extra time and effort to learn the "ins and outs" of Part D so 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. I know that many of our pharmacists have worked long hours to obtain correct billing information for beneficiaries as well as correct copay information. I cannot say enough about the dedication of the pharmacists that work for Walgreens – and pharmacists all across the country – in trying to make this benefit work.

Walgreens knew that implementing Part D would be a monumental task, and that the proverbial "rubber would meet the road" at the 52,000 community retail pharmacy counters across the country. Consequently, we did everything possible to prepare our pharmacists and pharmacy staffs understanding they would have an essential role in making the program work. That's because pharmacists know their patients' medication needs, and are ultimately responsible for providing them with their prescriptions. Pharmacists know the importance of medications in managing the chronic medical conditions of the elderly.

Current Implementation Issues with Part D

We want to provide you with an honest assessment of how the Part D program is going from the pharmacy perspective, now that we are well into the second month of the program's operation. In general, implementation of the program is going better as compared to the early weeks of the program. This is due primarily to tens of thousands of individual efforts by CMS staff, the insurance plans, and pharmacists across the country who found ways to navigate through the roadblocks of determining coverage for their Medicare patients.

As more and more beneficiaries receive their actual identification cards from Part D plans, and CMS and the plans enter data into the TrOOP facilitator more quickly, the situation is improving. Today, the chances are greater that the beneficiaries' plan and billing information will be active when the beneficiary comes into the pharmacy as compared to a few weeks ago. In fact, the lack of accurate data in the system was the primary reason why so many low income individuals may have been charged higher copays than they should have been charged.

Walgreens would like to make some recommendations on how CMS, states and Part D plans might address some of the implementation issues we are having with Part D:

Modify Enrollment Effective Dates: Because individuals are becoming eligible for Medicare everyday, and the dual eligibles have the option of changing plans every month, one systemic issue that needs addressing is what's commonly referred to as the "enrollment lag".

Right now, a beneficiary can join a Part D plan anytime during a month and expect the enrollment to be effective the first day of the next month. But if they apply in the last few days of the month, it is not possible for CMS and the plans to process the beneficiary's application, confirm eligibility with CMS, and provide the critical "4Rx" billing information to TrOOP facilitator – so that it is in the pharmacy system - in such a short timeframe.

In fact, the lack of data in the system as a result of late-month enrollments or plan switches has been, and may continue to be, the single most challenging issue that pharmacists face with Part D. If we don't have the data, we cannot fill the prescription, and that triggers a whole series of potential calls to CMS and the plans to obtain this billing information. For this reason, we suggest that policymakers address the "enrollment lag" issue.

Multiple options are available to address this issue, and we want to work with CMS and plans to find a solution. Some see the solution as educating beneficiaries that, by enrolling late in a month, there will be delays in the activation of their prescription drug coverage. Others have suggested that an enrollment deadline be established each month so that there is sufficient time to process applications and enter the billing information in the system. Whatever the options, it is important to address this systemic issue soon.

Promote Standardization among Plans' Policies and Procedures: Virtually 100% of all prescription claims are processed electronically today, making pharmacy claims processing far more efficient than any other segment of health care. Yet, third-party prescription administrative issues still consume almost one-quarter of the average pharmacist's work time. These administrative tasks have further multiplied as Part D has come on line due to the dozens of new Part D plans each having their own policies, processes and procedures for pharmacists to follow in order to fill prescriptions.

Like most chain pharmacy companies, Walgreens has developed standard workflow processes in our pharmacies that allow for the most efficient filling of prescriptions. But, these varied and onerous third party prescription processing issues disrupt the pharmacy workflow and dramatically reduce the efficiency in filling prescriptions for Medicare beneficiaries.

We would all agree that the pharmacist's time is better spent interacting with Medicare beneficiaries and other patients, helping them to understand how to take their medications, rather than sorting through paperwork. In addition, the tens of thousands of hours spent each year by pharmacy personnel in resolving these third party administrative issues needlessly drive up the costs of these programs for plans and the Federal government. Thus, it would seem to be to everyone's benefit to reduce the administrative costs of processing prescriptions.

To that end, we urge CMS to use its leverage, as the largest payer for prescription drugs in the nation, to bring plans and pharmacies together to create and require more standardization in third party prescription claims processing, pharmacy messaging, and procedures that would benefit Medicare Part D, Medicaid, and other Federal health care programs. For example:

- Some Part D plans require that we fax forms to physicians to obtain prior authorization to dispense some medications, while other plans require us to call the plans' "help desk." We need plans to develop consistent and standard messages and procedures for pharmacists. For example, all plans should have the same method for overriding messages on non-formulary drugs and for dispensing transitional supplies of medications. We also suggest that CMS standardize the plans' transition policies to reduce confusion among pharmacies and beneficiaries, and do a much better job of explaining the policies on the front end.

- Part D plans should also develop consistent messages to pharmacies that differentiate when a drug is "non formulary" in contrast to when a drug is "not a Part D covered drug", such as a benzodiazepine. A message that simply tells the pharmacist that a drug is "non formulary" is not descriptive enough for the pharmacist to make this distinction.

Because of the lack of clarity in the message, some pharmacists may spend time seeking approval from Part D plans for a drug that would never be covered under Part D. This is a poor use of time for the pharmacist, the plan, and the beneficiary.

If a plan is not going to cover a drug because it is not on the formulary, the pharmacist needs to know that information at the point of sale, so they can take necessary steps to bill any other wrap-around coverage that the beneficiary might have.

- Part D plans also need to return information to the pharmacist about formulary medication options if the medication prescribed by the physician is a non-formulary drug. The infrastructure is in place to allow for this, but no one has required plans to do this. This has become, and will continue to be, a big issue with dozens of Part D plans, each with a different formulary and different tiers within their formulary, not to mention that each plan can change the drugs on the formulary with a simple 60 days notice. It is literally impossible for pharmacists to keep track of all these formularies. Part D plans have posted formularies on their websites, and such information is also available through *Epocrates,* but it remains much more efficient for the pharmacist if the plan returns the information in a message to the pharmacist at point of sale. This reduces the wait time for the beneficiary and can reduce the number of inquiries to the plan; hence, the need for when a plan rejects coverage, it should include a message to the pharmacist indicating formulary options for the prescribed drug.

- It is important that we work through issues relating to when a drug is covered under Medicare Part B versus Part D. There is potential overlap for coverage under both programs depending on how a medication is being used and how it is being administered. We believe it's important to minimize the extent to which plans are using "prior authorization" on drugs that could be covered under either Part B or Part D. We need to work toward a solution that provides Part D plans with important clinical information from the Part B DMERCs so that the plan can determine whether the pharmacist should bill the drug to Part D or Part B without costly and burdensome prior authorizations.

Ensure that States Work Directly with Part D plans and CMS on Reimbursement: Many states felt compelled to step up to the plate during the early days of Part D implementation and cover the prescription drug costs and copays of some of their dual eligibles who couldn't obtain their drugs under Part D. We have been working with the states that have implemented these programs to ensure that we understand their interim policies. Some states have defined and implemented their programs better than others, and the wide variety of these programs has been another challenge to processing claims for dual eligibles.

Almost every state has indicated that they intend to seek recovery of the funds that they are spending for these temporary programs from Part D plans. Pharmacies have worked diligently to only bill these temporary state Medicaid programs as a payer of last resort. Pharmacists are making every reasonable effort to bill a Part D plan or the Wellpoint/Anthem Point of Service (POS) system, if the dual eligible individual comes to the pharmacy without their identification card, and/or the information cannot be found in the TrOOP facilitator. However, pharmacists cannot be expected to spend countless hours on the phone trying to get these two options to work before they bill a state.

States should work directly with Part D plans to recover any monies that they spent for Part D drugs without involving pharmacies as billing intermediaries. CMS has pledged to pay states for the costs of covered Part D drugs – without involving pharmacists - through a temporary demonstration program. To be eligible for this demonstration program, the state must cease operating their emergency coverage programs by February 15th. That may be an unrealistic deadline if additional problems occur in February with the dual eligibles, so we urge CMS to approach that deadline with flexibility.

However, we think that CMS and the states should recognize that retail pharmacy does not want to be caught in the middle of recovery and collection efforts if states and plans have disputes regarding whether prescriptions should have been dispensed. We encourage states to

carefully consider using this demonstration program to recoup their monies. We also ask CMS to use their influence to dissuade any state from using a pharmacy recoupment initiative to recover monies from Part D plans through retail pharmacies. Moreover, we urge CMS to require that states ensure that pharmacies are made whole for the tens of thousands of emergency prescriptions that they dispensed to Medicaid recipients when the pharmacist was unable to file a claim with a Part D plan.

Similarly, as in the case with states that are seeking recoupment of monies from Part D plans, we believe that pharmacies must not be caught in the middle of any payment reconciliation that might have to be made between Part D plans if, for example, the beneficiary has switched from one plan to another. Any adjustments that need to be made between plans in these situations should be done through a plan-to-plan reconciliation process, rather than involving retail pharmacies as billing intermediaries. We encourage CMS to do all they can to encourage plans to complete work on the plan-to-plan reconciliation process that was started several months ago to avoid these potential situations.

Addressing Part D Issues Moving Forward

Right now, we are all working together to address implementation issues in the very early stages of the new Part D benefit. We are making progress, but we obviously have more work to do and we are willing to do our part. The fact of the matter is that we may be fine-tuning this benefit for many years to come. Beyond the issues that we have already described, we see several other critical first-year implementation issues for the Part D program.

For example, we should consider that there will be significant challenges in moving millions of beneficiaries from the non-formulary drugs they currently take to a plan's formulary drugs. This will have to occur before exhausting their transition supplies of non-formulary drugs. This challenge will be especially pronounced for the dual eligibles. These individuals generally take more medications than other Medicare beneficiaries, so transitioning them to formulary medications should occur as soon as possible, but as safely as possible because of the time that it may take. We believe that CMS' recent decision to require

plans to provide a 90-day supply of transition medications – rather than just a 30-day supply -- will ease the transition to formulary drugs.

However, plans, beneficiaries, and physicians must use this extended time frame to aggressively start the transition now. To that end, CMS must monitor whether plans are taking the necessary steps over the next few weeks to help beneficiaries understand what they need to do and how they need to do it in order to transition to formulary drugs, so that confusion and delay at the pharmacy are minimized. The burden of helping beneficiaries to transition their medications is a shared responsibility, not just the responsibility of pharmacists.

We also think that there could be a significant last-minute enrollment surge among beneficiaries before the May 15th open enrollment deadline. This could create a sudden surge of individuals that want to use their benefit on June 1. The entire system needs to be prepared to process these applications quickly, get the information in the TrOOP facilitator, and be ready to fill prescriptions for these beneficiaries.

Finally, we are concerned about managing the expectations of individuals that will fall into the "donut hole" or coverage gap during the middle of the year. While many seniors were probably aware of the "donut hole" when they signed up for a plan, we are concerned that some did not or will not fully understand the issues relating to the "donut hole". CMS and the plans should consider ways to help educate beneficiaries about the implications of the "donut hole" as the middle of the year approaches so that pharmacists do not bear all the burden of helping seniors understand this component of the benefit design.

Other Challenges Facing the Industry

While this hearing has been called to examine Medicare Part D implementation issues, we want to provide the Committee with our views on another important issue facing the industry. The Budget Reconciliation bill includes significant cuts to Medicaid. In particular, the bill would reduce payments to pharmacies for generic medications by about $6.3 billion over the next 5 years. Walgreens is very concerned about these cuts for several reasons.

- We are concerned that these reductions in payment will take away much of the incentive for pharmacies to dispense generic medications. We are perplexed why policymakers and the Congressional Budget Office (CBO) believe that decreasing generic payments will increase generic drug dispensing. The total reimbursement to Walgreens for a Medicaid single-source brand-name drug averages $128, while the average generic reimbursement is $20. Clearly, increasing generic utilization is the most effective way to reduce Medicaid costs. In fact, with these payment reductions, just the opposite will happen, leading to higher – not lower – drug costs to the government. We believe that many states will need to take action this year to increase their generic dispensing fee, or they may see a reduction in generic drug dispensing in their states.

- There is an aggressive implementation timeline for the new Medicaid pharmacy payment provisions included in the legislation. In fact, the first implementation milestone occurs this July when CMS is supposed to make Average Manufacturers Price (AMP) data available to the states and the public. We are concerned that, under the current definition of AMP, these data will not reflect the actual prices paid by retail pharmacies for brand and generic medications. As a result, they could provide a misleading picture to states, private plans and consumers about the true acquisition costs of retail pharmacies.

  Unfortunately, these data will become public a whole year before CMS provides more specific direction to manufacturers on how to calculate AMP. That regulation is expected in July 2007. That means for at least a 12 months, data will be available in the public realm that may not accurately reflect retail pharmacies' acquisition costs for prescription drugs. We believe that these data should not be made public or shared with the states until the AMP can be more accurately, appropriately, and consistently defined.

- Reductions of this magnitude in Medicaid, coupled with the economic impact that Part D is having on pharmacy, will undoubtedly affect access to pharmacies. We do not believe that policymakers have considered the cumulative economic effect of these programs on the ability of retail pharmacies to continue to stay in business. Many pharmacies in the

United States – including those operated by Walgreens -- serve a high number of Medicaid recipients as a percentage of their business. If prescription revenues sharply decrease in these pharmacies as a result of Medicare Part D and generic payment reductions, these locations may have no option but to reduce hours or even close. This would seriously harm the ability to meet the health care needs of communities in which these pharmacies are located.

- The new Federal generic upper limits are supposed to be implemented in just 11 months – January 1, 2007. Given all the problems and issues that pharmacies have experienced with the January 1, 2006 implementation of Medicare Part D, we caution policymakers about implementing another major change in pharmacy payment streams in such a short period of time after Part D, and especially on January 1st – which is already a date of great changes for pharmacies every year.

We urge that policymakers consider the delay or revision of these Medicaid pharmacy payment changes as the industry adjusts to the operational and economic challenges of Medicare Part D.

Conclusion

Walgreens appreciates 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 ensure that the benefit is delivered in the most efficient manner. We know that many of these issues will eventually be resolved, but other issues will develop down the road that will also have to be addressed. We ask that you call on us if we can provide any further information about these issues. Thank you.

Follow-up Questions

David W. Bernauer
Chairman and Chief Executive Officer

Walgreen Co.
Deerfield, Illinois

on

Medicare Part D Implementation

to

United States Senate
Committee on Finance

March 1st, 2006

From Senator Grassley:

Mr. Bernauer, your written testimony states that promoting more standardization on forms and certain procedures could help the current situation. Right now, some plans want pharmacists to call. Others want a form sent by fax.

How far do you think more standardization on these forms and procedures could help the program run more smoothly?

The adoption of standardized forms and procedures would have an immediate and dramatic impact on several key program problem areas.

- For the prior authorization process, an immediate improvement would be a standardized form for pharmacies to submit to plans to initiate the prior approval process with the physician. This would be used when the pharmacy receives an electronic message that a prior authorization is required. The form would be faxed to the plan or PBM, which would then research the medical necessity with the prescriber to determine whether the prior authorization is approved or not approved. The plan or PBM is in the position to flag the patient's central record accordingly, so the prescription can be processed at point of sale from that point forward. The current process requiring individual pharmacies to decipher varied prior authorization procedures is inefficient and delay inducing. For the longer term, the current NCPDP 5.1 Standard supports electronic prior approval, and a date certain should be set that would require prior authorizations to be handled electronically, pursuant to that Standard.

- All plans should have a standard message that indicates when a drug is not covered versus when a drug is not on the formulary. For statutorily excluded drugs, like the benzodiazepines, a suggested message is "NDC is not covered, Medicare excluded, check for Medicaid/other state coverage". When a drug is not covered due to formulary exclusion, then the message should include the formulary medication options.

- There should be a standard process for dispensing transitional supplies of medications.

- Pharmacies need a standard process and plan message to indicate that a drug is covered under Part B or D thereby avoiding unnecessary prior authorization procedures. Part D plans should be provided clinical information from the Part B DMERCs (durable medical equipment regional carriers), that currently process Part B claims, so that Part D plans can determine and message to the pharmacist whether to bill Part D or B.

- Standardization needs to be adopted across state programs as well, including standardization of processes for state pharmaceutical assistance programs (SPAPs) and Medicaid plans that are paying for excluded Part D drugs and providing additional coverage as secondary payers

The standardization of these key processes would go a long way in making the program run more smoothly, reducing inefficiencies and additional costs associated with processing prescriptions, and most importantly, enabling our staffs to better serve patients.

From Senator Baucus:

1. You included comments regarding Medicaid in your testimony. The Deficit Reduction Act of 2005 included a new Medicaid generic payment rate of 250% of the AMP. You indicated this will be insufficient to encourage generic dispensing. However, the Congressional Budget Office (CBO) believes that these policies will encourage, not discourage generic use. What is the basis of your concerns, and do you believe there is something that CBO did not consider in its analysis of this provision? What do you think will be the economic impact on pharmacies of the new Medicaid generic payment rate?

If generic profit dollars are less than brand profit dollars, it will reduce the incentives for pharmacies to substitute a generic for every prescription possible. One example is a common brand anti -depressant which sells for $200, as compared to the generic which sells for approximately $20. When the pharmacist spends additional time calling the doctor and counseling the patient, the pharmacist may switch the patient to the generic, saving Medicaid $180. For this effort, the gross profit for the generic is $7 higher, clearly aligning pharmacy interests with that of Medicaid. Under the new payment formula, the gross profit dollars for the brand will be $3 higher than the generic, thereby decreasing the pharmacy's interest in spending the additional time attempting to switch to the lower cost drug.

An additional way that pharmacists can intervene and lower drug costs, is suggesting lower cost clinical alternatives. For example, one commonly prescribed cholesterol lowering drug sells for $90. This particular drug does not have a generic substitute. However, a pharmacist may call the doctor and suggest a clinically equivalent drug in the same therapeutic class that does in fact have a generic. In this example, the generic sells for $22, thereby saving Medicaid $68. Under the new payment formula, the pharmacist will be reimbursed $3 less by dispensing the generic rather than the brand. Clearly, pharmacists would not be incented to do the extra work when they are also paid less.

There are many other examples. The bottom line is that the new payment model favors dispensing brands rather than the lower cost generics, thereby decreasing the incentive for the pharmacist to perform extra work to make a Medicaid cost saving switch.

The new payment model, 250% of AMP, reduces pharmacy generic payment by $6.3 billion over the next 5 years, or $4 per generic prescription dispensed. Today 50% of prescriptions that are dispensed generically in Medicaid have total pharmacy revenue of less than $10. The loss of $4 means that now nearly 50% of all Medicaid prescriptions will have total revenue of less than $6. Recently, the University of Texas, completed an assessment of the cost to a retail pharmacy to fill a prescription. Accounting for pharmacist salary, technicians, expenses, inventory carrying costs, occupancy, etc, the cost to fill a retail prescription approximates $9.62. Pharmacies are currently filling half of all Medicaid prescriptions on a near break-even basis. Reimbursement levels that result in revenue below actual costs may lead to pharmacy closures, reduced pharmacy hours, and access problems for Medicaid recipients.

The lack of generic utilization incentives in the new Medicaid payment model seems counterproductive when compared with private third party plans. For comparison, private third party plans have their incentives aligned with maximizing generic utilization with gross profit dollars $6 higher for generics as compared to brands. Today, Medicaid has average gross profit dollars that are $2 higher for generics compared to brands.

We do not know the assumptions CBO used in reaching its conclusion that the new FUL (250% of AMP) would in fact encourage generic dispensing, although it appears they assume that states will act to increase generic dispensing fees to offset the reduction in generic drug product reimbursement. However, it is not clear how many states will act or if they do act, how much they will increase their dispensing fees. The legislation does not specify a minimum dispensing fee, so it is up to the states to act this year to increase their fees to assure that the profit dollars earned by the pharmacy on a

generic drug is equal to or greater than that earned on a brand name drug. The risk of their not doing so is the unintended consequence of Medicaid costs increasing.

2. Many independent pharmacists have raised concerns about some plans putting the logos of certain chain pharmacies on their Part D identification cards because it creates confusion in the minds of the beneficiaries who think that they can only use the pharmacies on the card. Does Walgreens participate in any of these co-branding relationships? If so, why, and what are your views on the appropriateness of such relationships?

We believe that this "co-branding" creates a presumptive restrictive network that not only discourages beneficiary choice and dampens competition among providers, but also causes confusion with patients, pharmacies, and physicians as to the actual choices available. However, the current regulations do allow co-branding and we have had many requests to participate in co-branding relationships. Although we have largely declined, for competitive reasons, because it *is* allowed, we felt it necessary to make one exception. We believe that beneficiaries should be fully informed that they have the option of using any pharmacy in the network, not just those that have co-branding relationships, and that all printed materials from plans, as well as messages from call operators, should indicate that.

From Senator Rockefeller:

Mr. Bernauer and Mr. Schule, pharmacies have been put in the middle of all of this, and as a group have done a commendable job trying to help beneficiaries get their drugs while dealing with long telephone waits, system glitches and other difficulties. I want to thank you for your efforts.

1. I have heard many complaints from pharmacists about not being able to access eligibility data that will allow them to bill plans at the time of sale. This breakdown seems to be the main cause of frustration among pharmacists and beneficiaries in determining what plan to bill and what co-payments to charge. What is you view on how this program is working and what can be done to address this situation? How adequately do you think you were prepared to use the new pharmacy billing system prior to the start of the benefit?

Most of the frustration, and wasted time for seniors and pharmacists alike has been, and will continue to be for most new enrollees, due to a very small oversight in the original legislation, in that no processing time is allowed between sign up and eligibility. MMA was written to allow for seniors to sign up until the last day of the month and be eligible on the first of the following month, as is the case with the Medicare+ Choice program. The critical distinction is that medical bills are largely paper-based and the patient is not expected to pay at time of receiving services while prescriptions are processed and co-pays are paid real time. Pharmacy electronic claims processing is a far more efficient process that eliminates huge amounts of paper processing and dramatically reduces costs to a couple of cents per prescription versus dollars.

It is unrealistic to expect a beneficiary to enroll in a plan or change plan enrollment the last week of the month and expect that their information would be available to the pharmacist the first of the following month given the processing necessary by the insurer, CMS, and in some cases, the state. The efficient and accurate processing and on line availability of this important beneficiary eligibility and enrollment information is critical. The only realistic solution to achieve this is to have a delay between enrollment and eligibility for benefits. There needs to be a 30-day eligibility processing window, and we would strongly recommend this be implemented as soon as possible by whatever process

necessary. Without a delay between enrollment and eligibility, every month of every year in the future, those tens of thousands of newly eligible seniors signing up will experience the same initial frustration with the program, and we will be adding millions of dollars of unnecessary costs to the system every year. For dual eligibles and disabled becoming eligible, the state Medicaid program should remain responsible for prescription coverage for the initial 30 days.

Pharmacists for years have known that there will be some problems with any large size group coming online for prescription benefits at the first of the year, but never has there been a first of the year enrollment of this size. The volume experienced would very possibly flood systems beyond capacity in and of itself under perfect conditions. But conditions were not perfect. Through most of January, the missing eligibility information due to the lack of a delay from sign up to eligibility, combined with the many problems with dual eligibles, created a traffic jam that made rush hour on a LA freeway look like a picnic.

Much of this is behind us now, but three things are essential to make sure we can provide seniors with the service they deserve in the future: (1) a 30-day eligibility processing window, (2) Plan messaging standardization, and (3) Proactive initiatives by plans or PBMs informing patients and alerting physicians of changes from existing medications to formulary medications.

We were well prepared, both systems and personnel, based on the information we were given. Essentially, we integrated Medicare Part D processing into our normal processes. The "eligibility check" functionality itself worked well, when there was (accurate) data available and the systems were up and running.

2. I would also like to hear about your experiences calling the plans and actually being able to talk with a customer service representative. When you are able to get through to somebody, how helpful are they? Can you also talk about your experiences with the prior authorization process and whether or not your feel that process is helping or hindering beneficiary access to their medications?

Prior authorizations can help plans better manage drug spending and encourage appropriate utilization. However, pharmacists should not have to shoulder the burden of this process and not be compensated appropriately. Part D plans are using prior authorization in a greater number of cases than in private sector commercial plans. Due to the lack of standardization, such as a standard prior authorization fax form, and centralized plan processes for obtaining prior authorization from prescribers, pharmacists are making the phone calls to plans and prescribers and completing the necessary paperwork which increases the costs to dispense a prescription and delays patients getting their prescription. The prior authorization process has been onerous for pharmacy because procedures vary between plans, and because the expertise of the person pharmacies may deal with at a plan call center also varies. Currently, the plans are paying the PBMs for this activity when pharmacists are doing most of the work. We believe that plans should initiate the prior authorization by contacting the physicians and obtaining appropriate medical necessity to determine prior authorization approval or denial.

3. I have heard that many pharmacists have provided drugs to patients without knowing who would reimburse them. Some have even taken out lines of credit to make sure their customers are able to get their medications while this all gets straightened out. Would you tell us about your experience in this area? What are your recommendations to Congress on how to reimburse pharmacies for unexpected prescription drug costs?

In January alone, our pharmacies have taken risk for $224,000 and we are uncertain as to how much of that will be reimbursed. CMS has stated that they plan to make sure states are reimbursed where they came forward to cover the drug costs for the dual eligibles caused by the Part D start-up

problems. We would suggest that not only pharmacies be paid, but that monies are not recouped from pharmacies based on differences between what state Medicaid programs paid and what Part D plans should have been paid. At the end of the day, there may be some claims that we simply may not be able to bill due to inadequate billing information. We would recommend that CMS pay these in some form or manner from some type of uncompensated care fund – similar to the way that CMS is paying for states' costs for Part D dual eligibles' drugs during the early stages of the benefit.

Ultimately, we would hope to have the patient's correct billing information upfront to bill the appropriate plan for the medication as prescribed. The adoption of a 30-day eligibility processing window would allow time for patients to receive plan identification cards and for correct billing and copay information to be entered into the system, thereby eliminating many of the problems experienced to date. State Medicaid programs should remain responsible for prescription coverage for the initial 30 days of newly eligible dual eligible beneficiaries.

STATEMENT FOR SENATOR JIM BUNNING
FINANCE COMMITTEE HEARING
FEBRUARY 8, 2006
MEDICARE DRUG BENEFIT

Mr. Chairman. Thank you for holding this important hearing today. I also appreciate the time Dr. McClellan has taken to be here today.

A little over a month ago, the new Medicare drug benefit went into effect. This was the largest change to the Medicare program since its creation 40 years ago. Finally, all Medicare beneficiaries have access to prescription drugs.

I was a strong supporter of this bill as it moved through Congress and believe that millions of seniors and disabled Americans will benefit from this prescription drug coverage.

However, rolling out a drug benefit for 43 million beneficiaries isn't an easy task, and there have certainly been some pitfalls along the way, including transitioning the dual eligibles from Medicaid drug coverage to Medicare, handling the number of phone requests for information and making sure pharmacists are up to speed on the new benefit and have access to the information they need.

These problems have cast a cloud over the rollout of this new drug benefit, and I'm afraid that some beneficiaries are getting the impression that the drug benefit isn't worth signing up for.

That cannot be farther from the truth.

This drug benefit could save many beneficiaries hundreds of dollars each year, and while wading through bureaucracy and picking the right plan may be a little confusing and time consuming, I believe it is definitely worth their while.

It is important to note that many beneficiaries have successfully enrolled in the drug benefit and are enjoying the benefits of drug coverage. The shortfalls Medicare beneficiaries have encountered are unacceptable, and I'm sure there is enough blame to go around. However, the issue before us today is how to we move forward, fix these problems, and help all beneficiaries who want it get the right drug coverage.

I am looking forward to hearing more from Dr. McClellan today about exactly what steps the agency has taken and will take in the future, along with the witnesses on the second panel who will be able to share with us their first-hand experiences. Thank you.

Testimony on

Implementation of the Medicare Part D Prescription Drug Program

By

William Fleming, PharmD
Vice President, Pharmacy and Clinical Integration
Humana Inc.

Before the United States Senate Committee on Finance

February 8, 2006

Mr. Chairman, Senator Baucus, and other members of the Committee, thank you for permitting me to testify about one of the most important benefits Medicare beneficiaries now receive – an outpatient prescription drug benefit. I am William Fleming, a pharmacist and Vice President of Pharmacy and Clinical Integration for Humana Inc. Humana is headquartered in Louisville, Kentucky. For more than twenty years, Humana has been serving Medicare beneficiaries through health plans that offer affordable, comprehensive health care coverage. We also offer private health plan options through the TRICARE program to military families, both active and retired; we offer plans to government employees through the Federal Employee Health Benefits Program, and, we offer plans to Medicaid recipients in Florida and in Puerto Rico. In total, today, we provide medical insurance to approximately 9 million members. We offer coordinated health insurance coverage and related services – through traditional and Internet-based plans to employer groups, government-sponsored plans and individuals.

I am pleased to talk about our participation in the new Medicare Part D prescription drug program. Humana has launched three, new stand-alone Medicare prescription drug plans in every state except Maine, New Hampshire, Alaska and Hawaii, and we are also offering coverage to beneficiaries in Puerto Rico. (Please see Attachment #1 for a description of these plans.) Each of these plans has the same formulary. This formulary contains all of the top 100 prescriptions prescribed for beneficiaries that are covered by Medicare. We have an open formulary, in that all FDA-approved medications covered under Part D are on our drug list.

Today, I look forward to talking to you about the great opportunity this new benefit is for Medicare beneficiaries, especially those who are low-income. This is an extraordinarily important benefit – 24 million Medicare beneficiaries have Medicare-supported prescription drug coverage either through plans or their employers. Tens of thousands of Medicare beneficiaries are enrolling every day, and many people with Medicare are experiencing lower drug costs. While this program is important for Medicare beneficiaries, today I will discuss our experience, including the challenges in program implementation, and, I will discuss some opportunities to improve the program.

OPPORTUNITY FOR MEDICARE BENEFICIARIES

As of January 13, there are more than 13.7 million Medicare beneficiaries who are receiving prescription drug coverage through either stand-alone Part D prescription drug plans or Medicare Advantage health plans. Today, over 2 million Medicare beneficiaries belong to a Humana prescription drug plan or a Medicare Advantage prescription drug plan, including over 600,000 dually-eligible beneficiaries. Over 600,000 of our members have enrolled through the CMS website or our Humana website.

Humana has contracted with more than 53,000 pharmacies, including all major chains, thousands of independent pharmacies, and long-term care pharmacies. We have a co-branded relationship with Wal-Mart to ensure maximum accessibility to beneficiaries, especially those who reside in rural areas. We have preferred arrangements with CVS, Rite Aid, Brooks/Eckerds and Albertsons. Our plans offer mail order, along with low premiums, broad formulary, and comprehensive health education programs. Other plans

have similar goals, and we are hopeful that more Medicare beneficiaries will sign up for this new benefit.

Since January 1, we have processed claims for nearly 8 million prescriptions. I wanted to share some specific success stories describing the true benefits of this new program:

William, from the State of Washington, wrote to our CEO: ". . .I read everything there was to read about the Medicare Rx plan, everything AARP wrote about it and spent hours at the Medicare website. The entire thing was a mystery to me. . .In desperation, I picked a plan that cost about what my drugs cost for a year and enrolled. . .online in late December. I promptly received an acknowledgement letter from Humana and a day or so later, my Humana card. I have used it twice already without any trouble. . .Yesterday I received the Summary of Benefits, Formulary, etc. Your summary of benefits does, in a single page column, what our great government has been unable to do for the last year, explain the plan. Your explanatory materials are complete, to the point, and easy to understand. . ." (For this beneficiary, we note that all our materials are reviewed by a nationally-recognized expert in beneficiary health literacy prior to submission to CMS for approval to ensure simplicity and ease of understanding by beneficiaries.)

The Idaho Statesman newspaper on January 9 carried a story that included the fact that Elizabeth Trudeau of Mountain Home, a low-income senior, got a prescription filled by showing the pharmacist her letter from Humana (she had not received her card yet) and was satisfied with her experience.

And from the Bloomington, IN, Herald Times, a retiree, Jack Tosti, is "ecstatic about his new prescription drug benefit. . . .Tosti said he used to pay $300 to $500 a month for several prescription medications and now—after having signed up for a Humana plan. . .he pays less than $50 a month for the same drugs. . ." 'I am as dumb as a box of rocks, but I went to Sam's Club and a guy explained it to me in 20 minutes. . .I wish people would stop whining and complaining. If they keep it up, the government might mess with the program and that would hurt me. . . .'"

For most beneficiaries and their families or caregivers, including low-income seniors, those with chronic diseases and those who are nursing home residents, this new prescription drug benefit provides savings and coverage relief. We hope that Congress works through the challenges presented these first 39 days of the program.

IMPLEMENTATION CHALLENGES

Humana and other Part D plans began preparing for implementation since enactment of the Medicare Modernization Act. In our case, planning and staffing were based on historical data we have acquired during more than 20 years of government program contracting. We increased the data drawn from our experience to reflect both increased membership and the unknown variables resulting from sweeping changes to the Medicare program. Our plans included: 1) Creating a consolidated Medicare operation with a dedicated Medicare focus (enrollment, calls and claims); 2) identifying and enhancing our systems, processes and procedures to support increased membership and new products; 3) increasing customer service staff from 210 in August to 975 employees

today—a 450% increase (customer service calls flow through two Humana call centers in Louisville, KY and Tampa, FL as well as through two U.S. call center contractors;

4) using outside contractors to help us respond to variations in staffing needs; and

5) developing detailed contingency plans for potential problems.

The Centers for Medicare & Medicaid Services (CMS) converted to a new information management system in November shortly before the launch of the annual enrollment period. CMS required PDP sponsors to test connectivity; CMS did not test end-to-end processing of file transmissions to CMS from PDP sponsors and vice-versa. Humana created its own test files following the file formats that CMS documented for each process to ensure we could process the new data files. Since we were unable to test our new files prior to production, changes had to be made after the program began. At the outset, we experienced errors in our pricing files and CMS provided immediate technical assistance. Additionally, there were, and continue to be, data issues surrounding subsidized beneficiaries.

The Part D program marks the first time that a new benefit under the Medicare program offers differing levels of subsidies to individuals based on income, institutional status and Medicaid eligibility. All of us have had to rely on data transmissions from various state and federal agencies to identify those beneficiaries who are dually-eligible or who qualify for a low-income subsidy or state pharmacy assistance wrap-around program benefits. CMS has had to rely on states' information, information from the Social Security Administration and internal information to reach out to low-income beneficiaries. This has proven to be quite a challenge since data is collected in various forms. Once the data is transmitted to CMS, it must flow to plan sponsors and other CMS vendors, who, in

turn, transmit that data to their vendors for pharmacies and others to process claims. Because of these data translation issues, many dually-eligible and low-income beneficiaries have experienced access to care issues. These issues increased both the volume of customer service calls and the length of each call. And, as previously noted, these issues caused us to have to reformat and or re-process data files once we received the information, causing processing delays.

CMS has been extremely responsive and has diligently worked with PDP sponsors to expeditiously resolve these and other program challenges, including access to care issues, predominantly driven by eligibility and subsidy data for dually-eligible and low-income seniors. When it became apparent that more needed to be done, we, along with all the other plans, worked with CMS to strengthen transitional policies to ensure that enrollees in our plans, including dual-eligibles and low-income seniors, receive their medications on a timely basis.

Understanding the potential impact of these and other start-up issues, we implemented an outreach strategy designed to address implementation challenges. We reached out to pharmacists, physicians, long-term care facilities, beneficiaries, community leaders, beneficiary counseling programs and CMS partners and various, related trade associations to educate those groups on pathways to smoother transition and to ensure program implementation barriers continue to be identified and addressed.

Largely due to data translation issues, but also related to benefit questions and administrative problems we encountered, we expanded our call center capabilities. In January, we experienced 40 calls per thousand members—50% higher than expected. The same situation occurred with respect to average length of calls. The actual call

length was 30% longer than expected. The combination of the volume of calls and the length of calls led to our implementing our contingency plans: we trained and moved staff from other areas of our service operations; we extended overtime hours; we prioritized calls related to access to care and eligibility issues; and, we used innovations in voice technology, including inbound call-messaging that contained answers to frequently-asked questions and other routine issues. Our call volume has decreased over the month as members' eligibility issues have been resolved and they have begun to understand and use their benefits. However, end-of-the-month enrollments for the next month caused initial February call volumes to increase due to eligibility issues. This week those volumes should also abate.

Let me talk about some specific implementation issues and how we and our partner, CMS, have worked together to address the issues outlined above:

Beneficiary eligibility information

As mentioned, there have been challenges in identifying dually-eligible beneficiaries and in determining eligibility for beneficiaries who qualify for low-income subsidies. The systems and standards used to transmit this data vary and cause end-users to experience data translation issues. (This is a key reason why Humana urges Congress to swiftly enact legislation that establishes a uniform interoperable health information system.) As an example of a work-around to a data translation issue, Humana noted that many pharmacies were having difficulty accessing the CMS eligibility system to determine member eligibility. Partnering with our claims processor, Argus, we built a "look-alike" telephonic system that replicates the eligibility system delivered via the TrOOP

Facilitator hired by CMS. Our system ensures that pharmacies receive real-time verification of eligibility and coverage at no cost and allows beneficiaries to receive their medications.

Pharmacy outreach

As discussed, Humana set out to develop a strong network of pharmacies--over 53,000 in total--including thousands of independent pharmacies. In fact, in some states, like my own, we have more independent pharmacies contracted than retail chains. We have established special call lines for pharmacists with real-time IVR messages to speed problem resolution or contact with live representatives. We issue regular pharmacy bulletins to all contracted pharmacies, long-term care pharmacies and pharmacy trade associations. We've fax-blasted 11 bulletins to date. State pharmacy associations are posting these bulletins on their web sites. We've reached out to 9 national pharmacy associations, 46 state pharmacy associations (all states in which we do business) and offered to participate in open door calls responding to local pharmacists' questions. We're working through calls to the top 50 pharmacies that fill our members' prescriptions in each state, and will have completed this initiative in 14 states, representing nearly 2/3rds of our prescription volume, by the end of this week.

We understand the need of all pharmacies, but especially independent pharmacies to be paid promptly. We pay pharmacies every 10 days and to date, have made three such payments totally over $330 million. Finally, we are working with our claims processor, Argus, to see if we can begin the process of paying pharmacies electronically, allowing physicians and pharmacies to refill online and perform other manual functions, electronically.

Finally, we are working through our trade association to try to standardize some of the forms and codes that we require pharmacies to use. We believe that this type of standardization can relieve pharmacies, especially independent pharmacies, of unnecessary administrative burdens, increase productivity and lower costs.

Transitional Policies

As CMS continues to work hard to address underlying systems issues, we understand that other Part D plans across the nation are taking strong measures – much like Humana – to promote a smooth transition for beneficiaries. For example, to meet the needs of the most vulnerable beneficiaries, sponsors have implemented expedited procedures and expanded teams of customer service representatives to ensure that dually-eligible and low-income beneficiaries receive the benefits to which they are entitled, including cost sharing support. Sponsors worked with CMS to develop transitional policies which include initial coverage for covered Part D drugs beneficiaries have been taking that otherwise would be subject to formulary rules. In addition, sponsors are working to ensure that beneficiaries and their providers have the opportunity to pursue exceptions before formulary rules take full effect. We have added transition periods to our agreements with CMS to smoothly move toward full implementation. These transitional policies are especially important for dually-eligible and low-income subsidy beneficiaries.

Let me describe Humana's transition policy:

- On January 1, 2006, Humana's transition policy provided for 30 day coverage of current prescription of a Part D covered drug for enrollees to consult their physician. As part of this policy, Humana sends a weekly letter to affected

beneficiaries providing them with information to share with their physicians to smooth the transition process the next time they need a refill.

- Long-term care facility residents receive coverage for 90-days.
- On January 26, 2006, Humana extended the transition period to 60 days from date of enrollment and long-term care facility residents continue to receive a 90-day transition period from date of enrollment.
- Last week, CMS announced that all sponsors must offer a 90-day transition period through March 31, 2006 for beneficiaries effective January 1; a 60-day transition period for beneficiaries effective February 1 and a 30-day transition period for beneficiaries effective March 1.
- Humana intends to maintain our more liberal transition policy as well as ensure that our members who enrolled on January 1 receive a 90-day transition period through March 31.

Call Center Staffing and Service Improvements

I've described above our increased staffing plans due to call volume and length of calls. Since August, we have increased call center workforce to more than 1,125 full-time employees (FTEs) who are dedicated to calls from beneficiaries, pharmacies and physicians. Over the next few months, that number will continue to grow as new service representatives complete training.

Our ability to effectively increase our call center staffing is tied to our ability to have well-trained staff. We require a minimum of 6 weeks of training for customer service representatives who respond to calls from members to ensure customer satisfaction. Representatives are expected to possess expertise in their professional area and are

trained to communicate with the Medicare population, understand the rules of the Medicare program, and fully understand our benefit and plan design.

We believe that increased call volumes are related to three issues: 1) beneficiary understanding of his/her Part D benefit and how it works; 2) data transmission issues with CMS related to eligibility; and 3) Humana administrative issues we encountered with beneficiary mailings and duplicate issuance of ID cards.

Part D is a new benefit for beneficiaries, and it will take some time for beneficiaries to understand how to use the benefit. While some calls are related to what benefits are covered and at what cost, the greatest number of calls have been from beneficiaries who are either dually-eligible or qualify for low-income subsidies. We have been working with CMS to resolve these issues and believe that issues relating to dual-eligibles have been largely resolved. We are working to resolve remaining low-income subsidy level data issues. We believe these issues will soon be resolved. We note that end-of-the-month enrollments will continue to cause a slight delay in entering subsidy information into the system.

Let me briefly describe the various call center phone lines we have in place and what we are doing to respond to the high usage of these lines:

Pharmacy call lines – Our claims processor, Argus, runs our Pharmacy Help Desk and responds to calls from pharmacies. These call lines, available 24 x 7, are equipped with both interactive voice technology for routine questions and live representatives to answer specific questions.

Physician call lines – We have a clinical hot line in place to assist physicians with coverage criteria, exceptions or authorizations. Over 30 percent of the calls

from physicians and pharmacists to this line concern whether a drug is covered under Part B versus Part D.

Beneficiary call lines – As discussed, we have increased FTEs to respond to requests by Medicare beneficiaries and have also implemented interactive voice technology if a beneficiary has a routine question that can be responded to quickly. As previously mentioned, we are adding staff as quickly as possible, ensuring that each person is adequately trained. We have separated our call lines in such a way that access to care and eligibility calls are first priority. During the last weeks of January, we averaged about 42,000 unique calls per day on our pharmacy and customer service lines. And, Humana's website, www.humana-medicare.com, received 500,000 hits per day from beneficiaries and their families seeking information on lower cost alternatives and drug information.

Like Humana, many Part D plans have added additional staff to handle the high volume of pharmacist calls during the start-up period. At the same time, plans have extended the hours of their customer service lines and have conducted outreach activities to ensure that pharmacists' questions are answered promptly.

BENEFIT PACKAGES IN THE PART D PROGRAM

We have provided each member of the Senate Finance Committee with the Part D prescription drug plans that Humana offers Medicare beneficiaries in your state. In addition, we have attached to this testimony our three general designs: *Standard*, *Enhanced*, and *Complete* coverage. These three designs offer Medicare beneficiaries with choices of premium and benefit coverage, and we worked to make these options easier to understand. The benefit structure in the law can be complicated, and all PDP

sponsors have worked to structure what they believe is best for Medicare beneficiaries. For example, Medicare beneficiaries have options in every state to select a plan that provides coverage during the coverage gap. We, too, offer such a plan.

One important development is that beneficiary premiums are much lower than Congress originally anticipated. According to CMS, the average premium for all prescription drug plans nationwide is $32.20 per month[1] – more than 15 percent lower than the $38 monthly premiums that were projected at the time the bill was enacted. Overall, beneficiaries in 49 states (all but Alaska) have Part D options with monthly premiums of less than $20. Humana offers plans below $20 in the states in which we operate, and as low as $1.87 for our Standard Plan in the region that includes Montana, North Dakota, South Dakota, Wyoming, Iowa, Minnesota and Nebraska. In addition, many plans have deductibles below the $250 maximum standard, including 58 percent of all stand-alone prescription drug plans that offer zero deductibles.[2]

Humana and other Part D prescription drug plans can offer quality coverage that is affordable to beneficiaries, because we have developed tools and techniques to reduce out-of-pocket costs for beneficiaries, improve quality by reducing medication errors and encourage clinically-appropriate drug use.

With regard to coverage of drugs, Humana made a business decision to have a single, broad formulary that covers all top 100 drugs used by seniors that are not excluded by the Part D requirements. The excluded drugs are those that are statutorily excluded from coverage, like benzodiazepines. We negotiate with drug manufacturers to receive the best price for covered prescription drugs. Besides making it simple for beneficiaries,

---

[1] CMS Press Release, August 29, 2005, Medicare Drug Plans Offer Premiums of $20 Per Month or Less Lower Deductibles, Enhanced Coverage Also Available.
[2] AHIP analysis of CMS data, November 2005.

physicians and pharmacists, we have early indications that our single formulary strategy may result in additional program efficiencies. At the same time, when a generic product is approved by the Food and Drug Administration, we make that product available to our beneficiaries. To ensure appropriate utilization, we have adopted four primary tiers for coverage of drugs, and have only adopted prior authorization (or step therapy) for a small number of drug categories, including proton pump inhibitors and Cox2 inhibitors. In addition, we have protections in place for certain categories of drugs, including monitoring the quantity of drug product dispensed on a monthly basis (i.e. dispensing limits).

A number of studies demonstrate that these strategies are highly effective in making prescription drugs more affordable for consumers. For example:

- A 2003 Lewin Group study[3] for the Center for Health Care Strategies found that Medicaid managed care plans reduced prescription drug costs by 15 percent below the level states would otherwise have experienced under Medicaid fee-for-service.
- In addition, the Government Accountability Office (GAO) has reported[4] that pharmacy benefit management techniques used by health plans in the Federal Employees Health Benefits Program (FEHBP) resulted in savings of 18 percent for brand-name drugs and 47 percent for generic drugs, compared to the average cash price customers would pay at retail pharmacies.

---

[3] Center for Health Care Strategies, January 2003, Comparison of Medicaid Pharmacy Costs and Usage Between the Fee-for-Service and Capitated Setting.

[4] Government Accountability Office, January 2003, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees, and Pharmacies (GAO-03-196).

These findings clearly demonstrate that the private sector has a strong track record of using its experience and capabilities to deliver affordable prescription drug benefits. At a time when federal resources are severely strained, it is important for policymakers to recognize the ability of health insurance plans to implement strategies that are enabling Medicare beneficiaries to receive the greatest possible value for the dollars the Medicare program is spending on their prescription drug coverage.

OPPORTUNITIES FOR IMPROVEMENT

There are many operational "lessons learned" about the complexity of offering a freestanding Part D prescription drug benefit to Medicare beneficiaries. I offer the following suggestions as to where we believe policy improvements can be made:

1. **Part B versus Part D drug coverage**. This is an enormous source of confusion for Part D sponsors, employer plans, pharmacies, physicians and beneficiaries. The same drug may be covered under Part B or Part D depending on the place of treatment or diagnosis. This means that Part D sponsors must evaluate each potential Part B coverable drug for whether it is Part B or Part D. Let me give you three examples:

   Medicare beneficiary with diabetes: The prescription products that this beneficiary need include a glucose monitor, a lancet, test strips, insulin, syringes, and alcohol swabs. The glucose monitor, lancet and test strip are all billed under Part B and subject to a 20% copayment. The insulin, syringes, and alcohol swabs are billed under Part D and subject to whatever the beneficiary's copayment requires.

Beneficiary taking prednisone: If an enrollee of a PDP plan is prescribed prednisone, then Humana must determine the diagnosis of the patient. If it is used following a Medicare-approved transplantation (e.g. kidney transplant), then this drug is covered under Part B and subject to a 20% copayment. If it is prescribed for anything else, it is covered under Part D. This product is a good example of a larger problem: that is, the administrative complexity of covering drugs in both Part B and Part D adds unnecessary costs and confusion into the system.

Beneficiary who is in a skilled nursing facility: Plans have received calls from nursing homes related to certain nursing home residents and their prescription drug coverage. Upon examination of these issues, we found that many were related to inhalation drugs. In the ambulatory population, these drugs are covered under Part B; however, in skilled nursing facilities, these drugs are now covered under Part D.

This confusion and concern over Parts B and D is a problem for Medicare beneficiaries who will be frustrated; a problem for PDPs who are working through the coverage criteria; and a problem for pharmacies that may have little experience in dispensing Part B products. CMS is working through some short and long-term approaches to clarify coverage under Part B and D; however, Congress needs to be mindful of the legal and technical issues we face.

2. **Enrollment timeframes**. The law and regulations permit Medicare beneficiaries to enroll or change enrollment up to the last day of the month with an effective date the first day of the following month. If a Medicare beneficiary enrolls in a plan on January 31, it is difficult, even with the most efficient systems, to have

that election effective on February 1. Humana is currently making outbound calls to beneficiaries who enroll at the end of the month, giving them directions on how to handle pharmacy needs the first of the next month. We also post such information on our web site. Through our trade association, we are working with CMS on alternatives.

3. **Reconciliation issues**. Along with our trade association, Humana and other sponsors are working with CMS to reconcile issues including coverage and beneficiary financial accumulators (such as true out-of-pocket costs and prescription drug costs). We're working with CMS to reconcile issues with states as it relates to low-income beneficiaries and we're working with CMS and other plan sponsors to reconcile issues as a result of beneficiaries switching plans and with other government agencies, including CMS.

While these policy areas are being examined, Humana will be taking additional steps to improve our service to our stakeholders using advanced call technology and website development.

CONCLUSION

Thank you again for giving me the opportunity to testify about this important new benefit for Medicare beneficiaries. Over the past 39 days, Humana has filled over 8 million prescriptions for Medicare beneficiaries. We have heard good stories about Medicare beneficiaries reducing their overall costs for prescription drugs. While CMS and all the plans have experienced operational challenges that include data translation issues and the need for more staffing than anyone ever anticipated, we have all reached out to our partners – pharmacists, physicians, long-term care

facilities, state and federal agencies and their partners as well as senior advocacy groups – to work in transitioning to a fully implemented new part D program. I encourage you to be vigilant in monitoring issues that affect your constituents and evaluate which of those issues need system-wide regulatory or implementation changes, versus case-by-case improvements. This program, the first major change in Medicare in over 40 years, has been operating for 39 days. While the first 39 days have had significant issues for some of our most vulnerable beneficiaries, operational and system fixes are in process and have our immediate attention. We urge you to give this program time to improve and to give beneficiaries time to adjust to a new benefit. We know from our initial experience that once a beneficiary has used his/her card, the process begins to work. Part D is an important benefit that Medicare beneficiaries need and want. We commend Congress for establishing this program, and we urge the Committee to support the program, ensure consistency and stabilization while recognizing the tremendous value it is providing to millions of Medicare beneficiaries across the nation.

DETAILS of Humana's Prescription Drug Plans

Costs and benefits of each plan

		Standard Plan $1.87 - $17.91 (range of monthly plan premium)	Enhanced Plan $4.91 - $25.36 (range of monthly plan premium)	Complete Plan $38.70 - $73.17 (range of monthly plan premium)
STAGE 1	YOU PAY	$250 deductible	Copayments until **total drug costs** reach **$250**: ▪Generics.....$0 ▪Preferred.....$30 ▪Non-preferred....$60 ▪Specialty.....25% coinsurance	Copayments until **total drug costs** reach **$250**: ▪Generics.....$0 ▪Preferred.....$30 ▪Non-preferred....$60 ▪Specialty.....25% coinsurance
	Humana pays	$0	Balance of costs	Balance of costs
STAGE 2	YOU PAY	25% of next $2,000 of total drug costs (= **$500**)	Copayments until **total drug costs** reach **$2000**: ▪Generics.....$7 ▪Preferred.....$30 ▪Non-preferred....$60 ▪Specialty.....25% coinsurance	Copayments until **out-of-pocket costs** reach **$2000**: ▪Generics.....$7 ▪Preferred.....$30 ▪Non-preferred....$60 ▪Specialty.....25% coinsurance
	Humana pays	75% ($1,500)	Balance of costs	Balance of costs
STAGE 3	YOU PAY	Next **$2,850** of total drug costs. (This brings your total out-of-pocket costs to $3,600) **This is the coverage gap**	Next **$2,850** of total drug costs. (This brings your total out-of-pocket costs to $3,600) **This is the coverage gap**	Copayments until your total **out-of-pocket costs** reach **$3,600:** ▪Generics.....$7 ▪Preferred.....$30 ▪Non-preferred....$60 ▪Specialty.....25% coinsurance **NO COVERAGE GAP**
	Humana pays	*$0*	*$0*	Balance of costs
STAGE 4	YOU PAY	5% of total drug costs for the rest of the year	5% of total drug costs for the rest of the year	5% of total drug costs for the rest of the year
	Humana pays	95% of total drug costs for the rest of the year[1]	95% of total drug costs for the rest of the year[1]	95% of total drug costs for the rest of the year[1]

(1) Member pays the greater of $2 for generic or a preferred drug that is a multiple source drug and $5 for all other drugs, or 5% coinsurance.

U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

Opening Statement of Sen. Chuck Grassley
Hearing, "Implementing of the Medicare Prescription Drug Benefit"
Wednesday, February 8, 2006

Today's hearing is on the implementation of the Medicare prescription drug benefit. I'd like to be able to say that the implementation has gone smoothly. But as we all know, it hasn't, especially for some of our nation's most frail and neediest beneficiaries. These beneficiaries – the dual eligibles – were transitioned from Medicaid to Medicare prescription drug coverage. Computer and information problems resulted in some beneficiaries being charged much higher cost-sharing. Some beneficiaries could not get their drugs. Pharmacists have had difficulty in getting through to plans. Many pharmacists filled prescriptions or gave emergency supplies and they are now waiting for payment. Some plan representatives have been unable to answer important questions, like which plan someone is enrolled in. Some beneficiaries didn't receive their cards or, in some cases, they got two!
States stepped in to pay for prescription drugs.

All of those situations are unacceptable. We need to fix those problems and fix them fast. And by all accounts -- CMS, the plans, the pharmacists, and others -- are working to do just that. On the problems faced by dual beneficiaries, we knew the transition to Medicare wouldn't be easy. During development of the bill, the Finance Committee thought long and hard about switching Medicaid coverage to Medicare. We considered the challenges that these beneficiaries face. They are frail; they have other impairments. Change can be disruptive for them. And frankly, in the end, the Finance Committee bill in 2003 called for these beneficiaries to continue their coverage under Medicaid – under a program that they knew.

But there were many folks on the other side of the aisle and in the House of Representatives who wanted to convert their coverage from Medicaid to Medicare. I appreciate that view. But we were very concerned about these transition issues. We knew it was bound to be problematic. The Senate debated this issue in June 2003. There was an amendment on the Senate floor to have dual eligibles' prescriptions covered by Medicare. That amendment failed by a vote of 47 to 51. But as we all know, the conference agreement called for the transition of dual eligible beneficiaries into Medicare.

So that's all just history now. And here we are. Don't get me wrong. I'm not happy that things haven't gone as well as they should have. But I find it a little disingenuous that folks who seemingly got what they wanted are now upset about it! Everyone knew full well that transitioning the duals could not be perfect and problems would be inevitable. And I know what the response will be. It will be, "yes, we wanted the duals in Medicare, but we would have handled the transition differently." I won't even try to respond to that. There is no response. It is very easy to sit up here and say, "well, I would have done a better job." My goal is not to assign blame and point fingers. But I do think that it's important that the record reflect the events that

led to this point. The history is part of the record. But it's time to move on. Now is not the time to make excuses. We need to have productive conversations and decisive actions to correct the recent shortcomings.

While there's clearly more to be done, progress has been made in the past few weeks. Secretary Leavitt and Administrator McClellan met with members of the Finance Committee two weeks ago. Dr. McClellan's testimony will follow up on some of the questions raised by members during that meeting. The Administration has ramped up call center capacity and created a dedicated phone line for pharmacists. They've required plans to extend their transition fill policies to ninety days. They created a process for states to be reimbursed for costs incurred during the transition. I might add that all of these actions were taken administratively – no legislation was needed.

As I said, this is good progress, but I'm not going to let up on this until it's crystal clear that the agency has gotten the start-up issues under control. This Committee has a tremendous responsibility to Medicare beneficiaries. We have a tremendous responsibility to taxpayers. I take those responsibilities with the utmost seriousness. I'll do whatever else we need to make sure that the problems are resolved. We need to become better informed about the true nature of the problems. That's has been happening over the past few weeks. Today's hearing will help us continue to do that so that we take appropriate actions. We have people who are on the front lines of implementing the benefit and helping beneficiaries to enroll. In addition to Dr. McClellan, we have representatives of two prescription drug plans, Humana and Wellpoint. Mr. Bernauer and Mr. Schule represent chain and independent pharmacists. Ms. Paeth and Mrs. Willoughby have been helping beneficiaries learn about the benefit and enroll. I look forward to hearing their testimony and to having a productive dialogue with all of our witnesses.

Senate Finance Committee
"Implementation of the New Medicare Drug Benefit"

Statement of U.S. 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. 38% of them have a cognitive or mental impairment. Over a third of them are disabled. Less than 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, diabetes, 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 uninformed 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. Arkansas has already spent over $3.8 million, covering 17,000 people.

These problems could have been avoided. And 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 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.

TESTIMONY OF

MARK B. McCLELLAN, M.D., Ph.D.

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

BEFORE THE

SENATE COMMITTEE ON FINANCE

HEARING ON

IMPLEMENTATION OF THE

NEW MEDICARE PRESCRIPTION DRUG BENEFIT

FEBRUARY 8, 2006

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of
Mark B. McClellan, MD, Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Before the Senate Finance Committee
Hearing on Implementation of the New Medicare Prescription Drug Benefit
February 8, 2006

Chairman Grassley, Senator Baucus, 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.

According to CMS' Office of the Actuary, Medicare's drug coverage will have significantly lower premiums and lower costs to federal taxpayers and states, as a result of stronger than expected competition in the prescription drug market. Moreover, beneficiary premiums are now expected to average $25 a month – down from the $37 projected in last July's budget estimates. The Federal government is now projected to spend about 20 percent less per person in 2006 and, over the next five years, payments are projected to be more than ten percent lower than first estimated, so taxpayers will see significant savings. And state contributions for a portion of Medicare drug costs for beneficiaries who are in both Medicaid and Medicare will be about 25 percent lower over the next decade. All these savings result from lower expected costs per beneficiary; projected enrollment in the drug benefit has not changed significantly.

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 his Medicaid patients about which prescription he couldn't fill completely because of Medicaid coverage limits.

Pharmacies have, though, had difficulty filling prescriptions for certain beneficiaries eligible for both Medicare and Medicaid (dual eligibles), and some states have turned their state billing systems back on to help cover medications needed in these situations. We have put in place a demonstration project to reimburse states for the direct and administrative costs they have incurred since the initiation of the drug benefit, in temporarily filling this coverage gap for dual eligibles transitioning from Medicaid to Medicare drug coverage and are working with them to fully resolve this issue. As part of this demonstration, CMS will reconcile with the drug plans to ensure that they pay for covered drugs.

Many reports from people who are getting their drugs under the new prescription drug benefit, however, 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 percent 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 percent. Tell me I didn't get a good deal..."[1]

---

1 *Wall Street Journal,* January 11, 2006, http://online.wsj.com/article/SB113684922094842048-search.html?KEYWORDS=medicare&COLLECTION=wsjie/6month.

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.

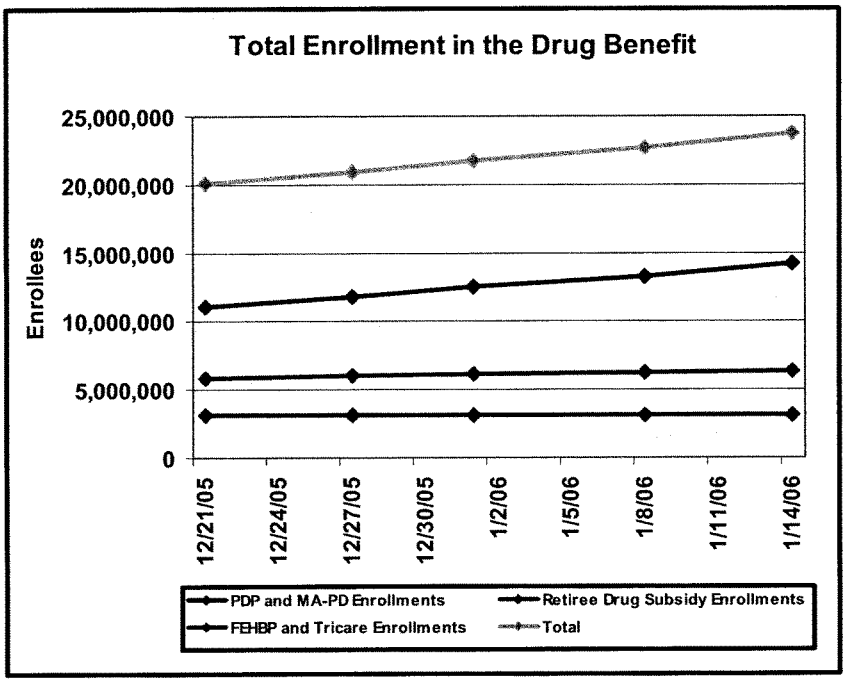


Figure 1: Enrollment in Medicare Prescription Drug Benefit, Medicare Advantage-PDPs, and the Retiree Drug Subsidy.[2, 3]

Between mid-December and mid-January, 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

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.

additional 4.5 million individuals, including 600,000 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. Tens of thousands of beneficiaries continue to enroll every day.

CMS Works to Resolve Start-up Challenges

We are fully focused on resolving the difficulties that some beneficiaries have had in initiating their new Medicare coverage, especially those transferring from state Medicaid drug coverage. Adding a benefit as significant as the new Medicare prescription drug program, involves some start-up challenges. Our problem-solving activities fall into several key categories including:

1. transition of dual eligible individuals and late enrollees
2. data transmission issues,
3. customer service,
4. pharmacy support,
5. State reimbursement issues, and
6. compliance issues.

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. Since the beginning of the year CMS has taken the following key actions to address our implementation challenges.

1. We have worked closely with the plans and our partners to get plan and enrollment information to dual eligible individuals who have not yet received complete

information about their drug plan. Also we have transmitted information on dual and low-income subsidy eligible individuals to the plans so that they have correct information. We have encouraged this population to enroll, or make plan changes early in the month so that their information is available in plan and CMS systems on the first of the next month when they go to a pharmacy to obtain their medications,

2. We are improving our data systems and collaborating with plans and states to ensure smooth and complete data transmissions between ourselves, plans, and the states.
3. To ensure no one – whether a pharmacist, a beneficiary, or a doctor – has to wait on the phone to get help when seeking information on their coverage, we have strengthened our 1-800-MEDICARE call center and pharmacy helpline, and have taken steps to promote better call center performance by the drug plans as well. We are tracking how plans respond to requests for assistance on their customer and provider help lines and while many have already done so effectively, we expect all plans to get their wait times down to appropriate levels.
4. We have conducted numerous outreach events with pharmacists, included them in workgroups to resolve implementation problems, and worked with plans so that pharmacists get correct information and coverage decisions with regard to dispensing transitional supplies of medications. Pharmacists are working hard to meet the demands of new enrollees in a new system and we have provided them with a new E1 eligibility computer tool to help them find enrollment information more quickly. We have provided them with a way to provide drugs for dual eligible individuals who are not in the computer system at the pharmacy counter through WellPoint.
5. We have worked with those States that have taken steps to help their dual eligibles by using their State payment system to pay pharmacies. These states are paying for prescriptions that should be paid for by the drug plans and they need to be reimbursed for their costs. We have worked with States to identify approaches that minimize the number of claims paid for through their State billing system and we have established a demonstration project to reconcile State payments with plan obligations. We will pay for the difference between State and plan payments, as well as administrative costs.

6. While most plans are complying with the requirements set forth in their contracts, we will use the full array of administrative tools and other enforcement remedies to ensure plans live up to the terms of their contracts. We have made it clear to plans that they need to provide adequate supplies of transitional medications and work on their data transmission issues with pharmacies.

As a result of these and other efforts, which we describe in more detail below, we are not seeing nearly the extent of start of the month issues as we did in January. We are seeing improvements on a daily basis as more people with Medicare receive their enrollment confirmations and their personal information is available in CMS' databases, which allows easy payment for their prescriptions. However, despite these efforts, we are very concerned that some people with Medicare have had difficulty accessing their drug coverage for the first time, in particular certain dual eligible beneficiaries with Medicare and Medicaid. These problems generally do not occur for people who completed their enrollment well in advance of the beginning of the month and received their drug benefit card before filling any prescriptions. Additionally, many of these initial problems have been relatively 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."[4] After people use the system once, these initial problems that some beneficiaries have faced do not recur.

We have been most concerned about helping dual eligible individuals use the new Medicare benefit. While the vast majority of the more than 6 million full benefit dual eligible individuals have already begun to use Medicare drug coverage, certain of these full benefit dual eligible individuals have had initial difficulties. In particular, the small number of full benefit dual eligible beneficiaries who switched plans towards the end of 2005 after their

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

initial auto-enrollment did not have complete information available on their new plan's coverage in early January. In addition, information transfers among states, CMS, and plans did not occur perfectly for all beneficiaries who changed plans. CMS is committed to ensuring that all beneficiaries receive their needed prescription drugs, and as outlined below, is taking steps, in conjunction with States to assure this happens.

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.

As a result of our successful outreach efforts, we experienced a substantial surge in enrollment at the end of the year and many full benefit dual eligible individuals elected 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.

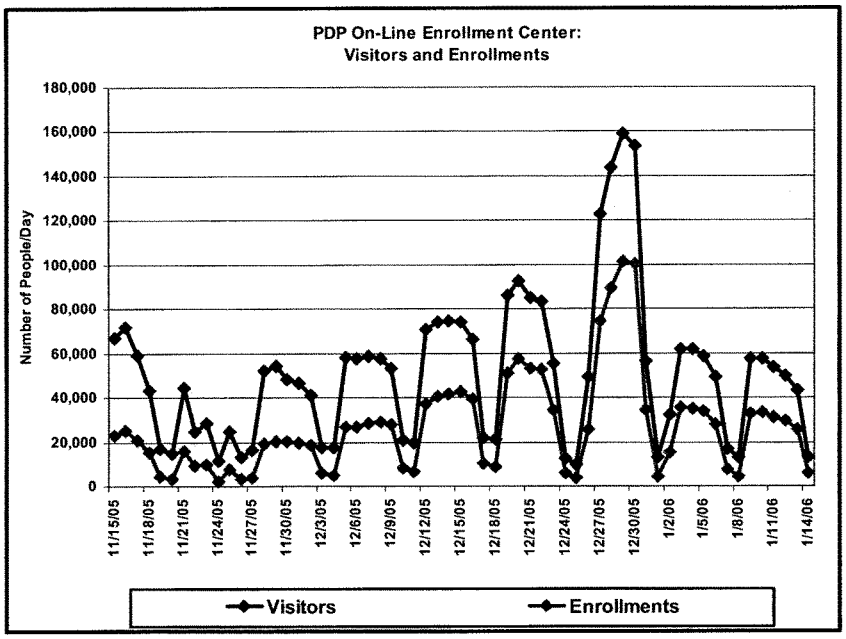


Figure 2: Prescription Drug Plan On-Line Visitors and Enrollments[5]

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 taken many steps and partners to get to where we are today.

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

5 Cyclical weekly low points are Saturdays and Sundays

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 application process for low-income beneficiaries who are not dual eligible individuals to apply for assistance with their drug costs;
- train, educate, and conduct outreach in a coordinated fashion;
- develop a process to auto-enroll every full benefit 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 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' full benefit dual eligible residents. These validation data matches achieved rates of over 99 percent for all States, according to an independent evaluation completed in the fall of 2005.

CMS Automatically Enrolled Full Benefit 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 full benefit 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 full benefit 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 work toward 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 – costs borne by the enrollee) 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 All Individuals

CMS required each Medicare prescription drug plan to establish an appropriate transition plan for all new enrollees. 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 within 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 Toward Achieving 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. A majority of individuals in long term care facilities are Medicare beneficiaries, many of them are dual eligible. 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 full benefit 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 without premiums and 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 to accommodate the needs of Medicare beneficiaries residing in long-term care facilities. 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 efforts included, for example, a three pronged approach for ensuring that nursing home residents who are in the process of spending down their assets to qualify for Medicaid, 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 relevant 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 full benefit 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 on a daily basis 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 full benefit 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 full benefit 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 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.

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 there was a previously described group of dual eligible individuals who had difficulty when they initially used their drug coverage. In addition, CMS has taken steps to address other issues that have arisen with the implementation of the drug benefit. These issues are being resolved as rapidly as we can address them and we are encouraged by the responses from the plans, pharmacies, and States who are working with us in these efforts. Meanwhile, millions of people with Medicare, who previously had no coverage at all, now have significant help, and many who had coverage through a State or employer plan, now have enhanced coverage.

CMS Works to Ensure 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 their 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. This occurs anytime someone enrolls in a new health insurance plan or changes plans, and we want people with Medicare to be aware of this.

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 drug coverage, and to be prepared to wait several weeks to be fully entered into the system and our data show that message is getting through. In the last half of December, hundreds of thousands of individuals who were auto-enrolled elected a different plan, compared to about 24,000 during the last week of January.

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.

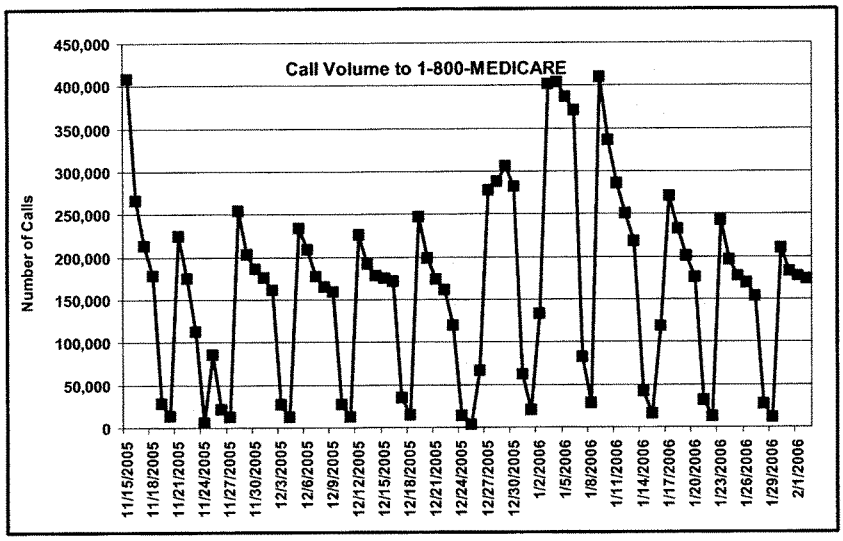


Figure 3: Call Volume to 1-800-Medicare

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 has 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.

CMS 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. CMS also required plans to inform their CSRs about their transition policies and empower them to permit a pharmacy to dispense these drugs. Most recently, we have notified plans, letting them know that the 30 day transitional coverage period would be extended another 60 days, to provide enough medications to their enrollees while implementation challenges are resolved.

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 resolution.

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.

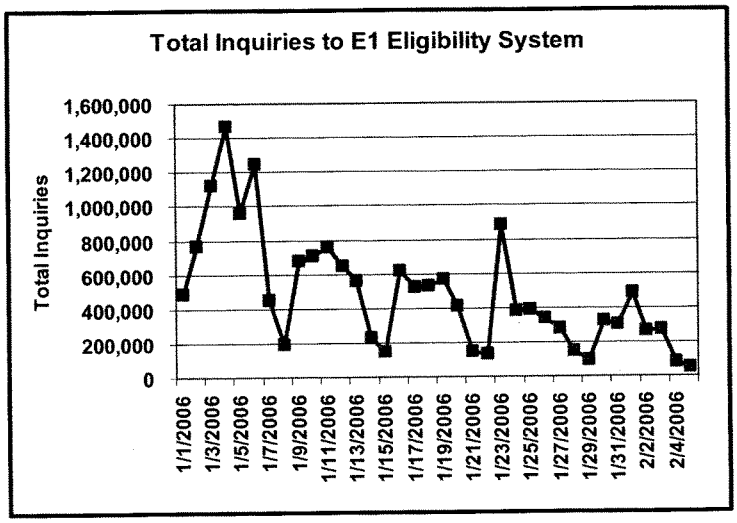


Figure 4: Total Inquiries to E1 Eligibility System

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."[6]

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 and other low-income beneficiaries. 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.

---

6 Winn-Dixie Pharmacist email January 11, 2006

Typically, under Medicaid, pharmacists were paid on a weekly basis. Most of the drug plans use a somewhat longer payment cycle and pharmacists have expressed concern over when they will be paid. We recognize this concern and want to let pharmacists know that we are aware of it. As we look forward to renewing plan's contracts for 2007, a plan's working relationship with its network pharmacies will be an important factor in our assessment of whether the plan has sufficient personnel and systems in place to effectively administer and manage its operations.

CMS continues to hold 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.

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.

In an effort to assist State Health Insurance Assistance Programs (SHIPs) with their backlog of beneficiary calls, CMS created a virtual call center comprised of over 150 staff from CMS, and the Administration on Aging (AoA). CMS and AoA returned thousands of calls to answer beneficiary questions and assist in finding a prescription drug plan to best fit their needs.

CMS Establishes Reimbursement Plan for States that Cover the Cost of Dual Eligible or Low-Income Subsidy Entitled 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 and other low-income subsidy entitled beneficiaries by using their State system of reimbursement to pharmacies. These States are now paying for prescriptions that should be paid for by the prescription drug plans, and, if States have stepped in they will be reimbursed.

On February 2, CMS sent a letter to all state Medicaid Directors, and State Pharmacy Assistance Program Directors to inform them of a new Medicare demonstration project to defray specific costs they have incurred surrounding the implementation of the Medicare prescription drug benefit. Specifically, the demonstration permits Medicare payment to be made to States for costs they have incurred for medications covered under the drug benefit, including transitional supplies, for both dual eligible and low-income subsidy entitled plan enrollee's, to the extend that those costs are not otherwise recoverable from a drug plan and are not the Medicare beneficiary's cost sharing requirement.

Under this demonstration, States will submit to CMS information on claims they paid for dual and low-income subsidy entitled individuals and CMS will work to ensure that prescription drug plans reimburse States for those expenses up to the amount they would otherwise have paid. The Federal government will reimburse States for any differential between plan reimbursement and State payment, as well as for certain administrative costs for paying the State claims and facilitating the correct enrollment of dual and low-income subsidy entitled 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.

The demonstration requires States to make significant progress by February 15, 2006, toward turning off their State reimbursement systems and supporting beneficiaries and pharmacists in using the Medicare prescription drug system, based on best practices identified by the States and CMS.

With input through a State workgroup, CMS developed a template to apply for this demonstration for use by those States. The template was made available on February 2.

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 co-payment.

Under the demonstration, plans, and then Medicare, will 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.

Medicare Prescription Drug Benefit Significantly Less Expensive than Expected

While we are working through the various implementation challenges, it is important that some extremely good news, mentioned earlier, not be overlooked. Robust competition in the prescription drug marketplace has resulted in impressive savings for people who enroll in a drug plan, Federal taxpayers, and the States.

Savings are not coming because enrollment is low. As discussed earlier, we are well on our way to meeting our projected enrollment figures. The savings are coming as a result of lower than expected per-beneficiary costs. Hard data that we now have, not simply estimates, tell us that the average monthly premium will be $25, only 68 percent of the $37 figure we had originally estimated.

The net cost to the Federal government for the drug coverage in 2006 is expected to be $30.5 billion down from a previously estimated $38.1 billion. The actual or "net" costs to the Federal government, accounting for Medicaid savings, are also significantly lower over 10 years, dropping from last year's estimated $737 billion to $678 billion. For the 10-year period from 2006-2015, the "total" Medicare drug benefit cost, without accounting for the Medicaid impact, is now estimated to be about $130 billion less - $797 billion compared to an estimated $926 billion last year.

State government will also see significant savings as a result of lower than expected phased-down contributions for the drug coverage. The state payments are now projected to be $37 billion (27 percent) less over a 10-year period. The Medicare Modernization Act included the phased-down contributions, sometimes known as "clawback" payments, to account for a portion of the costs that states had previously paid for Medicare beneficiaries who are also in Medicaid, because they are now getting their drug coverage from Medicare.

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.

To summarize, as I have laid out above, we are focusing on the following:

- Making sure drug plans have up-to-date information on all their dual eligible beneficiaries;
- Improving the "data translation" between Medicare, health plans, and states;
- Ensuring that calling 1-800-MEDICARE means virtually no wait time;
- Monitoring and reporting call wait times for drug plans;

- Assuring plans meet contractual payment terms for pharmacies;
- Extending transition coverage for a beneficiary's current drugs to 90 days;
- Working to reimburse the States that have turned on their State billing system and to assure a backup system is no longer needed;
- Continuing the process of problem-solving and improvement -- guided by the lessons we've learned

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."[7] 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. We are especially encouraged by the latest figures demonstrating that the projected costs of the new benefit are less than we had anticipated. I would be happy to answer your questions.

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

Senate Committee on Finance Hearing
"Implementation of Medicare Part D"
Answers to Additional Written Questions
Submitted for the Record
Dr. Mark McClellan
February 8, 2006

Senator Grassley

Q. Dr. McClellan, I want to ask you a question about formularies and changes to formularies. All of the plans' formularies had to meet stringent requirements. There's a lot of concern about plans making changes to their formularies after a beneficiary has joined - that there will be a bait and switch approach by some plans. Could you describe to me the process that the Agency will use to review a plan's request to make a formulary change?

A: CMS has clarified its formulary change policy, which applies to changes in specific drugs covered on a plan formulary, changes in prior authorization or tiering. Beneficiaries will not lose coverage for a drug they are using because of a mid-year formulary change, except in the case of changes based on clear scientific and cost reasons, including a new generic drug coming on market, or the availability of new FDA or clinical information.

Senator Baucus

Q1. Tribal leaders have expressed concerns about the many barriers to enrollment in Medicare Part D for Native Americans. Please provide the number of Native Americans who have enrolled in the program to-date, including a breakdown by state, and between Medicare-only and dual-eligible enrollees. Please also describe in detail the steps you have taken to work with Tribes and Indian Health/Tribal pharmacies to reduce or eliminate barriers to enrollment for this population.

A1. CMS is engaged in an ongoing effort to ensure that American Indians and Alaska Natives fully participate and fully enjoy the benefits of the Part D Medicare Benefit. CMS recognizes the particular needs for outreach and training and the local level for this population and the I/T/U system. CMS is fully committed to working with Indian Health Services (IHS) and tribal representatives to ensure that all Medicare eligibles receive the information they need to make informed choices and to reduce their prescription costs and that the I/T/U network is able to bill appropriately and accurately for Medicare services.

Those efforts began with the outreach and education activities Drug Discount Card and Transitional Assistance Program. CMS through an interagency agreement with the IHS conducted 14 training sessions in Indian Country and trained over 700 IHS and tribal staff on the benefit. CMS Central and Regional office staff, IHS staff, and representatives from the two card sponsors, CSC and Express Scripts that received special endorsements to administer the programs in Indian country, presented at each of

the trainings. CMS outreach and training materials, including posters and brochures, were adapted to address the special circumstances of the I/T/U system and American Indian and Alaska Native beneficiaries. CMS has conducted, and continues to sponsor, several Open Door Forums for the AI/AN population and continues to work with the CMS Tribal Technical Advisory Group (TTAG). In addition, CMS maintains a website (http://www.cms.hhs.gov/AIAN/) for the American Indian Alaska Native population. Information about Part D and links to materials and other resources are available on this site. CMS continues to sponsor open door forums on the drug benefit and has participated in several IHS national teleconferences with system users on the implementation process.

CMS is committed to ensuring that the I/T/U system will see the results of our efforts to assure accurate and up to date drug plan information, on dual eligibles, is available; data translation is improved between Medicare, health plans and states; there is responsive service through 1-800 Medicare, measuring and monitoring the plans' customer service and wait times; there is an extension of transitional coverage; and work with the states and the problem-solving process is continued.

CMS has been fully engaged with the American Indian and Alaska Native population during the both the preparation for and the initial phase of the enrollment period through coordinated outreach, education and enrollment activities. CMS is fully committed to continuing this relationship and is confident that the AIAN population will fully benefit from Part D.

CMS currently does not have state-by-state information on the number of Native Americans who have enrolled in the Part D program.

Q2. Your statement specifically noted that "CMS held 2 educational events <u>for pharmacists</u> in Kalispell Montana." Please provide the dates, times, locations and a copy of the notice sent about the educational events for pharmacists held in Kalispell. The events that Tobey Schule referred to in his testimony specifically referred to educational events for pharmacy providers and not for the public at large. Please provide information on the pharmacy provider events only.

A2.

- June 28, 2005 - Train the Trainer Session
  8:30am to 5:00pm
  Kalispell Center Mall (No Flyer available)

- October 27, 2005 - Train the Trainer Session
  8:30 AM to 5:00 PM
  Grouse Mountain Lodge (Invitation included below)

- December 21, 2005 – CMS Conference call for Montana pharmacies

The Denver regional Provider Relations office sent a mailing to 335 Montana Pharmacies. The mailing contained a one page spreadsheet with information on all plans available in Montana, the most recent information on the point of sale process, and the long term care convenient access statement. They also announced an upcoming free 1-800 conference call on December 21, 2005 at 7pm specifically for Montana pharmacists. The call had 29 callers. (Invitation and Agenda included below.)

A Special Invitation

Healthcare Providers, Advocates, Health Care Providers, Advocates and Other Professionals

The Montana Partners for Medicare Advocacy and
The Centers for Medicare and Medicaid Services present

Train the Trainer
Medicare Prescription Drug Coverage Enrollment

Please join us for the newest, no-cost national training program designed to educate and equip professionals who can further educate other professionals in their local area on **Medicare Prescription Drug Coverage, the Plan Finder and enrollment process**.

In this one-day, comprehensive training, attendees will have an opportunity to expand their understanding of the new Medicare Prescription Drug benefit, learn about plans and resources specific to Montana, and see the innovative new Plan Finder web tool. Prior to the training session, you can review the Medicare Prescription Drug Coverage and Plan Finder by linking to:

http://www.cms.hhs.gov/partnerships/ and
http://www.cms.hhs.gov/medicarereform/newcoverage.asp.

Trainings will run from 8:30 a.m. to 5:00 p.m. (lunch on your own), and are scheduled in ten convenient locations throughout Montana. Please **RSVP at 1-800-553-5341** to reserve your place at the training nearest you.

Monday, October 24	Butte
Wednesday, October 26	Missoula
Thursday, October 27	Kalispell
Friday, October 28	Libby
Monday, October 31	Havre
Tuesday, November 1	Great Falls
Wednesday, November 2	Helena
Monday, November 7	Bozeman
Tuesday, November 8	Billings
Wednesday, November 9	Sidney

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Office of the Regional Administrator
Region VIII
1600 Broadway, Suite 700
Denver CO 80202-4967

December 5, 2005

Dear Pharmacist:

The Region VIII Office for the Centers for Medicare & Medicaid Services cordially invites you to join us for our *Medicare Rx Chat With Montana Pharmacists.* This is a toll-free conference call scheduled for Wednesday, December 21, 2005 at 7:00 PM to 8:30 PM Mountain Time. At this call our CMS Region VIII pharmacist, Gary Pulvermacher, RPh, MS, will update you on the latest information on the new Medicare prescription drug coverage that begins January 1, 2006.

We enclosed the agenda and call-in instructions for the *Chat*, as well as materials that cover several topics of interest to pharmacists related to Medicare prescription drug coverage. Please pass all of this information along to your counterparts in the pharmacy community.

If you have any questions regarding this invitation, or specific questions concerning the prescription drug coverage that you would like us to cover on the call, please contact Gail Dize at gail.dize@cms.hhs.gov.

We are looking forward to talking with you about Medicare prescription drug coverage.

Sincerely,

Anne Kane, R.N., M.P.A.
Manager, Medicare Administration Branch

Enclosures

"Medicare Rx Chat With Montana Pharmacists"

A Centers for Medicare & Medicaid Services
Region VIII Toll-Free Conference Call

Agenda

Toll-Free Telephone Number For All Calls: 1-888-455-2535

Audience: Montana Pharmacists
Date/Time: Wednesday, December 21, 2005 at 7:00 PM to 8:30 PM Mountain Time
Passcode: CHATS
Call Leader: Beverly Mendicello

Pre-Registration for this call is NOT required.

Presenter: Gary Pulvermacher, RPh, MS
CMS Region VIII
Phone: 303-844-2760
Email: gary.pulvermacher@cms.hhs.gov

Agenda Topics:

I. **Medicare Drug Plan Finder/Formulary Finder**

II. **Montana Plans**

III. **Point of Sale**

IV. **Marketing Guidelines**

V. **Long Term Care Convenient Access Standard Update**

VI. **Questions and Answer Session**

Q3. Whose responsibility was and is it to educate pharmacists on the availability and operation of E1 and Point of Sale systems, particularly as they could be used to dispense medications to dual eligibles who had problems accessing their Part D benefits?

A3. CMS worked directly with Per-Se Technologies (formerly NDCHealth), pharmacy organizations, software vendors and American Society for Automation in Pharmacy (ASAP) to design, develop and implement the eligibility and TrOOP processing systems. Pharmacies access these systems through dozens of software vendors. As a result, training and instruction for new functionality is system-specific and may have to be customized by individual software vendors. CMS and Per-Se Technologies initiated and have maintained contact with vendors to ensure that they have the necessary information to train on the new systems. CMS also designed and released a training CD for pharmacists. This training is available on the webpage CMS created specifically for pharmacists (www.cms.hhs.gov/pharmacy). In addition, CMS held three national conference calls on January 31, 2006 to provide information and answer questions about the E1 and POS systems.

CMS provided extensive direct outreach to pharmacists specifically about the Point of Sale Facilitated Enrollment (POS FE) solution. Specifically, we released several Medicare Rx Updates, a national press release and placed instructions for its use on (www.cms.hhs.gov/pharmacy). Furthermore, CMS' regional pharmacists traveled the country, giving speeches, participating in panels and disseminating their contact information for any pharmacist with questions.

As the contracted plan, Wellpoint regularly communicates directly with pharmacies regarding the procedures for the POS FE. This communication includes detailed instructions for using the POS FE solution, payment information, an extensive list of FAQs and more. This information is also available on their website (www.anthemprescription.com).

Q4. Since a significant share of pharmacists do not belong to a state or national trade group, what outreach did CMS conduct to directly communicate with pharmacists on the E1 and POS systems? What did CMS require of drug plans to educate pharmacists on the E1 and POS.

A4. CMS worked directly with Per-Se Technologies (formerly NDCHealth), pharmacy organizations, software vendors and American Society for Automation in Pharmacy (ASAP) to design, develop and implement the eligibility and TrOOP processing systems. Pharmacies access these systems through dozens of software vendors. As a result, training and instruction for new functionality is system-specific and may have to be customized by individual software vendors. CMS and Per-Se Technologies initiated and have maintained contact with vendors to ensure that they have the necessary information to train on the new systems. CMS also designed and released a training CD for

pharmacists. This training is available on the webpage CMS created specifically for pharmacists (www.cms.hhs.gov/pharmacy). In addition, CMS held three national conference calls on January 31, 2006 to provide information and answer questions about the E1 and POS systems.

CMS provided extensive direct outreach to pharmacists specifically about the Point of Sale Facilitated Enrollment (POS FE) solution. Specifically, we released several Medicare Rx Updates, a national press release and placed instructions for its use on (www.cms.hhs.gov/pharmacy). Furthermore, CMS' regional pharmacists traveled the country, giving speeches, participating in panels and disseminating their contact information for any pharmacist with questions.

As the contracted plan, Wellpoint regularly communicates directly with pharmacies regarding the procedures for the POS FE. This communication includes detailed instructions for using the POS FE solution, payment information, an extensive list of FAQs and more. This information is also available on their website (www.anthemprescription.com).

Q5. Participation in Part D by safety net pharmacies is a concern that has not received much attention. Some PDP participation contracts specifically exclude 340B pharmacies from being network pharmacies. CMS and HRSA anticipated that safety net pharmacies that participate in the federal 340B drug discount program could have difficulty accepting certain terms and conditions of standard PDP network participation contracts, so they developed the Model Safety Net Pharmacy Addendum.

A5. a. Have you assessed whether PDPs are accepting the Addendum and allowing safety net pharmacies into their Part D provider networks? If so, what have you learned?

Answer: Since the inclusion of safety-net pharmacies in Part D plan networks, as well as use of the addendum is optional, CMS is not tracking this information. It is difficult to identify pharmacies in networks as safety net pharmacies because they are not coded in any way as such (unlike long-term care pharmacies, which have NCPDP "locator" codes that identify them as such).

b. What provision(s) are currently in place to ensure that safety net providers are not being excluded from Part D participation because of their status under the 340B program?

Answer: To date, we have not received any actionable complaints in this area.

c. What additional measures, procedures and/or processes could be undertaken to protect these providers from exclusion?

Answer: The any willing pharmacy provisions are the most critical protection for pharmacies (including safety-net pharmacies) against network exclusion. CMS primarily works through the complaints process to ensure that there are no violations of our requirements in this area. Since contracting with these entities is voluntary CMS has no contracting requirements. However, we continue to educate plan sponsors about these pharmacies, their importance to low-income beneficiaries, and the existence of the HRSA addendum.

d. Do you know how many 340B safety net pharmacies are currently contracted as network providers with at least one PDP?

Answer: CMS is unable to track this information. As explained above, there is no meaningful way to single out a "safety net pharmacy" versus a regular "retail pharmacy."

Q6. During the initial transition period to Part D, CMS agreed to reimburse states for dual-eligible prescription costs not covered by PDPs. Many safety net providers incurred unreimbursed costs for dual-eligibles because of the data problems between CMS and PDPs or because of participation contract problems. Does CMS plan to reimburse these safety net providers for such costs? If so, how and when will reimbursement occur?

A6. CMS recognizes and applauds the efforts made by safety net providers during implementation of Part D. Especially in the early days of the benefit, when safety net providers could not easily get coverage information on a number of people with Medicare and Medicaid, many phone calls resulted in long phone delays. We have seen most drug plans respond with enhanced customer and pharmacy service. It is our understanding that wait times for most of the individual drug plans are improving. CMS monitoring of the customer and pharmacy help lines is confirming this. Good service is a requirement in the Medicare drug benefit, and we are pleased that many plans are meeting and exceeding these expectations now. To help make sure that all drug plans are producing good service and are recognized for it, we have increased our monitoring and reporting of wait times. Any plan that does not meet its commitment to provide prompt service will be dealt with through the corrective actions that the Secretary has authority to take.

As you are aware, through a new Medicare demonstration project, developed in consultation with State Medicaid Directors, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts. If a safety net provider has a preexisting contract with a prescription drug plan (PDP), the PDP is required to pay them for the Part D drug. Payment between plans and pharmacies is a term and condition of the contract between those two parties. Plans are required to comply with the terms and conditions of their contracts, including paying pharmacies according to the terms outlined in such contracts. To the extent that a pharmacy believes that a plan is not making payments according to their contract, the safety net pharmacy should notify CMS and we will investigate and take corrective action as necessary. In cases in which a safety net provider does not have a contract with a PDP, we suggest the provider work

with the state to obtain payment for drug provided to dual eligibles and low-income subsidy eligible individuals.

Q7. CMS randomly auto-enrolled all dual-eligibles into Part D plans with premiums below a benchmark amount. As a result, some nursing home residents were auto-enrolled in plans that did not cover the drugs they needed, or which subjected the drugs to prior authorization requirements. The Part D marketing guidelines limit nursing homes and pharmacists in the help they can provide dual-eligibles in choosing a drug plan that meets their particular needs. Yet nursing homes remain responsible under federal and state regulations for providing prescription drug coverage to their residents. Will CMS consider revising the guidelines to allow nursing home professionals and pharmacists to assist residents in selecting Part D plans that meet their needs?

A7. Nursing home staff are allowed to help beneficiaries compare plans objectively given the individual's needs. However, nursing home staff are not allowed to select plans for individuals, in order, to avoid allowing staff to steer patients to plans that contract with favored pharmacies rather than ones that are best for patients. The Part D benefit is a voluntary benefit, which means that all beneficiaries must be given a choice of plans - including the choice to decline coverage. Allowing nursing homes to select a plan for their patients could result in a beneficiary not having access to the benefit structure they prefer.

Q8. Prior authorization requirements vary greatly by plan. These requirements pose particular difficulties in the long-term care setting, where Medicare beneficiaries must have 24/7 access to medically necessary prescription drugs. Is CMS considering any requirements for Part D plans to use uniform prior authorization forms and processes?

A8. CMS' top priority is to ensure that Medicare beneficiaries have access to the prescription drugs they need. We have been working with Part D plans and the pharmacy community to facilitate the adoption of uniform codes at the pharmacy counter. In addition, CMS worked with industry partners to develop a standardized prior authorization and appeals form for providers, which plans are expected to accept.

Q9. Many of the Medicare beneficiaries residing in assisted living facilities are frail elderly individuals who require the same specialized pharmacy services as residents of other long-term care facilities. Assisted living residents have been given the same protections under Part D as other long-term care residents, including special enrollment periods and exemption from cost-sharing requirements. Does CMS plan to reconsider the regulatory definition of "long-term care facilities" to include assisted living facilities?

A9. Medicare plans are required to contract with a broad network of retail pharmacies that meet our regulatory standard, in order to provide convenient access to beneficiaries. It is

our understanding that community-based facilities, such as assisted living facilities, often have pharmacies that exclusively serve their residents, some of which are in-house. To the extent that these pharmacies also serve nursing homes, it may be very feasible for them to set up similar pharmacy arrangements with Medicare plans to include the assisted living facilities in their plan networks. This kind of access may prove to be a very marketable way for Medicare plans to attract enrollees who live in these facilities. We certainly encourage plans and pharmacies to contract with one another to provide convenient access to all Medicare beneficiaries.

However, CMS does not require Medicare plans to contract with community based facilities, such as assisted living facilities. Unlike nursing homes and skilled nursing facilities, CMS does not regulate assisted living and other congregate housing arrangements, and they are not subject to the same Medicare and Medicaid conditions of participation.

Q10. CMS has proposed a plan to assist states in reconciling claims against Part D plans and to ensure they are "made whole" for their drug expenditures on behalf of Medicare beneficiaries who were not able to access their Part D drug benefits. Pharmacists have also dispensed drugs to Medicare beneficiaries for free when they could not determine who to bill, due to computer malfunctions, inaccurate information, etc. Pharmacies are facing rejection and unpaid claims from drug plans for these expenditures. What specific steps will CMS take to facilitate prompt and accurate reimbursement to pharmacies for these expenditures?

A10. CMS cannot make payment directly to pharmacies for Part D covered drugs. However, CMS recognizes that some pharmacists may have faced challenges in accessing beneficiary enrollment or cost-sharing information during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This will help to ensure that pharmacists have enough time to submit these claims to the plans and receive the appropriate payment.

Q11. Does CMS require Part D plans to meet minimum standards for billing cycles or for how often they update the pricing benchmarks (*i.e.*, AWP, WAC) used as the basis of pharmacy reimbursement? If not, why not?

A11. No, this is between the plan and the pharmacy to negotiate.

Q12. Did CMS require plans to have longer billing windows to accommodate the longer billing cycles of long-term care pharmacies? If not, has CMS offered any guidance for how long-term care pharmacies, which traditionally bill on 30-day cycles, should submit claims to plans?

A12. CMS is requiring Part D Plans to implement a 180-day timely claims filing limit for claims incurred January 1 through June 30, 2006. CMS has proposed to continue to require a 180-day claims filing limit for plans in 2007.

Q13. How does CMS plan to monitor the contract terms between Part D plans and pharmacists?

A13. CMS Central Office receives information about Part D sponsors' compliance with program requirements through a variety of sources, including CMS Regional Office caseworkers, Medicare beneficiaries, State officials, Congressional offices, and health care providers. Each Part D sponsor has been assigned a CMS account manager, who is responsible for maintaining regular contact with sponsors' senior officials to resolve operational issues quickly.

When a compliance issue arises, the CMS account manager contacts an official at the affected Part D sponsor, usually the organization's compliance officer. The account manager describes the issue and directs the sponsor to investigate and report back promptly with information about how the matter was resolved (e.g., additional customer service representative training, installing additional telephone lines). CMS is tracking these issues internally, and senior CMS leadership reviews daily reports on account manager activities. Where Part D sponsors do not report back in a timely manner or refuse to comply, CMS account managers elevate the issue to senior CMS management for further action.

In this first month of Part D operations, CMS account manager interaction with sponsors more frequently takes the form of technical assistance rather than enforcement actions. Most Part D issues have arisen so far from three basic sources: sponsor misunderstanding of Part D policy, Part D policy needing clarification, and information systems/data exchange problems. In the first two instances, CMS account managers educate the sponsors about the details of the applicable policy, or where necessary, CMS issues a memorandum clarifying a Part D operational requirement. This policy clarification may require that the Part D sponsor revise its electronic benefit edits and train its staff accordingly. To address information systems issues, CMS has established a SWAT team of senior managers and CMS Office of Information Systems staff that is focused exclusively on resolving questions concerning the data exchanges required under Part D. The SWAT team, like the account managers, reports daily to the CMS leadership on the status of Part D sponsors' operations.

Where Part D sponsors demonstrate a pattern of non-compliance, or where the conduct in question is egregious, CMS pursues regular program enforcement strategies, including requiring sponsors to implement corrective action plans and, if warranted, the imposition of intermediate sanctions or contract termination. Account managers are documenting all contact with sponsors to support enforcement actions, should they be necessary. CMS has already placed some sponsors under corrective action plans for non-compliance with the Part D marketing guidelines.

CMS has addressed Part D sponsors' compliance with the benefit transition policy requirements using the approaches described above. Mostly, this effort has involved technical assistance to the sponsors. During January 2006, CMS has issued memoranda

clarifying the Part D sponsors' obligations (i.e., sponsors should limit the use of prior authorization controls; where they use such controls, they must make certain that authorization telephone lines are adequately staffed to minimize hold times for providers). CMS account managers have been in routine contact with their assigned sponsors to resolve benefit transition issues quickly. Where sponsors have questioned CMS requirements on transition policies, senior CMS officials have contacted the sponsors directly to talk through the matter. In the event that CMS' incident tracking indicates that a sponsor remains out of compliance with the transition policy requirements, CMS will pursue appropriate enforcement actions, as described above.

Q14. Please provide a summary of the types of medication therapy management (MTM) programs that are being offered by Part D plans, including the extent to which retail pharmacies are being used to provide MTM services.

A14. a. Has CMS reviewed the contracts for MTM services that drug plans offer to pharmacies?

Answer: CMS does not review the individual contracts and arrangements made between the Plans and the providers of MTM services, which may include pharmacies and pharmacists. CMS does evaluate and approve each Part D sponsor's Medication Therapy Management Program (MTMP) descriptions annually. New applicants and renewing Sponsors must submit a description of their proposed MTMP to CMS, including the criteria used to target beneficiaries for MTMP eligibility, the procedures used to identify those beneficiaries, methods used for MTMP enrollment and disenrollment, the type and frequency of interventions the MTMP will provide, resources used to provide MTMP services, how MTMP fees will be established, and methods used to document and measure the interventions and their outcomes. A CMS-approved MTMP is a required condition to obtain an approved Part D bid.

b. Are drug plans required to inform in-network pharmacies about the potential to be reimbursed for providing MTM?

Answer: Our goal for this year, as indicated in our final regulation, was to not be prescriptive in terms of how plans design their MTMPs. We are working to collect information and develop best practices for MTM in the future. The Pharmacy Quality Alliance (PQA) will help to accelerate this process.

c. What percent of plans are only offering MTM through call centers?

Answer: During the review of contract year 2006 MTMPs in June 2005, CMS reviewed each MTMP to ensure that the programs met the minimum program requirements for contract year 2006 and collected minimal data to characterize the programs. CMS did not specifically collect data on the percentage of Plans solely offering MTM through a call center. CMS analyzed notes from the review of the 2006 MTMPs which characterized the interventions offered for the following keywords: call, phone, telephonic, and telephone. Based on this analysis, at least 45.4% of programs reviewed

(251 out of 553) offer a telephonic or phone-based type intervention. This analysis is limited because it does not assess the number of programs that solely offer MTM services through a call center, telephonic MTM interventions may be offered through means other than a call center, and exclusion of those keywords in notes does not rule out that additional programs may have offered telephonic MTM interventions.

d. Where call centers are used, how is CMS ensuring that the plan's call-center staff is sufficiently qualified to provide MTM services?

Answer: Plan Sponsors would be held to the same standards whether using a call center or other provider staff to provide MTM services. The Part D audit program monitors requirements that CMS has put forward either through statute, regulations, contract, or guidance. Currently, through the Part D audit program, CMS monitors that each MTMP was developed by licensed and practicing pharmacists and physicians in compliance with 42 CFR § 423.153(d)(3).

Q15. Many independent pharmacists have raised concerns about some plans putting the logos of certain chain pharmacies on their Part D identification cards because it creates confusion in the minds of beneficiaries who think that they can only use the pharmacies on the card.

a. Are plans required to actively inform enrollees of all pharmacies that <u>contract</u> with them, including, co-branded, preferred, AND non-preferred pharmacies?

A15. Answer: Yes. Plans are required to list all network pharmacies – including co-branded, preferred and non-preferred – on their plan websites. All network pharmacies must be listed by name and location.

b. Through a co-branding agreement, some plans set up staffed information tables within stores that house retail pharmacies?

Answer: Yes. The Part D marketing guidelines address promotional activities in a health care setting, which includes a pharmacy (co-branded or not).

Q16. Has CMS offered guidance on whether the presence of an agent in close proximity to a pharmacy may constitute enrollment "steering" by the pharmacy?

A16. Yes. The Part D marketing guidelines address promotional activities in a health care setting, which includes a pharmacy (co-branded or not).

Q17. Are plans allowed to require mail-order for any drugs? Are plans limited in any way in their cost-sharing differential between drugs offered though mail-order and the same drug purchased at a retail pharmacy?

A17. Many beneficiaries may prefer to receive their prescription medications through mail order. The MMA requires plans to permit retail pharmacies to provide the same extended

supply of a prescription available through mail-order to a beneficiary. CMS has made clear that it expects plans to include in their contracts with retail pharmacies a provision that will allow a retail pharmacy to offer an extended supply of drugs to any plan beneficiary at the same price, reimbursement rate (including dispensing fee, if any) and cost sharing as the plan's mail order pharmacy or pharmacies. Additionally, a plan may allow retail pharmacies to dispense an extended supply of drugs for a higher contracted reimbursement rate (including dispensing fee, if any) than the Plan's network Mail Order Pharmacy Rate. Beneficiaries are responsible for any cost-sharing differential between an extended supply received from a mail order pharmacy and a retail pharmacy.

Q18. Some Medicare beneficiaries reside in VA long-term care facilities (LTC) but they are not eligible for Tricare. These LTC facilities are serviced by VA pharmacies. Some of the Medicare-eligible residents of VA LTC facilities have enrolled in Part D. Can VA pharmacies serving VA long-term care facilities contract with Medicare drug plans? Do VA pharmacies qualify for the "any willing provider" provision?

A18. The Part D rules do not prohibit a VA pharmacy from contracting with a Medicare drug plan. However, we cannot comment on whether the VA program would limit such pharmacies.

Q19. Can drug plans ever deny a claim based on the number of pills dispensed per day?

A19. Plans may apply utilization checks, such as dosage or quantity limits, to prevent unsafe dosing (i.e., beyond FDA safety indications).

Q20. Is CMS planning to revise its formulary guidance for the 2007 plan year? If so, please describe the process for involving stakeholders and the timetable for issuance of revised guidance.

A20. The revised guidance will be released later this spring, taking into account Part D program experience to date and input from stakeholders.

Q21. SHIP benefit advisors play a critical role in ensuring individuals understand the complex new Medicare prescription drug benefit, know their plan options for enrollment, and understand how to enroll in the benefit. In Montana, our SHIP advisors have found they do not have the resources they need to educate and advise eligible beneficiaries, especially those in rural areas. What efforts is CMS taking to ensure that SHIP funding is targeted to help those in rural areas meet the demand for service? Have you made or would you consider making rurally-targeted grants that provide laptops with wireless access, funding for travel, and funds for additional field staff to meet this demand?

A21. CMS recognizes the challenges of providing benefits counseling services in rural areas and instructs states to use SHIP funds to support those efforts. By statute (Public Law 101-508, codified at 42 USC 1395 b-4), the State Health Insurance Assistance Program (SHIP) grants are from CMS to state governments, either to the state unit on aging or to

the state insurance commissioner based on a decision of the governor. As such, CMS cannot specifically grant funds through the SHIP grant process to specific community-based organizations in rural areas, but relies on states to follow CMS instructions to use grant funds principally to support and provide locally accessible counseling services to individual beneficiaries. In the grant announcement for the FY06 SHIP grant year that begins on April 1, 2006, CMS further instructs states that, "CMS recognizes that establishing locally accessible counseling services in rural or frontier areas involves additional challenges to states. CMS also recognizes that locally accessible counseling services established by SHIPs in rural areas are vitally important as they often represent the only local partner involved in Medicare education and assistance." CMS will continue to encourage states to use SHIP funds to support locally accessible SHIP counseling services for people living in rural areas.

Q22. I understand that some CMS-sponsored SHIP grants included enrollment targets and incentives that conditioned receipt of funding on the SHIP's proof of enrollment of a target number of beneficiaries, or paid out a set amount per beneficiary. This type of grant appears to violate the mandate that SHIPs provide neutral beneficiary advice and advocate for the interests of the beneficiary, not any particular prescription drug plan, or Medicare itself. Can you answer the following questions:

a. How many contracts awarded by or in cooperation with CMS include similar provisions that condition funds in whole or in part on attainment of an enrollment target? How does this compare with the total number of contracts awarded by or in cooperation with CMS? How much funding is at stake?

A22. Answer: CMS does not have contracts with SHIPs, nor has it set enrollment targets for SHIPs. The SHIP grant application outlines CMS' expectations of SHIPs specifically to provide objective and impartial enrollment assistance to as many beneficiaries as possible. Separate and apart from SHIP grants, CMS and AoA have an intra-agency agreement through which nine national organizations and more than a hundred community-level organizations are sub-contracted by n4a to provide enrollment assistance to vulnerable beneficiaries. To ensure that the contracts were focused on enrollment assistance, enrollment targets were originally included in all contracts. The contracts were later modified just to include tracking and reporting of activities without any condition on attainment of enrollment targets. Subcontractors are required to follow the same guidelines for objective and impartial enrollment assistance that CMS provides to SHIPs. There are no other CMS beneficiary outreach contracts, intra-agency agreements or grants that involve targets at this time.

b. Upon what rationale does CMS believe these contracts are appropriate and consistent with SHIPs' mandate to provide neutral advice to beneficiaries about a voluntary prescription drug benefit?

Answer: CMS does not have contracts with SHIPs, nor has it set enrollment targets for SHIPs. The SHIP grant application outlines CMS' expectations of SHIPs specifically to provide objective and impartial enrollment assistance to as many beneficiaries as

possible. Separate and apart from SHIP grants, CMS and AoA have an intra-agency agreement through which nine national organizations and more than a hundred community-level organizations are sub-contracted by n4a to provide enrollment assistance to vulnerable beneficiaries. To ensure that the contracts were focused on enrollment assistance, enrollment targets were originally included in all contracts. The contracts were later modified just to include tracking and reporting of activities without any condition on attainment of enrollment targets. Subcontractors are required to follow the same guidelines for objective and impartial enrollment assistance that CMS provides to SHIPs. There are no other CMS beneficiary outreach contracts, intra-agency agreements or grants that involve targets at this time.

c. How many contracts awarded by other agencies within HHS also included these enrollment targets or incentives? How does this compare with the total number of contracts awarded by HHS agencies? How much funding is at stake?

Answer: CMS does not have contracts with SHIPs, nor has it set enrollment targets for SHIPs. The SHIP grant application outlines CMS' expectations of SHIPs specifically to provide objective and impartial enrollment assistance to as many beneficiaries as possible. Separate and apart from SHIP grants, CMS and AoA have an intra-agency agreement through which nine national organizations and more than a hundred community-level organizations are sub-contracted to provide enrollment assistance to vulnerable beneficiaries. To ensure that the contracts were focused on enrollment assistance, enrollment targets were originally included in all contracts. The contracts were later modified just to include tracking and reporting of activities without any condition on attainment of enrollment targets. Subcontractors are required to follow the same guidelines for objective and impartial enrollment assistance that CMS provides to SHIPs. There are no other CMS beneficiary outreach contracts, intra-agency agreements or grants that involve targets at this time.

d. CMS received substantial funding for outreach and enrollment activities under Part D – can you provide a complete accounting of how such funds have been allocated to date?

Answer: Adequate funding for education and beneficiary outreach was critical to the success of the new drug benefit. CMS used the funding in five key areas: beneficiary materials, 1-800-MEDICARE, website, community-based outreach and program support services. CMS has spent about $305 million in FY 2004 and about $414 million in FY 2005 on outreach.

Q23. Have you considered designating SHIP-only call-numbers for CMS for Medicare prescription drug inquiries, just as you have done for pharmacists?

A23. On November 15, 2005, CMS established a special SHIP-only call-in number for prescription drug inquiries. SHIPs used the line only sparingly, with all 54 SHIPs making as few as 20 calls per day to this special number. SHIPs continue to have direct access to CMS staff through dedicated staff at each of the 10 CMS Regional Offices and

through the SHIP Team at CMS Central Office. Additionally, CMS contracts with a SHIP Resource Center to provide dedicated assistance to SHIPs.

Q24. I am hearing that many prescription drug plans participating in the new Medicare benefit are not complying with CMS guidelines regarding the 6 protected classes and categories of drugs that must be covered for dual eligible individuals. Specifically, it appears that some plans do not cover all drugs in a class, or that they require pre-authorization or step-therapy requirements that are administratively burdensome, making it very difficult for beneficiaries to get their prescriptions. I have also heard that some plans are only covering prescriptions at a lower dose than would be appropriate for individuals with severe chronic illnesses. What steps is CMS taking to ensure that plans are complying with its guidance in this area? What plans, if any, does CMS have to monitor compliance to ensure ongoing access to needed medications for these individuals. What enforcement actions, if any, have been taken?

A24. Plans are required to meet Part D program and contractual requirements as a condition of participation. All formularies are reviewed and must be approved by CMS as a condition of entering a Part D contract. CMS will continue to monitor plan formularies to ensure that enrolled beneficiaries have appropriate access to covered drugs. A plan found out-of-compliance will be instructed by CMS to immediately resolve any formulary deficiencies. Failure to satisfactorily comply with Part D program requirements in 2006 will be grounds for non-renewal in 2007.

Q25. What process is being used to refund to enrollees, particularly dual eligible individuals, the copayments and deductibles they have paid for out of pocket during this transition period to the new Medicare benefit? How will CMS educate individuals about this process? What efforts will CMS make to help those who don't have the resources to pursue claims with private plans? Can individual claims be submitted to CMS' new reconciliation intermediary for states?

A25. The Centers for Medicare & Medicaid Services (CMS) is concerned that low-income beneficiaries are reimbursed when they were inappropriately charged incorrect cost-sharing amounts. Part D plans must reimburse enrollees for costs incorrectly incurred. If a person with the LIS is overcharged a deductible or copayment amount, they should contact their plan to find out how to submit a claim for reimbursement of the amount the plan should have paid and the cost sharing they should have paid, if applicable. The person will need to save the original receipt from the purchase in case they need to submit it with the claim. The Medicare drug plan will refund any amount that is due. To contact their plan, the person with the LIS can look on their membership card, read the plan's printed materials, or look on the plan's member website for the customer service number.

Q26. When will the exceptions and appeals processes be up and running? I am hearing that plans still do not have processes in place and that many are failing to notify

beneficiaries of plans' processes when a denial is made. Would CMS support standardizing the exceptions and appeals process to apply to all plans?

A26. Plans are required to comply with Part D program requirements, including those related to exceptions and appeals, at all times as of January 1, 2006. The MMA and CMS have requirements in place to ensure appropriate and timely handling of beneficiary exception requests and appeals.

Q27. I am hearing that plans are requiring physicians to submit extensive and differing documentation for pre-authorization requests, and that many doctors are finding the pre-authorization process very time consuming. Would you support standardizing plan pre-authorization requirements? Is this something that would require a legislative change?

A27. CMS' top priority is to ensure that Medicare beneficiaries have access to the prescription drugs they need. We have been working with Part D plans and the pharmacy community to facilitate the adoption of uniform codes at the pharmacy counter. In addition, CMS worked with industry partners to develop a standardized prior authorization and appeals form for providers, which plans are expected to accept.

Q28. Are there any other prescription drugs, beside Niacins, that have been included on then removed from formularies because they are excluded under Part D? Has CMS gotten any other reports of prescription drug plans removing prescriptions from the formulary after January 1? If so, how many plans? Did these plans seek approval and provide due notice? If not, what enforcement action is CMS taking against these plans?

A28. CMS has updated its policy for the Part D coverage of prescription niacin products. For contract year 2007 formularies, prescription niacin products used at dosages much higher than appropriate for nutritional supplementation should be considered for formulary inclusion similar to all other Part D drugs. As outlined in the Final Formulary Guidance for 2007, we will review formularies for appropriate access to drugs and drug classes addressed in widely accepted treatment guidelines, including the guidelines for lipid disorders.

All proposed formulary changes, excluding formulary expansion changes, must be submitted to CMS for review and approval. The formulary change policy addresses changes in specific drugs covered on the formulary, changes in prior authorization or tiering. CMS has clarified its formulary change policy, which applies to changes in specific drugs covered on a plan formulary, changes in prior authorization or tiering. Beneficiaries will not lose coverage for a drug they are using because of a mid-year formulary change, except in the case of changes based on clear scientific and cost reasons, including a new generic drug coming on market, or the availability of new FDA or clinical information.

Q29. How is CMS monitoring the new 90-day transitional supply requirements? Has CMS taken any enforcement action against any non-compliant plans? If so, please quantify how many plans and what actions were taken.

A29. CMS Central Office receives information about Part D sponsors' compliance with program requirements through a variety of sources, including CMS Regional Office caseworkers, Medicare beneficiaries, State officials, Congressional offices, and health care providers' advocates. Each Part D sponsor has been assigned a CMS account manager, who is responsible for maintaining regular contact with sponsors' senior officials to resolve operational issues quickly. When a compliance issue arises, the CMS account manager contacts an official at the affected Part D sponsor, usually the organization's compliance officer. The account manager describes the issue and directs the sponsor to investigate and report back promptly with information about how the matter was resolved (e.g., additional customer service representative training, installing additional telephone lines). CMS is tracking these issues internally, and senior CMS leadership reviews daily reports on account manager activities.

Where Part D sponsors do not report back in a timely manner or refuse to comply, CMS account managers elevate the issue to senior CMS management for further action. In this first month of Part D operations, CMS account manager interaction with sponsors more frequently takes the form of technical assistance rather than enforcement actions. Most Part D issues have arisen so far from three basic sources: sponsor misunderstanding of Part D policy, Part D policy needing clarification, and information systems/data exchange problems. In the first two instances, CMS account managers educate the sponsors about the details of the applicable policy, or where necessary, CMS issues a memorandum clarifying a Part D operational requirement. This policy clarification may require that the Part D sponsor revise its electronic benefit edits and train its staff accordingly. To address information systems issues, CMS has established a SWAT team of senior managers and CMS Office of Information Systems staff that is focused exclusively on resolving questions concerning the data exchanges required under Part D. The SWAT team, like the account managers, reports daily to the CMS leadership on the status of Part D sponsors' operations.

Where Part D sponsors demonstrate a pattern of non-compliance, or where the conduct in question is egregious, CMS pursues regular program enforcement strategies, including requiring sponsors to implement corrective action plans and, if warranted, the imposition of intermediate sanctions or contract termination. Account managers are documenting all contact with sponsors to support enforcement actions, should they be necessary. CMS has already placed some sponsors under corrective action plans for non-compliance with the Part D marketing guidelines. CMS has addressed Part D sponsors' compliance with the benefit transition policy requirements using the approaches described above. Mostly, this effort has involved technical assistance to the sponsors.

During January 2006, CMS issued memoranda clarifying expectations in this area for Part D sponsors. In addition, CMS account managers have been in routine contact with

their assigned sponsors to resolve benefit transition issues quickly. Where sponsors have questioned CMS requirements on transition policies, senior CMS officials have contacted the sponsors directly to talk through the matter. In the event that CMS' incident tracking indicates that a sponsor remains out of compliance with the transition policy requirements, CMS will pursue appropriate enforcement actions, as described above.

Q30. CMS has made extraordinary efforts to educate seniors and people with disabilities about the new Part D program. However, I was struck by how much confusion there was among beneficiaries on Jan. 1st. Given Part D's tremendous complexity, did CMS do anything special on outreach and education for persons with Alzheimer's disease, mental retardation and mental illnesses? In particular, what has your agency done to comply with a Senate Appropriations Committee instruction to provide one-on-one pharmaceutical benefits counseling for people with mental disabilities through community-based organizations.....including safety net community mental health providers? In my state, state agencies and mental health providers have played an important role with these at-risk dual eligible populations. In the past, they would have billed for such services as a targeted case management service. Will Medicaid reimbursement for TCM services provided to dual eligibles continue to be available in the future given the changes to the definition of TCM under the Deficit Reconciliation Act?

A30. CMS developed an integrated and multi-pronged education effort that includes media advertising, plain language fact sheets, tip sheets, posters, detailed publications including the annual "Medicare & You" handbook, direct mail, and community-based grassroots efforts to target specific populations with messages directed to their specific needs, including low-income beneficiaries. The campaign also encourages potentially eligible people with Medicare to apply for the extra help. Outreach strategies include community events, and partnering with stakeholders such as States and community-based organizations as well as the Access to Benefits Coalition. CMS currently works with many national, regional, state, and local partnership communities including the following:

- Advocacy organizations and coalitions
- Caregiver organizations and coalitions
- Disability organizations and coalitions
- Employer and union organizations and coalitions
- Faith-Based organizations and coalitions
- Federal and State organizations and coalitions
- Health organizations and coalitions
- National Medicare Education Program Partnerships
- Pharmacy organizations and workgroups
- Provider organizations and coalitions
- Racial, ethnic, and cultural organizations and coalitions
- Rural Health organizations and coalitions
- State Health Insurance Programs (SHIPs)

CMS has worked extensively with the Alzheimer's Association on outreach through their national network. The Alzheimer's Association has provided their affiliates with training and information including resources made available to them through CMS publications and training. We partnered with a number of Alzheimer's Association affiliates directly on their Memory Walk initiative in the Fall of 2005.

CMS provided funding through the Substance Abuse and Mental health Services Administration (SAMHSA), to four national mental health advocacy organizations to provide outreach and training for their local staff who would provide education and enrollment assistance to constituents. These organizations include the National Alliance on Mental Illness (NAMI), the National Mental Health Association, the National Council for Community Behavioral Healthcare and the National Association of State Mental Health Program Directors. We have met weekly with these groups as well as with the American Psychiatric Association to provide them with updates and provide answers to questions and issues that they bring to us.

Regarding your question about targeted case management (TCM) service, reimbursement for TCM services will continue to be available as long as TCM produces better care and better outcomes for individuals. The changes in DRA were intended to address abuses in the current system where Medicaid was billed for services that are clearly non-medical in nature.

Senator Hatch

Q1. There are still many beneficiaries whose plan information cannot be located or whose low-income subsidy information is not correct. How will CMS address this so pharmacies are able to determine the plan in which a Medicare beneficiary is enrolled? When will all of the enrollment information, including the low-income subsidy data, be available to pharmacies?

A1. Please be assured that the Centers for Medicare & Medicaid Services (CMS) has aggressively worked on solutions so that all people with Medicare are effectively enrolled in plans and receive the medications they need and are charged the correct cost sharing amount. Despite the best efforts of CMS, there was a group of people who have great need, some of whom may have been turned away or overcharged at the pharmacy counter. This was due in part to data-lags in the data processing systems. CMS did notify prescription drug plans of a dual-eligible's subsidy status upon completion of the enrollment; however, in some cases, the change from one plan to another was not fully updated before the dual eligible beneficiary appeared at the pharmacy counter. To improve data transmission issues, we've taken steps to make sure drug plans have up-to-date information on all their dual eligible beneficiaries and have sent additional files to plans to assist them in updating and reconciling their enrollment files and records of member's cost sharing status. To address those issues we increased the frequency of our data communications with plans and worked to ensure appropriate and timely data transfers between CMS and the states. We are pleased that these efforts have reduced the number of

instances when beneficiaries have been unable to receive their medications, or have paid more than they ought to, due to an unavailability of correct data.

Q2. CMS sought to randomly auto-enroll all dual eligibles into Medicare Part D plans with premiums below a benchmark amount. Unfortunately, many nursing home residents were auto-enrolled in plans that did not cover the drugs they needed, or which subjected the drugs to prior authorization requirements. Nursing homes and pharmacy staff are prohibited from helping dual eligibles choose a Medicare prescription drug plan. Yet nursing homes remain responsible under federal and state regulations for providing prescription drug coverage to their residents. How will CMS assist nursing home personnel and pharmacists in providing help to residents with their drug plan issues?

A2. Nursing home staff are allowed to help beneficiaries compare plans objectively given the individual's needs. However, nursing home staff are not allowed to select plans for individuals, in order, to avoid allowing staff to steer patients to plans that contract with favored pharmacies rather than ones that are best for patients. The Part D benefit is a voluntary benefit, which means that all beneficiaries must be given a choice of plans - including the choice to decline coverage. Allowing nursing homes to select a plan for their patients could result in a beneficiary not having access to the benefit structure they prefer.

Q3. Pharmacies that have dispensed medications during the transition to Medicare Part D are now facing rejected claims, resulting from confusion during the first month of implementation of the new drug benefit. CMS has given assurances to the states that it will assist them in reconciling claims against Medicare Part D plans and ensure they are "made whole" on behalf of Medicare beneficiaries. Will CMS also assist pharmacies?

A3. CMS cannot make payment directly to pharmacies for Part D covered drugs. However, CMS recognizes that some pharmacists may have faced challenges in accessing beneficiary enrollment or cost-sharing information during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This will help to ensure that pharmacists have enough time to submit these claims to the plans and receive the appropriate payment.

Q4. CMS has acted to enforce transition policies to ensure that beneficiaries receive appropriate medications. However, prior authorization requirements that vary by plan may cause problems in Medicare Part D once the "first-fill" transition phase of the program concludes. These requirements may cause difficulties in the long-term care setting, where Medicare beneficiaries must have access to medically necessary prescription drugs at all times. How will CMS address this problem? Is it possible that CMS will require standardized prior authorization forms and processes for Medicare Part D plans?

A4. CMS' top priority is to ensure that Medicare beneficiaries have access to the prescription drugs they need. Since the date of this hearing in early February, CMS did extend the initial "first-fill" transition phase through March 31, and also clarified with plans the need to effectively transition beneficiaries stabilized on non-formulary drugs to therapeutic alternatives that are included on their formulary. CMS also has been working with Part D plans and the pharmacy community to facilitate the adoption of uniform codes at the pharmacy counter. In addition, CMS worked with industry partners to develop a standardized prior authorization and appeals form for providers, which plans are expected to accept.

Q5. Some Medicare beneficiaries residing in assisted living facilities are frail elderly individuals who need specialized pharmacy services similar to residents of long-term care facilities. Is it possible for assisted living residents to receive the same protections as other long-term care residents, including special enrollment periods and exemption from cost-sharing requirements. Why doesn't the regulatory definition of "long-term care facilities" include assisted living facilities? Is it likely that the definition of long-term care facilities could be expanded to include assisted living facilities?

A5. We understand your concerns regarding the imposition of cost sharing on the full benefit dual eligible population enrolled in home and community-based waiver programs or in assisted living facilities. However, based on the specific statutory language, we do not believe we have latitude to treat these beneficiaries as institutionalized for the purpose of the cost sharing exemption.

Section 1860D-14(a)(1)(D)(i) eliminates copayments for full-benefit dual eligible individuals who are institutionalized (as defined in section 1902(q)(1)(B)) under the Medicare prescription drug benefit. Section 1902(q)(1)(B) of the statute defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility for which payments are made under the Medicaid program throughout a month, and who is determined to be eligible for medical assistance under the State plan.

An inpatient is someone who is physically in a medical institution or nursing facility. Beneficiaries living in the community, assisted living facilities, boarding homes, residential care homes, etc do not meet the general definition of an institutionalized individual as defined in section 1902(q)(1)(B). This includes individuals receiving services under the waiver authority provided by section 1915(c) of the Act. We have reviewed this issue and because the definition is written into statute, we are unable to expand it to include individuals receiving care in community-based settings.

Q6. Could you walk through the steps that CMS took initially to educate pharmacists about the Medicare Part D program, including the processing of prescriptions? Unfortunately, there was an assumption among some state officials that the

prescription drug plans themselves would educate the pharmacists on site. What steps are being taken now?

A6. CMS has provided a tremendous amount of outreach to the pharmacy community about Medicare Part D. Tens of thousands of pharmacists have received information through our LIS outreach program, Medicare Rx Update list serv, pharmacy website and hundreds of speeches, conference calls and mailings from CMS' central office and regional office pharmacy team. CMS has worked closely with the National Community Pharmacists Association, National Association of Chain Drug Stores, National Council of State Pharmacy Association Executives, the American Pharmacists Association and others to disseminate information to their membership. In addition, our regional offices have worked directly with State Pharmacy Associations, Boards of Pharmacy and Colleges of Pharmacy to provide outreach.

Q7. How will the prescription drug plans help beneficiaries who are taking prescriptions that are not on their plans' formulary? As you know, Medicaid beneficiaries have many problems that make them unable or unwilling to discuss these matters with their physicians, especially when it involves psychiatric medications.

A7. Where there are multiple therapeutic equivalents in a given category or class of drugs, beneficiaries taking a non-formulary drug may be able to work with their doctor to switch to an alternative that is on the formulary. Beneficiaries also have the option of requesting an exception from the plan, allowing a non-formulary drug to be treated as "on formulary." Plans make comprehensive formulary information available on the Prescription Drug Plan Finder tool at www.medicare.gov, and on their plan websites. Beneficiaries are advised to consider formulary coverage when selecting a plan. All beneficiaries newly enrolled in a prescription drug plan are entitled to a transition period of at least 30 days, which entitles them to a "first fill" of a non-formulary drug they were previously using. This policy ensures beneficiaries have time to either switch to a therapeutic equivalent or request an exception.

Q8. When do you expect pharmacists to be reimbursed for the medications that they gave to dual eligible beneficiaries (in good faith) when the prescription drug plans would not pay for their drugs? I have independent pharmacists in Utah who are very concerned about the debt that they have undertaken as a result of problems that occurred during the initial implementation of the drug program. What should these individuals do to be repaid?

A8. CMS cannot make payment directly to pharmacies for Part D covered drugs. However, CMS recognizes that some pharmacists may have faced challenges in accessing beneficiary enrollment or cost-sharing information during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This will help to ensure that pharmacists have enough time to submit these claims to the plans and receive the appropriate payments. Beneficiaries were instructed by CMS to save their receipts, and

should submit amounts paid in excess of the appropriate cost-sharing level to their prescription drug plan for reimbursement.

Q9. There have clearly been significant improvements in implementation of the Medicare Part D program since January 1, 2006. I would like to focus on some of the problems that are potentially recurring and to get an understanding of how you are addressing these issues. From your current and past comments, if individuals enroll at the end of the month or change plans at the end of the month and then attempt to obtain drugs from a pharmacy in the next few days, their data may not yet be available on a pharmacist's computer. How is this issue being addressed so that there will not be ongoing dissatisfaction with the Medicare Part D program?

A9. CMS has been reaching out to beneficiaries and educating our partner network about the importance of enrolling in the first half of the month to maximize chances of a smooth transition to new Part D coverage. We also have taken steps to improve the regularity and consistency of data exchanges between plans and CMS to increase the likelihood that pharmacies will have enrollment and cost-sharing information available to them when new enrollees first try to fill a prescription using their new coverage.

Q10. In the long term, individuals enrolled in specific plans will be allowed to change their plan once per year yet the plans themselves can change their formulary content when they desire to do so. If their drug is no longer covered following a formulary change, it is not a simple matter to get an exception or to go back to their physician to get a different prescription. Will there be any provision to allow an individual to continue to receive a drug that was previously on the formulary for an extended period of time?

A10. CMS has clarified its formulary change policy, which applies to changes in specific drugs covered on a plan formulary, changes in prior authorization or tiering. Beneficiaries will not lose coverage for a drug they are using because of a mid-year formulary change, except in the case of changes based on clear scientific and cost reasons, including a new generic drug coming on market, or the availability of new FDA or clinical information.

Q11. It is my understanding that a core problem in failure of dual eligible patients to obtain coverage related to a technical failure of communications between different databases. What has been done to fix this problem and why was the transfer of information not tested before the program was initiated?

A11. The coordination of the Part D benefit across States, a variety of plans' systems, and pharmacies was operationally challenging. While the vast majority of dual eligibles were enrolled without a problem, we inevitably had some that were not. As noted in the answer to your first question, in some cases when dual eligible beneficiaries changed plans near the end of the month, the necessary systems change from one plan to another were not fully updated before the dual eligible beneficiary appeared at the pharmacy counter. Since that time, we've taken steps to make sure drug plans have up-to-date information on all their

dual eligible beneficiaries and have sent additional files to plans to assist them in updating and reconciling their enrollment files and records of member's cost sharing status.

Senator Snowe

Q1. Of the approximately 3.6 million beneficiaries who have enrolled on their own - who were not auto-enrolled in some fashion...only a very small fraction were found eligible for the low income subsidy. It is unclear how much the application process may be impeding some from obtaining assistance, compared to actual disqualification of their application.

I understand that a variety of factors can disqualify seniors from low income assistance. One concern is that a relatively limited amount of assets could prevent those with low incomes from obtaining assistance which could help them maintain their health and prevent unnecessary illness and hospitalization. Thus, it is crucial that we examine why so few seniors are receiving the additional low income assistance.

First, could you describe what efforts HHS is making to improve outreach efforts to low income individuals and to simplify the application process?

Second, in light of the number of seniors who are not qualifying for a low-income subsidy, and the data you have seen thus far on applications for assistance, could you describe the relative contribution of factors which are contributing to the high rejection rate for applications? In particular, how much and what kind of assets are disqualifying seniors from low-income assistance?

A1. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), established the Medicare Prescription Drug Program, making prescription drug coverage available to all Medicare beneficiaries. The MMA also provides extra help in the form of a low-income subsidy, with prescription drug costs for eligible individuals whose income and resources are limited. The new law requires both the Social Security Administration (SSA) and the States to accept and process applications for the low-income subsidy (LIS).

Certain groups of Medicare beneficiaries will automatically qualify for the low-income subsidy and do not have to apply. The following groups are deemed eligible: full-benefit dual eligibles (FBDEs) who are persons eligible for both Medicare and full Medicaid benefits; supplemental Security Income (SSI) recipients, including SSI recipients who receive a cash benefit but not Medicaid; and Medicare beneficiaries who are participants in the Medicare Saving Programs (MSP), which are QMB, SLMB, and QI. Deemed eligibles do not need to file an application for the subsidy. All others wishing to receive extra help must apply for the subsidy.

A simplified application form and process for determination and verification of an eligible beneficiary's income and resources for purposes of the Medicare Prescription

Drug benefit has been developed by SSA and will be available for on-line, mail, in-person, and phone filing. SSA has mailed these applications to 19 million potentially eligible people with Medicare in May through August of 2005.

While SSA has primary responsibility for processing LIS applications, CMS is committed to ensuring that beneficiaries can take advantage of the extra help that is provided through the LIS. CMS is actively engaged in a comprehensive outreach campaign to encourage potentially eligible people with Medicare to apply for the extra help. Outreach strategies include community events, and partnering with stakeholders such as States and community-based organizations as well as the Access to Benefits Coalition. CMS currently works with many national, regional, state, and local partnership communities including the following:

- Advocacy organizations and coalitions
- Caregiver organizations and coalitions
- Disability organizations and coalitions
- Employer and union organizations and coalitions
- Faith-Based organizations and coalitions
- Federal and State organizations and coalitions
- Health organizations and coalitions
- National Medicare Education Program Partnerships
- Pharmacy organizations and workgroups
- Provider organizations and coalitions
- Racial, ethnic, and cultural organizations and coalitions
- Rural Health organizations and coalitions
- State Health Insurance Programs (SHIPs)

CMS feels confident that working with our partners is a key to helping people with Medicare maximize their benefits and improve the health and wellness of seniors, and people with disabilities.

Regarding your question about rejection rates for the low income subsidy, while it may be too early to tell, we believe that the Social Security Administration would be in the best position to answer these questions as they have responsibility for processing LIS application.

Senator Kyl

Q1. CMS has been hard at work to implement the Medicare drug program and I must say, has given assurances to me, my colleagues, to the Governors and most importantly, to the beneficiaries that any problems will be resolved quickly and completely. In order for CMS to do this, you must have a scope of the problem and a plan and the resources necessary to address the problems. Do you have a clear understanding of the problems with Part D, particularly with the low-income and the dually eligible individuals?

A1. Please be assured that the Centers for Medicare & Medicaid Services (CMS) has a clear understanding of the start-up problems with the new Medicare prescription drug benefit. CMS continues to work hard to implement the new Medicare prescription drug benefit. While we are pleased that enrollment has exceeded expectations and millions of prescriptions are being filled, we are also sensitive to dual eligible beneficiaries who have experienced problems. With a new program of this size, there are bound to be problems with the transition to new coverage and we take these problems very seriously. Please be assured that CMS is aggressively working on solutions to ensure that all people with Medicare are effectively enrolled in drug plans and are receiving the medications they need.

These efforts include working to address issues that arise when individuals join or switch plans at the end of the month and use their coverage soon after, working with plans to continue to improve the performance of plan help lines, and continuing to improve direct plan-to-pharmacist technical support contacts; streamlining the data submission and reporting procedures from plans to Medicare; and working with plans to make sure that they adjudicate pharmacy claims correctly and according to their contract with the pharmacy. We are also meeting regularly with pharmacists around the country and working with pharmacy associations to provide additional technical support for pharmacies that are having difficulty using the new Medicare systems, and to address specific issues that pharmacists have identified. We are also in constant communication with the Medicare prescription drug plans on issues as they arise, and is working with the plans to resolve problems as quickly as possible.

From our ongoing discussions with States, pharmacists and advocates, I understand that we see results showing significant progress. The drug benefit is working well for people who are using their Medicare prescription drug coverage. CMS and the states have resolved the vast majority of billing and access issues and most states no longer need to use the state payment system to ensure that low-income beneficiaries continue to get the drugs they need.

Q2. Does CMS have the necessary resources, either internally or contractually to handle the problems? Can you provide a list of the contractors that CMS is using to implement Part D who are responsible for the electronic transactions, the data transfer, and the eligibility and verification checks?

A2. The President's budget details CMS' resource requests for 2007. We are working through problems as they arise in partnership with the plans and our major contractors: Northrop Grumman, Computer Sciences Corporation and Per Se Technologies.

Q3. The benefit was crafted by my colleagues and I in hopes that we had accounted for every aspect and we turned over the portions which didn't require direct legislation to the Agency. We didn't expect to have the problems which we have seen, for example the issues with late enrollment penalty and open enrollment dates.

The legislation contains the date May 15 as the deadline for enrollment in a plan for the current year. Furthermore, it imposes a 1 percent penalty for each month that a person who was eligible does not elect coverage.

Are there any aspects of the program which need to be revisited in light of the enrollment and implementation problems?

A3. The Administration is not supporting any legislative changes to the program at this time.

Q4. What are the metrics CMS is using to judge progress with the program?

A4. We are closely monitoring beneficiary enrollment, plan performance on a variety of required data elements, response times at our 1-800-MEDICARE call centers, beneficiary savings, and satisfaction with the new program.

Q5. How often can we expect to get good information on the benefit? Has CMS developed a full 'report card' of metrics across the program to judge its success and to provide a basis for us to determine if further action – legislative or administrative – is necessary?

A5. The Administration is not supporting any legislative changes to the program at this time. The Secretary has released a series of progress reports on the implementation of the benefit. We will continue to provide updated enrollment information, and will soon begin releasing information on plan performance.

Senator Thomas

Q1. I am sure that progress is being made to improve communication, but I am still hearing reports from Wyoming folks that not all plans and not all pharmacies are aware of the options available to address problems when they come up. What is CMS doing to make sure this issue is resolved?

A1. CMS has conducted extensive outreach through plans, pharmacy and provider associations, a network of thousands of partners, beneficiary advocacy groups, and the media, in addition to direct communications to providers.

Q2. What are you doing to make sure that rural beneficiaries know what plans may or may not be available at their local, independent pharmacy, especially in communities with only one pharmacy?

A2. Beneficiaries have several options for determining which of the available Part D plans have contracted with their preferred pharmacy. This information is available on the Prescription Drug Plan Finder tool at www.Medicare.gov, through 1-800-MEDICARE, through individualized counseling provided by federally-funded State Health Insurance Assistance Programs, and from the plans themselves.

Q3. There is support in my state for streamlining the pre-approval process across all plans. Each plan has its own pre-approval process. Pharmacists and physicians in my state say this has become a barrier in timely processing claims and getting medications to folks. Should we require all plans to use one, uniform pre-approval process?

A3. CMS' top priority is to ensure that Medicare beneficiaries have access to the prescription drugs they need. We have been working with Part D plans and the pharmacy community to facilitate the adoption of uniform codes at the pharmacy counter. In addition, CMS worked with industry partners to develop a standardized prior authorization and appeals form for providers, which plans are expected to accept.

Q4. **As you know, the State Health Insurance Information Programs (SHIIP) were established in each state to help seniors and others on Medicare understand their rights and answer their questions. Wyoming has over eighty volunteers in almost every county who can counsel beneficiaries and help solve problems. There are many people in Wyoming who believe the SHIIP program is overwhelmed. Do the SHIIP programs have adequate resources?**

A4. CMS is sensitive to the fact that SHIPs are experiencing a significant transition demand with the start up of this important new benefit and we have therefore placed heavy emphasis on building a more extensive network of partners to assist these programs in the education effort. In addition, in response to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS increased funding to SHIPs by 150%, with total funding of over $31 million for FY 2005. This increased level of funding was maintained for FY 2006 and has been supplemented by additional grants for SHIP services in rural areas.

The additional funding allowed SHIPs to increase their capacity to provide locally accessible assistance with enrollment. CMS has also increased funding to the SHIP Resource Center, which provides technical support to SHIPs such as a weekly newsletter containing current news about Part D as well as the deployment of trainers to the field to assist in training counselors on providing enrollment assistance and using the Prescription Drug Plan Finder tool and Online Enrollment Center.

The SHIPs efforts are supplemented by partnerships cultivated through the CMS Regional Offices with community-based organizations and coalitions able to provide education, information, and enrollment assistance support at the community level. Through joint efforts of CMS and the Administration on Aging (AoA), the Aging Network has enlisted the active support of 10,000 aging services community provider organizations in beneficiary education and enrollment activities.

CMS has also provided extensive refresher training to our 1-800-MEDICARE customer service representatives (CSRs). The role of the CSR is to provide plan comparison information and enrollment assistance to callers. They are instructed to only refer callers to SHIPs for more local, personalized counseling for callers having difficulty understanding the information presented or who request local help. To make sure that 1-

800-MEDICARE CSRs follow this policy, CMS tracks the number of times they hit the SHIP script to access the phone number.

Finally, CMS provided direct resources to assist SHIPs through special performance project funding to the SHIP Resource Center to work with selected SHIPs on boosting hotline capacity. Additionally, CMS makes a new volunteer recruitment resource available to SHIPs, AAA, and other community-based partners engaged in enrollment assistance. The project uses a web site that facilitates the matching of volunteers with organizations needing additional help. In an effort to assist SHIPs with backlogs of beneficiary calls early in the enrollment process, CMS created a virtual call center comprised of over 150 staff from its Central and Regional Offices, its Office of External Affairs in DC, and the AoA's Central and Regional Offices. An offer was made to each SHIP to submit names and phone numbers of callers the SHIP was unable to reach due to the high volume of requests, and those calls were returned by the CMS virtual call center.

Q5. **Dr. McClellan, advocates for dual eligible beneficiaries have expressed strong support for the formulary guidance CMS developed last year that requires PDPs and MA plans to cover "all or substantially all" of the medications in 6 therapeutic classes that cover treatment for diseases such as AIDS, severe mental illness and cancer. This same guidance limits the ability of plans to impose access restrictions such as prior authorization and step therapy to "extraordinary circumstances." As you know, this guidance covers only the 2006 contract year and must be renewed by CMS to apply to drug coverage in 2007 and beyond.**

A5. We understand your concern, and are in the process of finalizing formulary guidance for contract year 2007.

Q6. In the absence of renewal of this guidance, many patient advocacy groups are concerned that the breadth of coverage of medications to treat severe chronic diseases will deteriorate substantially. Many view this guidance as central to making Part D work effectively for dual eligibles living diseases such as AIDS, cancer and severe mental illness. Can you update us on CMS's plans regarding renewal of the formulary guidance?

A6. We currently are in the process of finalizing formulary guidance for contract year 2007. We recognize the importance of the "all or substantially all" policy in assuring access to necessary medicines for beneficiaries living with AIDS, severe mental illness, and cancer.

Senator Santorum

Q1. **Last week you testified before the Senate Special Committee on Aging with regard to the work CMS was doing to correct system problems. One week later, what metrics can CMS provide that confirm that improvements are occurring and the steps CMS continues to take to correct system problems are indeed helping?**

A1. A significant portion of the early problems for beneficiaries centered on certain beneficiaries who enrolled or switched plans late in a month, particularly dual eligible beneficiaries. CMS took action to address those issues so that all beneficiaries enrolled in a Medicare prescription drug plan could obtain their medications without incident. We also worked to correct data transmission problems between Medicare, health plans, pharmacists, and the States.

Customer service also is a priority, and we have been working to eliminate any delays or other difficulties for those needing assistance. In order to assist pharmacists, who have been outstanding in their commitment to service, CMS is working to ensure they have the resources and support they need. CMS also is coordinating with the States that used their state reimbursement systems to pay for prescriptions that should be paid by the new Medicare prescription drug plans. CMS believes they should be reimbursed for any legitimate expenses beyond the payments they will receive from the plans and is doing so through a demonstration program. We also are monitoring plan activities and will use our enforcement measures, if necessary, to ensure they are adhering to the requirements of participating in the Medicare prescription drug program. These efforts build on the preparations that were made long before the January 1, 2006 launch of the Medicare prescription drug benefit.

Q2. In late December, CMS experienced a significant surge in enrollment—much of the confusion and problems with the launch of the program have been attributed to this large influx. Seniors were encouraged to enroll up until the last day of December to have coverage beginning on January 1st, yet in highsight this timeframe appears to have been overly ambitious. Would requiring beneficiaries to enroll by a cut-off date, such as the 15th of the month before their coverage would begin the following month, ensure that such confusion is not repeated? Does CMS have the authority to institute such a timeframe for beneficiaries who are not dual eligibiles?

A2. CMS does not at this time believe it has authority to implement a mid-month enrollment cut-off date for all Medicare beneficiaries who enroll during the annual coordinated election period; however, since the date of this hearing in early February we have conducted aggressive outreach to encourage beneficiaries to enroll early in the month. Transition-related issues such as those occurring in early January have declined considerably.

Q3. CMS has encouraged prescription drug plans and states to follow their approved transition policies, yet we continue to hear reports of plan customer service representatives, states, and pharmacists who are uninformed or misinformed of the steps that need to be taken to meet the approved policies to ensure beneficiaries get needed prescriptions. How will CMS hold plans and states accountable to ensure that transition policies are abided?

A3. CMS has been closely monitoring plan compliance with all Part D program requirements, including the requirement that plans have a transition policy in place. Where necessary to ensure compliance, CMS will take enforcement actions against plans.

Q4. CMS experienced a surge in enrollment in prescription drug plans at the end of December, illustrating problems with seniors waiting until the end of the month to enroll in a plan. Given the issues experienced as a result of this surge, what steps is CMS taking now to ensure that similar problems are not repeated at the end of each month, and as we approach the end of open enrollment on May 15th?

A4. CMS has been reaching out to beneficiaries and educating our partner network about the importance of enrolling in the first half of the month to maximize chances of a smooth transition to new Part D coverage. We also have taken steps to improve the regularity and consistency of data exchanges between plans and CMS to increase the likelihood that pharmacies will have enrollment and cost-sharing information available to them when new enrollees first try to fill a prescription using their new coverage. These efforts have resulted in significant improvements.

Senator Rockefeller

Q1. Dr. McClellan, dual-eligibles have had a particularly difficult time transitioning to Medicare drug coverage. CMS has automatically enrolled many dual eligibles in plans that do not meet their needs. Because of incorrect or incomplete data exchanges, many have been inappropriately charged the $250 deductible, full co-payment amounts, and, in some cases, the full costs of their drugs. Some dual eligibles have not been able to get their prescriptions at all because plans are not providing a transitional supply of the drugs they have been taking or because their local pharmacies cannot verify enrollment in a plan.

As a result of these problems, our most vulnerable citizens – those who should have been the highest priority – have been left to fend for themselves. Luckily, nearly 30 heroic states have stepped in to fill the coverage gaps. But, these problems still persist in all 50 states.

Wouldn't it have been much easier to have a planned transition for the dual eligibles to Medicare prescription drug coverage? Shouldn't they have been given six months to consider their options like every other Medicare beneficiary?

A1. The Centers for Medicare & Medicaid Services recognizes the enormity of the transition from Medicaid drug coverage to Medicare and has been working hard to implement the new benefit, which commenced January 1, 2006. We are pleased that millions of prescriptions are being filled as the vast majority of beneficiaries are using their new drug coverage. However, we are also sensitive to certain beneficiaries that have experienced problems at the start, particularly dual eligibles.

Prior to January 1, 2006, CMS instituted various protections to help ensure a smooth transition for dual eligibles including the following:

- To ensure no lapse in drug coverage, CMS enrolled full-benefit dual eligibles into Medicare prescription drug plans if they did not enroll on their own.
- CMS established 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.
- CMS required Medicare prescription drug plans to establish an appropriate transition process for new enrollees including full-benefit dual eligibles who are transitioning to the Medicare benefit from other prescription drug coverage.
- CMS developed appeals procedures which ensure that enrollees quickly receive decisions regarding medically necessary medications.
- CMS established specific protections for beneficiaries who live in long-term care facilities, may of whom are dual eligibles, and get their prescriptions from long-term care pharmacies.
- CMS instituted the WellPoint point-of-sale option to allow full benefit dual eligibles not previously enrolled in a Part D plan, or where enrollment information cannot be found, to have immediate access to Medicare coverage for prescription drugs.

However, with a new program of this size, there are bound to be problems with the transition to new coverage. We take these problems very seriously. Please be assured that CMS has aggressively worked on solutions so that all people with Medicare are effectively enrolled in plans and receive the medications they need and are charged the correct cost sharing amount. These efforts include working to address issues that arise when individuals join or switch plans at the end of the month and use their coverage soon after, working with plans to continue to improve the performance of plan help lines, continuing to improve direct plan-to-pharmacist technical support contacts, streamlining the data submission and reporting procedures from plans to Medicare, and working with plans to make sure that they adjudicate pharmacy claims correctly and according to their contract with the pharmacy. We are also meeting regularly with pharmacists and pharmacy associations around the country to address specific issues that pharmacists have identified and to provide additional technical support for pharmacies that are having difficulty using the new Medicare systems. CMS is also in constant communication with the Medicare prescription drug plans on issues as they arise and is working with the plans to resolve problems as quickly as possible.

Q2. **I believe a longer transition period would have helped CMS address the serious implementation problems that have occurred, many of which were brought to CMS' attention long before January 1. There must be a net cost to the government for not providing a smooth transition to Medicare for the dual eligibles.**

How much more in federal dollars does HHS estimate it will take to reimburse states, pharmacies, other health care providers, and individual beneficiaries for the inappropriate costs they incurred because of the poor transition of dual eligibles to Medicare?

A2. We very much appreciate the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled

beneficiaries receive the prescription medication they need. Specifically, through the Medicare demonstration project, developed in consultation with State Medicaid Directors, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts. The demonstration relies on "best practices" that have been identified by many states to work with CMS and HHS to minimize state billing and help any remaining dual eligible and low-income subsidy beneficiaries complete the transition to their new Medicare coverage. We are currently working with states to collect the data necessary for reimbursement, so we do not yet have information about how much money will be used to reimburse the states through the demonstration project.

Unlike states, pharmacies administering Part D drugs have preexisting contracts with prescription drug plans (PDPs). Claims for reimbursements should be made directly to the plans. CMS will play its part by continuing to monitor PDP wait times to ensure they are responsive to pharmacists.

In the case of individual beneficiaries, Part D plans must reimburse enrollees directly for costs incorrectly incurred. If a person with the LIS is overcharged a deductible or copayment amount, they should contact their plan to find out how to submit a claim for reimbursement of the amount the plan should have paid and the cost sharing they should have paid, if applicable. The person will need to save the original receipt from the purchase in case they need to submit it with the claim. The Medicare drug plan will refund any amount that is due.

Q3. **CMS recently put out a press release on Medicare that stated, "the overall cost to taxpayers for 2006 will drop 20 percent over the July 2005 estimate, according to the CMS Office of the Actuary. The savings result from lower expected costs per beneficiary; projected enrollment in the drug benefit has not changed significantly."**

Dr. McClellan, I think it's interesting that you mention "lower expected costs per beneficiary" as the reason for these savings. And, I think these savings confirm one of my worst fears about this drug benefit – that people are not getting the prescription drugs they need.

Can you tell me how much of these new cost-savings are a result of beneficiaries, particularly poor beneficiaries, being locked out of the drug benefit completely or being charged much more than they should for their drugs?

A3. Unlike Medicaid, which differs from state to state and is subject to limitations on drug coverage in many states, the new Medicare prescription drug benefit is national, uniform, and comprehensive, and provides beneficiaries the same protections they have come to expect from Medicare. The new Medicare prescription drug program also includes extensive beneficiary protections that will ensure that an appropriate range of drugs is conveniently available to all beneficiaries, including those with serious illnesses who need costly medicines. Additionally, some States (AZ, CA, CT, HI, IL, ME, MA, NE, NV, NH, NJ) are using a portion of their savings from Part D to pay the $1/$3

copayments for some or all dually eligible beneficiaries – so the State has savings, and beneficiaries have the same or lower copayments than before.

While you are correct in your statement that estimated costs have decreased 20% from last summer's Mid-Session Review to the 2007 President's Budget, changes to our estimates are not due to the factors that you cited. The largest single factor accounting for the change in our estimates was updates we made in the assumptions about what would happen to drug costs between our base year (then 2001 and now 2002) and the first year of the benefit. Vigorous competition in the prescription drug marketplace, especially the substantial deceleration in prices increases for generic drugs and increased use of these alternatives, was responsible for a 15% reduction in our estimate of spending over the ten year period.

Secondly, when we reviewed bids submitted by plan sponsors, it became clear that sponsors were going to be able to deliver savings that were higher than we had anticipated. These higher savings were responsible for a 5% reduction in projected 10-year spending. Partially offsetting these factors were the following factors: plan estimated reinsurance costs were higher than we had previously anticipated; state clawback payments were lower than previously estimated and anticipated savings to the Medicaid program were lower than anticipated due to both the lower drug spending trend, described above, and to the higher costs associated with the Medicaid "woodwork" effect due to the Part D low income subsidy program, because of higher Medicare Part A and Part B costs than had been previously projected.

Q4. **In October, during the budget reconciliation mark-up, I repeatedly raised concerns about whether CMS had an effective system in place to collect beneficiary data from the states and the Social Security Administration (SSA), verify that data, and then transmit it to plans. I was told that – despite the fact that CMS had never maintained data on the dual eligibles or transferred data of this magnitude before – CMS had everything under control and there would be a seamless transition of dual eligibles to Medicare on January 1.**

We now know that the transition was not as seamless as any of us hoped. If fact, it is my understanding that CMS was not able to verify data from the states until after the drug benefit had already started. Is that indeed the case? Has CMS since implemented a routine schedule for verifying data that is transmitted from the states and SSA on a regular basis?

A4. It is not true that the Centers for Medicare & Medicaid Services' (CMS) was not able to verify data from states until after the drug benefit had already started. Since 2004, CMS has been working with States on an ongoing and collaborative basis to ensure a smooth transition for their dual eligible residents. States report monthly files to CMS which include the enrollment status of Medicaid/Medicare dual eligibles. These files are transmitted electronically to CMS in the last half of each month and provide a basis for CMS action to deem individuals eligible for low-income subsidy, auto-enroll individuals

in Part D plans, and to establish the amount of the Phased-down State contribution (or "clawback") payments. This process also provides for States to transmit retroactive correction data to keep CMS records current. We contracted with Mathematica Policy Research, a nationally recognized expert in Medicaid data, to validate the quality of the state MMA data. All states have met the thresholds for data quality and have successfully transmitted these files to CMS since June, 2005.

Additionally, in an effort to ensure newly-dually eligible beneficiaries have appropriate access to prescription drugs, CMS is taking steps to prospectively identify these beneficiaries to ensure they may have immediate access to prescription drugs. CMS is working with states on a means to identify and enroll those Medicaid beneficiaries about to become Medicare eligible, who either turn 65 or reach the end of their 24-month Medicare disability waiting period.

Q5. Because CMS has not been providing plans with accurate and timely information about beneficiaries eligible for extra financial assistance, people who have qualified for extra help and signed up for Part D plans are being billed premiums and co-pays. Recently, I received a call from the daughter of a Medicare beneficiary in Marion County. Her mother, who is a dual eligible, was enrolled in a Humana plan on January 9 and received her drug card on January 14. However, when the daughter took her to the CVS Pharmacy in Marion Square on February 1, they were told her three prescriptions would cost over $150.00 and that she had a $250 deductible.

What has CMS done since January 1 to ensure that plans and pharmacies receive accurate information about a beneficiary's eligibility for extra help and that this information follows a beneficiary when he or she changes plans or pharmacies?

A5. Please be assured that the Centers for Medicare & Medicaid Services (CMS) has aggressively worked on solutions so that all people with Medicare who are enrolled in plans can receive the medications they need and are charged the correct cost sharing amount. As you know, some Medicare beneficiaries who were auto enrolled in a plan, or who enrolled late in a month have had trouble obtaining needed medications. Challenges in transmitting accurate and timely data are the primary cause in most of these cases. CMS has worked diligently before implementation and after, to ensure that its data systems were as accurate and complete as possible, however, there were problems in the first few weeks of implementation. To address those issues we increased the frequency of our data communications with plans and worked to ensure appropriate and timely data transfers between CMS and the states. We are pleased that these efforts have reduced the number of instances when beneficiaries have been unable to receive their medications, or have paid more than they ought to, due to an unavailability of correct data.

Q6. As I mentioned earlier, many beneficiaries who are eligible for extra help have been inappropriately charged the $250 deductible, full co-payment amounts, and, in some cases, the full costs of their drugs. Some beneficiaries who tried to get their drugs didn't even receive their prescriptions in January, but were still required to pay the

monthly premiums. Beneficiaries should be immediately reimbursed for these costs and the burden for reimbursement should not be on them. Has CMS put a system in place to guarantee that these individuals get reimbursed?

A6. The Centers for Medicare & Medicaid Services (CMS) is concerned that low-income beneficiaries are reimbursed when they were inappropriately charged incorrect cost-sharing amounts. Part D plans must reimburse enrollees for costs incorrectly incurred. If a person with the LIS is overcharged a deductible or copayment amount, they should contact their plan to find out how to submit a claim for reimbursement of the amount the plan should have paid and the cost sharing they should have paid, if applicable. The person will need to save the original receipt from the purchase in case they need to submit it with the claim. The Medicare drug plan will refund any amount that is due. To contact their plan, the person with the LIS can look on their membership card, read the plan's printed materials, or look on the plan's member website for the customer service number.

Q7. I question CMS' ability to enforce a 30-day or 90-day first-fill requirement on plans. CMS never required every plan to have a 30-day first-fill transition policy. CMS guidance dated March 16, 2005, specifically states "As a general indicator, we believe that a temporary 'first fill' supply of 30 days may be reasonable for new enrollees who first present at a pharmacy with a prescription for a drug not on the formulary..." "May be reasonable" does not sound like an enforceable requirement to me.

Dr. McClellan, what enforcement authority do you believe CMS has given that CMS guidance never REQUIRED plans to have a minimum 30-day first fill policy specifically, but rather a "transition policy" generally?

A7. Under 1860D-11(d)(2)(B) of the Social Security Act, CMS has authority, similar to the Director of OPM with respect to health benefits, to prescribe reasonable minimum standards for health plans. Under this authority we have required all Medicare drug plans to offer enrollees a transition process. We have made clear that we expect all plans to comply with the minimum 30-day first fill policy, which in fact was extended to 90-days for beneficiaries enrolling in a prescription drug plan effective January 1, 2006. CMS has an ongoing compliance monitoring program in place, and will follow-up with plans and take enforcement actions if necessary to ensure compliance with requirements.

Q8. It is my understanding that private drug plans have put in place several obstacles – such as prior authorization and prescription dose changes – that prevent people from getting the transitional supply of drugs they need and undermine the decisions of their doctors. What systems does CMS have in place to monitor plan denials? Has CMS developed specific protocols for sanctioning plans?

A8. CMS is tracking beneficiary complaints and addressing observed patterns of problems or non-compliance at the plan level, as well as program-wide across plans. CMS oversight activities begin with direct contact with the prescription drug plans, which typically results in resolution of the problem. If this action does not lead to timely resolution,

CMS follows up with a formal notice to the plan to resolve the compliance problem, and will employ progressively more severe enforcement tactics as needed to bring a plan into compliance.

Q9. Pharmacists in my state and all of the country are on the front lines of this crisis. They are overworked, underpaid, and many go home in tears at night because they are so frustrated. And, many small independent pharmacies in rural parts of the country either don't know about this special billing system CMS put in place for them to check beneficiary records or they can't use it.

One of our pharmacists in West Virginia has been experiencing difficulty with verifying his patients' Medicare Part D coverage and the plans they are enrolled in. Prior to the implementation of the Medicare Part D Program, he was open from 8:30 a.m. to 5:00 p.m. Up until last week, he remained open until 10:30 p.m. just to serve Medicare enrollees. He is dealing with the verification problems by dispensing a 2-week supply of medications to his customers and is hopeful that he will eventually be able bill the insurance plans after the glitches have been resolved. Although his office hours have about returned to normal, he and his wife have to return to the pharmacy after they eat dinner to make billing calls to plans from 7:00 p.m. to 1:00 a.m.

CMS has given assurances to the states that it will assist them in reconciling claims against Part D plans and getting "made whole" for their drug expenditures on behalf of beneficiaries. Dr. McClellan, why hasn't CMS offered the same assurance to pharmacies?

A9. CMS cannot make payment directly to pharmacies for Part D covered drugs. However, CMS recognizes that some pharmacists may have faced challenges in accessing beneficiary enrollment or cost-sharing information during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This will help to ensure that pharmacists have enough time to submit these claims to the plans and receive the appropriate payment.

Q10. The HHS Inspector General reports that at least 32 percent of dual eligibles – about two million people – were automatically assigned to prescription drug plans that do not cover at least one of their prescription drugs. The Inspector General also reports that dual eligibles need extra assistance to navigate the processes for changing plans and asking for an exception. How is CMS addressing this issue?

A10. Even if a drug is not on a plan's formulary, all Medicare drug plans must cover Part D drugs that are determined medically appropriate in accordance with our regulatory standards. Plans would cover such an off-formulary drug by granting an exception request made by the enrollee, when the plan determines that the on-formulary drug would have adverse effects, would not be as effective as the prescribed drug, or both. In most classes, at least two drugs – and in many cases many more than two – are covered. For

some conditions, such as mental illness, cancer and HIV/AIDS, all or substantially all of the drugs must be covered.

The OIG report has serious flaws and its conclusions are suspect, because rather than examine drugs that *individual* beneficiaries are taking, it merely examined a list of drugs. Medicare beneficiaries who are also on Medicaid take an average of eight prescriptions, not 200. The OIG report also fails to account for state-imposed Medicaid limits, which vary from state to state.

In contrast, CMS's own analysis, which through contact with clinicians and pharmacists examines actual prescriptions, found that on average about 93 percent of the medications dual eligibles used under Medicaid before their transition to the new Medicare drug coverage are on the prescription drug plan formularies available to them. CMS disagrees with OIG that the CMS study validates OIG's conclusions. CMS found that, on average, about 93 percent of drugs people actually use are on the formularies in contrast with the OIG which compared a list to a list.

Even if a plan's formulary does not cover the drug a Medicare beneficiary takes, it should include drugs also used to treat that condition. So *all* Medicare beneficiaries, including those who are in Medicaid and Medicare, are in plans that cover drugs similar to those they take now. For example, many drugs treat stomach acid or cholesterol or hay fever, so even if a plan doesn't cover one drug, it will cover another drug that also is used to treat the condition.

More than two-thirds of beneficiaries were in plans that covered *all* of their drugs. On average, less than one drug per beneficiary was not covered, according to the CMS analysis. It is actually likely that some dual eligibles will receive *more* generous coverage under Medicare. For example, about one-fourth of states limit the number of prescriptions that dual eligibles can fill each month.

In regards to outreach efforts, CMS has undertaken a variety of activities to assist individuals with the application process. One example is the State Health Insurance Assistance Programs (SHIPs). SHIPs are one of the key partners in Medicare's education and outreach efforts, which have contributed to over 27 million Americans receiving drug coverage in plans that offer prescription drug coverage that best suits their needs. SHIP volunteers have assisted Medicare beneficiaries by offering personalized face-to-face counseling concerning the drug benefit and advice on how to significantly lower their prescription drug costs. Over the past year, each SHIP has demonstrated unique methods and strategies to reach beneficiaries and their families where they live about new prescription drug coverage. Across the nation, SHIPs have hosted and participated in nearly 36,000 events in the last twelve months, more than double the previous year's 14,500 events. More than 4.2 million beneficiaries have received information and assistance from SHIP staff and volunteers about Medicare drug coverage.

CMS has worked with plans to ensure that new enrollees, including those who are moving from Medicaid to Medicare, are properly connected to coverage. CMS is

working with drug plans to ensure that each beneficiary is enrolled in the plan of their choice. These beneficiaries will be receiving a CMS letter stating clearly that the beneficiary changed plans and providing them with the opportunity and assistance to reaffirm their enrollment choice.

Q11. It is my understanding that some plans have extremely high co-payments and coinsurance for people with certain chronic conditions needing costly medications. I am very concerned that these plans are discriminating against the individuals who need the high cost drugs by using these high co-payments in much the same way that some HMOs discriminate against people needing costly medical services. Two weeks ago, I received a call from one of my constituents whose fiancé receives $1203.00 a month from Social Security Disability and cannot afford his Medicare Part D premiums. He is enrolled in Ameri-health Rx, option 2, and is currently without his medications. What, if anything, is CMS doing to prevent cherry picking of enrollees by private drug plans?

A11. Before entering into a Part D contract with a plan sponsor, CMS reviews plan bids and formulary designs to ensure they will not discriminate by substantially discouraging enrollment by certain classes of beneficiaries. If CMS determined that a plan's benefit package is designed to "cherry pick" by discriminating against sicker beneficiaries, CMS would not approve the plan's bid. CMS also monitors the marketing and enrollment activities of approved Part D sponsors to ensure that they do not discriminate against certain classes of beneficiaries.

Q12. While nearly 30 states have stepped in on a temporary basis to fill prescriptions for people with Medicare and Medicaid otherwise unable to fill them through their Part D plans, about 20 states, including West Virginia, have not stepped in. Is CMS studying what is going on in these states? For example, are the number of emergency room visits among Medicare beneficiaries in these states rising? How is CMS helping pharmacies and individual beneficiaries in these states?

A12. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled beneficiaries receive the prescription medication they need. As you know, through a Medicare demonstration project, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts.

For the majority of states, the demonstration ended on March 8, 2006 as the states no longer needed to use their Medicaid systems to pay for Medicare drug coverage. Since that time, CMS is pleased to see that the drug benefit is generally working well and beneficiaries are able to use their Medicare prescription drug coverage. CMS and the Medicare drug plans have resolved eligibility and billing issues, and most pharmacies in the states that activated their billing systems no longer need to bill those systems.

CMS is not specifically studying emergency room utilization in states that did not activate state billing systems. CMS is, however, helping pharmacies and beneficiaries in those states as part of the overall efforts the agency is making to ensure that beneficiaries have access to prescription drug coverage. We believe the Medicare prescription drug benefit is working well and millions of beneficiaries are saving money as a result of the new coverage.

Q13. Instead of having an arbitrary reimbursement policy that only helps pharmacies and beneficiaries in the 30 states that could afford to fill the gaps in drug coverage, why not have a universal policy that provides a Medicaid safety net for dual eligibles in any state who cannot access their medications through a private drug plan?

A13. The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring that all dual eligible beneficiaries are effectively enrolled in Medicare prescription drug plans so they are able to receive the medications they need. We believe we have a universal policy that provides dual eligible beneficiaries who are not enrolled in a Part D plan to access needed medication. CMS is making its best effort to identify and auto-enroll dual eligible individuals prior to the effective date of their Medicare Part D eligibility. However, it is possible that some individuals may go to pharmacies before they have been auto-enrolled in a Part D plan. For this reason CMS developed the Wellpoint point-of-sale (POS) interaction to ensure full-benefit dual eligible beneficiaries experience no coverage gap. Beneficiaries who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a Part D plan, can have the claim for their medication submitted to a single account for payment. The beneficiary can leave the pharmacy with a filled prescription, and a CMS contractor will immediately follow up to validate eligibility and facilitate enrollment of the full-benefit dual eligible into a Part D plan. We are performing a variety of outreach activities to educate beneficiaries and pharmacists on the use of the Wellpoint point-of-service (POS) system as a mechanism to get their prescriptions filled when necessary.

Q14. What is the current average wait time on the 1-800-MEDICARE help line? How does this compare to the experience during the first week of January?

A14. During the open enrollment period, speed to answer times averaged under two minutes. Call wait times spiked around the beginning of the enrollment period and during the first week of January. Weekend wait times also tend to be longer than during the week due to reduced staffing in our call centers.

Q15. What is the average wait time beneficiaries and pharmacists experience when they call the toll-free help lines of the prescription drug plans? Are some plans consistently worse than others? If so, what is the CMS oversight process for identifying and correcting the problems?

A15. Plans are required to submit data on a number of their activities, including their call center responsiveness, to CMS on a quarterly basis. We expect that data after the close of

the first quarter and, after appropriately analyzing it will be able to provide this information.

Q16. My staff tells me that a new email address [partdcomplaints_ro3@cms.hhs.gov] was created last week to address beneficiary problems. This was a change from the previous process of sending problems and complaints to a CMS regional representative – in West Virginia's case Jaime Clark, who has done an outstanding job. I imagine that changing from a real person to an email address has increased response times. What is the average response time for problems sent to the email address?

A16. The Part D Complaints Mailboxes were set up primarily for communication between the CMS Regional Offices and their partners, such as Congressional Offices and advocates on Part D implementation issues and complaints. Beneficiaries were always encouraged to call 1800-Medicare directly with Part D complaints.

Q17. When does CMS expect that the seven major implementation problems outlined so far will be resolved and people will get the coverage they need?

A17. CMS is working diligently to address all observed problems as quickly as possible. Ensuring all enrolled beneficiaries are able to access their drug coverage is a top priority.

Q18. Recently, I read an article in CQ Health Beat in which Secretary Leavitt is quoted as saying that "the number of 'dual eligibles' experiencing problems with the Medicare drug benefit has declined from about 10 percent to somewhere between 3 percent and 5 percent." Dr. McClellan, I'm hoping you can shed further light on these percents for me. I'm not sure what these percents are based on. Is it 3 to 5 percent of all dual eligibles who are having problems or is it 3 to 5 percent of all Medicare beneficiaries?

A18. During the first few weeks of implementation of the new Medicare prescription drug benefit, some Medicare beneficiaries who were auto-enrolled in a plan, or who enrolled late in a month had trouble obtaining needed medications. Challenges in transmitting accurate and timely data are the primary cause in most of these cases. Secretary Leavitt stated that between 3 percent and 5 percent of dual eligibles experienced problems with the Medicare drug benefit.

CMS has worked diligently before implementation and after, to ensure that its data systems were as accurate and complete as possible. We are pleased to see that millions of beneficiaries are receiving prescription drug coverage, and are enjoying significant savings in their drug prescription costs. Please be assured that CMS has aggressively worked on solutions so that all people with Medicare are effectively enrolled in plans and receive the medications they need and are charged the correct cost sharing amount. We believe that the vast majority of beneficiaries have been able to access the prescription drug benefit without any problems.

Q19. Also, can you tell me how the Administration defines "problems?" Do you mean people who showed up at the pharmacy who were not able to get their drugs at all? Or do you include in your definition of "problems" individuals who were ultimately able to get their drugs, but who faced obstacles in order to do so, such as

- **paying more than they should have for their prescriptions;**
- **not being in the system when the pharmacy when to check the plan they were enrolled in;**
- **being forced to wait to get their necessary medications because of arbitrary plan prior authorization requirements; or**
- **having to wait weeks for their Medicare card?**

A19. We would consider both of these scenarios to be problems. It is a top priority at CMS to ensure that beneficiaries who enroll in Part D have access to needed drugs covered by their plan, without unanticipated obstacles.

Q20. In enacting the Medicare law, Congress provided for a subsidy for employers that retain retiree health benefits that are at least equal to the Medicare Part D benefit. Within that statute, the Administration has broad authority to implement the employer subsidy, particularly in the way in which the test for "actuarial equivalence" is defined and applied. Can you tell me how many employers have applied for and received the employer subsidy so far? Of those that have received the subsidy, can you tell me how many have reduced the prescription drug benefits they offer in order to meet the actuarial equivalence standard set forth in the Medicare law?

A20. Approximately 3,650 plan sponsors providing coverage for 6.9 million retirees have been approved for the retiree drug subsidy for all or part of 2006. Note that some plan sponsors are entities providing coverage to retirees of multiple employers or unions. The exact number of employers or unions associated with these sponsors cannot be determined, because the retiree drug subsidy application collects information at the plan sponsor level.

CMS does not have information that would allow us to answer your second question. For example, plan sponsors that wish to participate in the retiree drug subsidy program for 2006 submit applications that attest to the fact that their coverage meets or exceeds actuarial equivalence for 2006; CMS has no information about the benefits they may have previously provided. Moreover, the question incorrectly suggests that MMA requires plan sponsors to *reduce* benefits in order to meet the actuarial equivalence standard. Sponsors satisfy the test if their plans equal *or exceed* the actuarial equivalence standard.

We believe most sponsors' plans provide prescription drug benefits that more heavily subsidize retirees than the Medicare standard benefit. In fact, the MMA provided a strong

incentive for plan sponsors that did not initially meet the standard to *increase* benefit levels in order to meet or exceed the standard and qualify for the retiree drug subsidy.

Q21. Can you give me the final enrollment figures for participation in the Medicare Oral Anti-Cancer Demonstration project? Is CMS tracking the Medicare beneficiaries who participated in this demonstration project to ensure that they have a smooth transition to drug coverage under the Medicare prescription drug benefit and are enrolled in plans that meet their prescription drug needs?

A21. We believe you are referring to the Medicare Replacement Drug Demonstration, which was designed to provide Medicare beneficiaries with coverage for a limited set of drugs and biologicals (including oral anti-cancer drugs) that replace the need for drugs already covered under Medicare Part B. At this point in time we expect to be able to release final enrollment numbers for this demonstration in a Report to Congress this summer.

CMS realized early on the importance of having in place a smooth transition process for all Medicare beneficiaries enrolling in a new Medicare prescription drug plan. One of the key elements included extending the transition period to 90 days for beneficiaries who enrolled with a January 1 effective date. All newly enrolled beneficiaries are eligible for at least a 30-day transition period. During this transition period, beneficiaries are able to access the prescription drugs on which they are already stabilized even if those drugs are not on the plan formulary. This "first fill" policy gave beneficiaries time to work with their providers to either find a therapeutic equivalent or file an exception.

Senator Bingaman

Q1. Drug Plan Implementation Data on Dual Eligibles: I would like to request the following information from CMS on drug plan implementation for dual eligibles:

- **a. Data, CMS or CMS contractor reports on the number of dual eligibles who were not auto-enrolled into a prescription drug plan (PDP).**
- **b. Data, CMS or CMS contractor reports on the number of dual eligibles not enrolled in a prescription drug plan who were subsequently enrolled through the point-of-service into Wellpoint (Anthem).**
- **c. Data, CMS or CMS contractor reports on the number of dual eligibles who were not recognized by the PDP or MA-PD in which they were enrolled as eligible for the Low Income Subsidy (Extra Help).**
- **d. Data, CMS or CMS contractor reports on the number of prescriptions denied by an MA-PD or PDP during the month of January because the drug was off formulary or subject to prior authorization, step therapy edits or quantity limits.**
- **e. Data, CMS or CMS contractor reports on the number of prescriptions denied for the above reasons that were subsequently filled under PDP or MA-PD transition policies and the length of those fills.**

A1. a. CMS enrolled all dual eligible beneficiaries for which data was received from the States.

b. We do not have data at this time, but expect that we will later in the year.

c. We do not have quantifiable data at this time.

d. There are no data available on the number of prescriptions denied by a Part D sponsor during the month of January at this time.

e. We do not have quantifiable data at this time.

Q2. **Data on Average Premiums for Different Types of Enrollees in Different Plans:** **CMS has reported that the average monthly premium is $25 per month for enrollees. However, what is the average monthly premium for people that were specifically:**

a. Enrolled in MA-PD plans;
b. Enrolled in PDP plans voluntarily; or,
c. Auto-enrolled in PDP plans (dual eligibles)?

A2. We do not currently have the further break-outs of average premiums, since enrollment is ongoing. We will revise average premium calculations to account for actual beneficiary choices in the future.

Q3. **Data on Enrollees Enrolled and Rejected for Low-Income Subsidy (LIS):** SSA reports that 1.36 million people have been enrolled in the low-income subsidy (LIS) or "Extra Help" as of January 27, 2006. They also report that 60% of the applications are rejected with the majority of those due to excessive assets. I would ask that you please provide me with the following information:

d. Data on the number of the 1.36 million people that qualify for the full LIS subsidy;
e. Data on the number of the 1.36 million people that qualify for the more limited LIS subsidy; and,
f. Data on the number of people that have income below 135% of poverty but are denied any LIS subsidy due to the assets test?

A3. The Social Security Administration is in the best position to answer your specific questions. SSA was given authority to process low-income subsidy applications and to make extra help eligibility determinations for individuals who were not automatically eligible. We expect SSA will make relevant data available later in the year.

Q4. **Ensuring Comprehensive Coverage of Mental Health Medications:** **The Centers for Medicare and Medicaid Services (CMS) issued a Question and Answer policy statement last June indicating that Medicare Part D plans would be expected to cover "all or substantially all" medications in six critical categories including anti-depressants, anti-psychotics, and anti-convulsants. CMS also stated its expectation that plans would not apply utilization management restrictions like prior authorization and step therapy to beneficiaries already stabilized on medications in**

these categories prior to enrolling or being enrolled in Part D. However, since the beginning of this year we have heard numerous instances of plans not complying with CMS's directions to cover substantially all drugs in these categories and of plans informing consumers that they must go through prior authorization processes in order to stay on medications they've already been taking.

How will CMS enforce this important policy position? I am aware of CMS's attempts to address this on a case-by-case basis but firmly believe that a more systematic approach is needed. Is legislation needed to ensure that your "substantially all" policy is heeded?

A4. The Administration is not supporting any legislative changes to the Part D program at this time. We will be issuing our 2007 formulary guidance later this spring.

Q5. **Monitoring Compliance and Impacts of "Substantially All" Policy: As you know there are grave risks inherent in suddenly denying psychiatric medications to mental health consumers or forcing them to abruptly switch medications. We are beginning to hear already of instances when individuals who were previously living in the community have been admitted for inpatient treatment because they were unable to access their medications through the Part D benefit (see, for example, stories in the *New York Times* and *Washington Post* in recent weeks).**

What is CMS doing to monitor the impact of the Part D benefit on consumers' health and well-being? How is CMS monitoring plan compliance with the "substantially all" policy?

A5. CMS' top priority is to ensure beneficiaries have access to the prescriptions they need. CMS expects plans to work directly with beneficiaries to resolve any complaints as they arise. However, in cases where that does not work, CMS has established a complaint tracking process for receiving and resolving individual complaints about plan service. As part of this process, CMS monitors the number and type of complaints from calls to 1-800-MEDICARE and those referred through CMS local offices. CMS will take enforcement actions as needed to ensure plan compliance with program requirements, leading up to contract termination or non-renewal where warranted.

Q6. **Reimbursement for Costs Inappropriately Incurred by Beneficiaries and Pharmacists Due to System Failures: Many have asked questions about how CMS would reimburse states for costs they have incurred in extending Medicaid coverage for dual eligibles during this initial transition period for the Part D benefit. However, there are other parties who have also had to shoulder unexpected and inappropriate costs due to failures in the enrollment and low-income subsidy processes. Many beneficiaries who should have received the Extra Help subsidy by now have been incorrectly charged high co-pays and deductibles that they cannot afford. In addition, many pharmacists are also either providing medications despite**

uncertainty as to whether they will be reimbursed or refusing to fill prescriptions because of this uncertainty.

It is not fair to put the burden on beneficiaries to go through any complicated administrative process in order to receive reimbursement for these costs. What is CMS doing to facilitate reimbursement for beneficiaries who paid higher co-pays or deductibles when these costs should have been covered for them by the Extra Help benefit?

A7. The Centers for Medicare & Medicaid Services (CMS) is concerned that low-income beneficiaries are reimbursed when they were inappropriately charged incorrect cost-sharing amounts. Part D plans must reimburse enrollees for costs incorrectly incurred. If a person with the LIS is overcharged a deductible or copayment amount, they should contact their plan to find out how to submit a claim for reimbursement of the amount the plan should have paid and the cost sharing they should have paid, if applicable. The person will need to save the original receipt from the purchase in case they need to submit it with the claim. The Medicare drug plan will refund any amount that is due. To contact their plan, the person with the LIS can look on their membership card, read the plan's printed materials, or look on the plan's member website for the customer service number.

Q8. What is CMS doing to ensure that pharmacists are fully reimbursed for medications dispensed to dual eligibles regardless of whether or not they have the correct billing code or can verify enrollment in a Part D plan?

A8. CMS cannot make payment directly to pharmacies for Part D covered drugs. However, CMS recognizes that some pharmacists may have faced challenges in accessing beneficiary enrollment or cost-sharing information during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This will help to ensure that pharmacists have enough time to submit these claims to the plans and receive the appropriate payment.

Q9. **<u>Exceptions and Appeals:</u> The next major challenge for Medicare beneficiaries and particularly those with mental illness will be navigating the Part D plans' exceptions and appeals processes. Although most mental health medications are supposed to be included on plan formularies, many mental health consumers, and especially those with serious mental illness, have numerous other conditions for which they also need medication, including diabetes, heart disease, and high blood pressure. Many may now be receiving the medications they need because of the transition coverage plans have been required to supply, the Medicaid wrap around coverage that so many states have volunteered to provide, or because these individuals got a multiple-month refill of their prescriptions at the end of December. However, to receive more lasting coverage of critical medicines many will have to seek exceptions and go through plan appeals processes. This will be a daunting task even for the**

most healthy among us, but for individuals struggling with mental illness the frustrations inherent in this kind of process will be overwhelming.

What is CMS doing to ensure that plan exceptions and appeals processes are as accessible and easy to use as possible for individuals with mental illness?

A9. Plans are required to have comprehensive formularies with at least two drugs from each therapeutic category and class. These formularies have been approved by CMS using industry best practices as a guide for their review. CMS required plans to cover all or substantially all drugs in six categories including antidepressant, anticonvulsant and antipsychotic to ensure that all beneficiaries receive access to medically necessary treatments. In addition, plans are required to have a simple and straightforward process to appeal for coverage of drugs not on the plan's formulary. Plans must respond to an exception request within 72 hours for standard request and 24 hours for an expedited request. Furthermore, plans must grant exception requests when determined medically appropriate under the standards in regulation and statute (i.e., the on-formulary drug would have adverse effects for the individual, would not be as effective, or both).

Q10. How will CMS monitor exceptions and appeals processes to see whether beneficiaries are getting a fair hearing and timely responses to their requests? What other enforcement authority does CMS need to ensure that the exceptions and appeals processes offer real avenues of assistance and are not just futile exercises in frustration for beneficiaries?

A10. Medicare prescription drug plans are subject to a number of statutory, regulatory and contractual requirements that hold them accountable to CMS for a wide variety of policies and actions. Additionally, CMS has communicated its expectations for complying with many statutory and regulatory requirements through comprehensive guidance documents (e.g., focusing on enrollment, appeals and grievances, and plan oversight to name just a few). CMS has a team of plan contract managers who are in constant communication with the plans to assure that any performance problems – and particularly those impacting beneficiaries or providers – are addressed quickly. If the problems persist, they are referred to senior level CMS people who work with senior level plan managers to reach resolution. In rare cases, plans are asked to work with CMS to develop a formal corrective action plan. CMS can elect not to renew a plan's contract for significant performance shortcomings.

Q11. <u>Burdens of Switching Medications and Appeals:</u> Millions of beneficiaries will need to work with doctors to switch medications when drugs are not covered under drug plans' formulary policies. Those who are unable to access important medications under formulary policies will have to work with their doctor to file appeals to obtain exceptions to coverage determinations made by the plans. It is important that the kinds of problems that marked the initial phase of Part D implementation – where enrollment problems meant that large numbers of beneficiaries couldn't obtain their medications – are not replicated as beneficiaries begin to use exceptions and appeals processes.

Related to the last question, it is now clear that doctors working with beneficiaries to file appeals are facing cumbersome exceptions and appeals processes. There are reports that doctors' offices must handle 30 or more different forms, requiring different kinds of clinical information specific to patient's cases. Instead, shouldn't CMS streamline this process by reducing the paperwork requirement to a simple standardized document for appeals?

A11. CMS continues to work with groups representing physicians, pharmacists, patients and Part D plans to simplify and standardize the information that physicians need to provide to plans. CMS has developed a model template that can be adopted by plans to receive requests for prescription information or changes and a model template that can be adopted and/or modified to request coverage determinations. A number of resources for physicians are listed on the provider section of the CMS web site at www.cms.hhs.gov/center/provider.asp where physician offices will find phone numbers to the plan's coverage determination telephone lines, as well as copies of model forms that will help streamline and expedite the process. In addition, this information is available through Medicare Learning Network at www.cms.hhs.gov/medlearn/drugcoverage.asp

Q12. **<u>Problems for Dual Eligibles, States, and Pharmacies:</u> If we are spending hundreds of billions of new dollars on this program, certainly we should ensure that dual eligibles, who have low-incomes and are more likely to suffer from cognitive impairment and mental disorders and have higher rates of diabetes, pulmonary disease, stroke and Alzheimer's disease than other beneficiaries, should not be worse off. They should not be subjected to increased cost sharing or more restricted formularies than they had been previously while enrolled in Medicaid.**

It is important to note that for dual eligibles, the Medicare drug benefit has not been voluntary, as they were automatically enrolled into Medicare drug plans, including some restricted Medicare managed care plans. Therefore, I urge HHS to consider supporting legislation to eliminate copayments for dually eligibles, particularly those that have income below poverty.

In addition, due to problems with the transition from Medicaid to Medicare for hundreds of thousands of the 6.2 million dual eligibles, states, pharmacies (including long term care pharmacies), and beneficiaries have all experienced varying levels of unreimbursed costs in addressed problems when dual eligibles have been unable to access the prescription drugs they needed for whatever reason.

Just three weeks ago, CMS stated that the agency did not have the legal authority to reimburse states (Knight Ridder Newspapers, "Medicare Won't Reimburse States for Emergency Drug Costs," January 17, 2006, or "States Told To Pay for Medicare Mix-Ups," January 18, 2006). So, a number of bills were introduced. Shortly thereafter, CMS said legislation was unnecessary because CMS would make the drug plans reimburse states (Knight Ridder Newspapers, "U.S. to Reimburse States

for Emergency Drug Costs," January 24, 2006). When that was deemed not fully acceptable, CMS then found 1967 waiver authority for Medicare provider payments and said the agency would reimburse states directly through the waiver authority.

While I appreciate the creativity of the Office of General Counsel, I remain deeply concerned about reimbursement for the pharmacies and the low-income Medicare beneficiaries themselves that have wrongly absorbed costs and even debt due to problems with the drug bill implementation and transition. In just one case handled by my Las Cruces office, a dual eligible resident in New Mexico was charged copayments ranging from $8 to $200 per prescription instead of $2 and $5.

To address such problems, Senator Jay Rockefeller introduced legislation (S. 2183, "Requiring Emergency Pharmaceutical Access for Individual Relief Act of 2006") that now has 29 cosponsors. In addition, Senator Nelson received a majority vote in the Senate for an amendment containing many of the provisions from that legislation on February 2, 2006, to address these problems.

Would HHS consider and support something like these legislative initiatives?

A12. We do not feel that legislation is needed at this time and have taken administrative actions to address many initial transitional issues.

The Centers for Medicare & Medicaid Services continues to work hard to implement the new Medicare prescription drug benefit. While we are pleased that enrollment has exceeded expectations and millions of prescriptions are being filled, we are also sensitive to dual eligible beneficiaries who have experienced problems.

With a new program of this size, there are bound to be problems with the transition to new coverage and we take these problems very seriously. Please be assured that CMS is aggressively working on solutions to ensure that all people with Medicare are effectively enrolled in drug plans and are receiving the medications they need.

These efforts include working to address issues that arise when individuals join or switch plans at the end of the month and use their coverage soon after, working with plans to continue to improve the performance of plan help lines, and continuing to improve direct plan-to-pharmacist technical support contacts; streamlining the data submission and reporting procedures from plans to Medicare; and working with plans to make sure that they adjudicate pharmacy claims correctly and according to their contract with the pharmacy. We are also meeting regularly with pharmacists around the country and working with pharmacy associations to provide additional technical support for pharmacies that are having difficulty using the new Medicare systems, and to address specific issues that pharmacists have identified. We are also in constant communication with the Medicare prescription drug plans on issues as they arise, and are working with the plans to resolve problems as quickly as possible.

We very much appreciate the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled beneficiaries receive the prescription medication they need. Specifically, through the Medicare demonstration project, developed in consultation with State Medicaid Directors, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts. The demonstration relies on "best practices" that have been identified by many states to work with CMS and HHS to minimize state billing and help any remaining dual eligible and low-income subsidy beneficiaries complete the transition to their new Medicare coverage.

From our ongoing discussions with States, pharmacists and advocates, I understand that we see results showing significant progress. The drug benefit is working well for people who are using their Medicare prescription drug coverage. CMS and the states have resolved the vast majority of billing and access issues and most states no longer need to use the state payment system to ensure that low-income beneficiaries continue to get the drugs they need.

Q13. **<u>Poor Enrollment Levels for the Low-Income Subsidy:</u> When the Medicare drug bill was enacted, it was recognized that the drug benefit only provides coverage for about one-third of the prescription drug costs for Medicare beneficiaries. Therefore, it was agreed that one-third of the Medicare beneficiaries, or those with income below 150 percent of the poverty level would need to receive a critically important low-income subsidy (LIS), or what the Social Security Administration (SSA) calls "Extra Help."**

Other than the dual eligibles, CMS estimated that there are 8.2 million low-income Medicare beneficiaries that would be eligible for "Extra Help," including over 100,000 in New Mexico (CMS, "What MMA Means to New Mexico," April 8, 2004). Unfortunately, to date, less than 1.4 million people, or just 17 percent, have been enrolled for the low-income subsidy and just over 10,000 have been enrolled in New Mexico, according to the SSA based on enrollment through January 27, 2006.

SSA data indicates that 60 percent of the applications they receive for "Extra Help" are rejected and the vast majority of those rejections are due to the assets test, which includes knowledge of the cash value of one's life insurance policy. According to a Kaiser Family Foundation study, nearly half (46 percent) of those deemed ineligible are widows who are very low-income due to the death of a spouse but have some assets, including a life insurance policy.

Another enormous barrier is that the eight-page application is difficult to fill out, as it asks Medicare beneficiaries to list numerous assets, and warns beneficiaries that could be punished for perjury and sent to prison or fined if they knowingly submit incorrect information.

Furthermore, over the past weekend, the *Los Angeles Times* reported that SSA is being admittedly "overwhelmed" with trying to find phone calls and process the millions of applications for the low-income subsidy ("Drug-Plan Woes Spread Past Medicare," February 4, 2006). In e-mail correspondence, the Deputy Administrator acknowledged that callers to the agency had a one-in-three chance of getting a busy signal and that they had "large backlogs in our Processing Centers" and visits to field offices had more than tripled. She added that she would have to redirect resources away from Social Security functions and noted "[i]t's not a rosy picture, and the news doesn't get better."

Considering that SSA received hundreds of millions of dollars in recent years to conduct outreach and enrollment determinations for "Extra Help" at a cost of hundreds of dollars per enrollee, the assets test has resulted in a major and costly barrier to coverage for some of our nation's most vulnerable citizens, including widows. Less than one-fifth of those promised "Extra Help" are realizing the benefits that were promised. Moreover, the assets test has resulted in enormous bureaucratic costs and is now having a profound negative impact on the operation of the Social Security program as well.

In light of these facts, would the Administration support legislation or to, at least, support some modification and simplification of the assets test?

A13. We do not believe legislation is needed at this time. CMS is committed to working hand-in-hand with other Federal agencies, such as the Social Security Administration, states, employers, unions, and national and community-based organizations to educate people with Medicare about the new Medicare prescription drug coverage and the low income subsidy. CMS wants to ensure that all beneficiaries eligible for the extra help available through the low-income subsidy can take advantage of the generous benefit.

Q14. **<u>Problems with the Coverage Gap, Particularly for Native Americans, People Living with HIV/AIDS, and Low-Income People Served by Community Health Centers:</u>**
As you know, when benefits hit the drug benefit coverage gap, they will be paying premiums to their Medicare drug plan while not getting drug coverage from the plan. For people that go to Indian pharmacies, AIDS Drug Assistance Programs (ADAP), or community health centers (CHCs) for their prescription drugs in the coverage gap, according to CMS regulations, spending for those drugs do <u>not</u> count toward the catastrophic limit.

Therefore, for Native Americans, people with HIV/AIDS, or low-income people receiving subsidized coverage from a community health center but not deemed eligible for "Extra Help," this policy will result in their absorbing monthly drug costs for a drug benefit that will never be able to access, as they will never reach the catastrophic limit.

This policy is nothing more than a direct cost shift by Medicare back on to the already horribly underfunded Indian Health Service, AIDS Drug Assistance

Programs, and community health centers. It is also wasteful government spending as Medicare would be making a monthly subsidy to a private drug plan while another federal program is simultaneously paying the full freight for those prescription drug costs.

I will also be introducing legislation in the near future to fix this problem. Just as spending by State Pharmacy Assistance Programs (SPAPs), which disproportionately operate in wealthier states, are specifically allowed to count toward the catastrophic limit, so should spending by those other safety net government programs. Would the Administration support a legislative initiative to address this problem?

A14. CMS recognizes that ADAPs, Community Health Centers and Indian Health Service Facilities are an integral component of the safety net for low income beneficiaries because they fill coverage gaps in public and private insurance for critical coverage. We believe that the law does not permit us to count costs incurred by these entities for drugs for Medicare beneficiaries toward the true out of pocket limit (TrOOP).

ADAPs, IHS, and other programs providing coverage that supplements the benefits provided under Part D may subsidize costs incurred against a Part D enrollee's deductible for those patients unable to afford these costs. Such provision of supplemental coverage would not affect an enrollee's ability to satisfy the deductible and therefore qualify for reduced cost-sharing between the deductible and the initial coverage limit. In addition, these entities are not precluded from paying a Part D enrollee's cost-sharing above the out-of-pocket threshold.

Q15. **Unexpected Beneficiary Cost Increases Due to Changes in Drug Plan Formularies: There are reports from a number of states that drug plans have changed their formularies since the beginning of the enrollment period, which has left beneficiaries with much higher out-of-pocket costs than they expected when they close a drug plan. As you will recall, Senators Craig Thomas and Jim Bunning raised this issue to you at the Senate Finance Committee meeting we held with both of you in January.**

Furthermore, Senators Dianne Feinstein, Susan Collins, and others introduced bipartisan legislation today ("Medicare Drug Formulary Protection Act") to prevent Medicare drug plans from ending coverage for drugs that were available when seniors enrolled in the private drug plan until the next open enrollment period.

Currently, private drug plans are allowed to change which drugs they cover, as long as they notify CMS and give advance notice to their enrollees. However, seniors have no recourse to change plans, as they must wait until the next open enrollment period and that may be as many as nine months away.

Senator Charles Schumer raised this issue with both of you during the Senate Finance Committee hearings this week. While you both spoke to CMS review of such changes, clearly a statutory prohibition provides Medicare beneficiaries with better protections to ensure they get the drugs they need and thought they signed up to be covered. Consequently, would the Administration support something like Senator Feinstein's bipartisan legislation in this area?

A15. The Administration is not supporting any legislative changes to the Part D program at this time. However, CMS will be considering non-legislative options for addressing your concerns.

Q16. **Extending the May 15th Deadline for Enrollment in the Drug Bill: On May 15, 2006, there is a pending deadline for enrolling in the Medicare drug benefit or beneficiaries will have to wait until January 1, 2007, to be enrolled and would face a one percent monthly penalty for having failed to enroll by May 15th. CMS and the Congress have now experienced that it was a mistake to dump millions of people overnight into a new system and the May 15th deadline for enrolling without penalty is creating this scenario all over again. Furthermore, for those enrolling in mid-year, they are penalized because they are less likely to be able to access the prescription drug bill's most significant benefit, which is the catastrophic limit, during the calendar year.**

Senator Bill Nelson of Florida has twice offered this amendment and has received a majority support in the Senate for this legislation to both the spending and tax reconciliation packages. Most recently, the Nelson Amendment received the support of a majority in the Senate (52-45), but failed due to a budget point of order (Senate Amendment #2707, February 2, 2006).

With the very low voluntary enrollment levels for the prescription drug bill due to the extreme complexity of the benefit, choice overload, and a number of other reasons, there is clearly a strong bipartisan sentiment in the Senate to extend the enrollment period and waive the penalty to ensure that beneficiaries are allowed to make informed and beneficial choices. As such, will the Administration to support Senator Nelson's legislation (S. 1841, the "Medicare Informed Choice Act of 2005") or something to extend the May 15th deadline for enrollment?

A16. At this time, our sole focus is on getting as many people enrolled as possible prior to May 15, 2006. The new Part D benefit is the biggest change to Medicare in the program's 40-year history, and offers significant savings for beneficiaries, including protection against catastrophic drug expenses should their need for prescription medicines change suddenly. We have been working hard to help beneficiaries understand their drug coverage options and how to enroll in a plan that will provide high quality coverage for prescription drugs. CMS Office of the Actuary anticipates a likely surge in beneficiary enrollment near the end of the open enrollment period. The actuaries believe that a number of people with very low drug costs are purposely postponing enrollment until close to May 15th in order to minimize the premiums they will pay in 2006 and still avoid the late enrollment

penalty. Additionally, our research shows that many beneficiaries are waiting until April or May to decide about their prescription drug coverage as they look at how the program works for their family and friends. We believe that the impending deadline will serve as an important incentive to generate enrollments among individuals who might otherwise put off signing up for coverage. Many sources of help are available right now for beneficiaries who want to enroll. This includes access to 1-800-MEDICARE with wait times of less than a few minutes for talking to a live person, huge capacity on the medicare.gov online enrollment tools, and thousands of enrollment and counseling events scheduled all over the country each week between now and May 15th. In addition, beneficiaries can contact their local State Health Insurance Assistance Program (SHIP) for assistance. We encourage beneficiaries to take advantage of all these resources now.

Q17. **Striking Copayments to Individuals in Community-Based Long Term Care Settings: While nursing home beneficiaries are exempt from prescription drug copayments, beneficiaries in community-based long term care settings are not. Major problems for Medicare beneficiaries living in such settings have been documented, particularly for those with cognitive disabilities (see, for example, *New York Times*, "Medicare Woes Take High Toll on Mentally Ill," January 21, 2006, and *Washington Post*, "Stability of Mentally Ill Shaken by Medicare Drug Plan Problems; Some Prescription Denials Have Heightened Distress," February 6, 2006).**

Senator Gordon Smith and I introduced bipartisan legislation to address this problem on February 1, 2006 (S. 2234, the "Home and Community Services Copayment Equity Act of 2006"). This issue was raised by Senators Smith, Nelson, and Clinton to you, Dr. McClellan, at a hearing before the Senate Select Committee on Aging last week.

Would the Administration support passage of this important legislation?

A17. We understand your concerns regarding the imposition of cost sharing on full benefit dual eligibles who are residents of assisted living facilities. Unfortunately, based on the specific statutory language in the MMA, we do not believe we have latitude to treat beneficiaries in assisted living facilities as institutionalized for the purpose of cost sharing exemption.

Section 1860D-14(a)(1)(D)(i) of the Social Security Act waives cost sharing for full benefit dual eligibles under the Medicare prescription drug program who meets the definition of and institutionalized individual in section 1902(q)(1)(B) of the Act. Section 1902(q)(1)(B) of the Act defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility for which payments are made under the Medicaid program throughout a month, and who is determined to be eligible for medical assistance under the State plan. An inpatient is someone who is physically in a medical institution or nursing facility. Therefore, beneficiaries living in the community, assisted living facilities, boarding homes, residential care homes, etc, do not meet the general definition of an institutionalized individual as specified in 1902(q)(1)(B). We

would like to work with you and your state to address ways to provide help with prescription drug copayments for vulnerable beneficiaries in home and community based settings.

Q18. **Pharmacy Assistance Programs: A number of drug companies have had pharmacy assistance programs that provide low-income people with critically needed free or discounted prescription drugs. However, the Office of Inspector General has deemed that, with the implementation of the prescription drug bill, that these pharmacy assistance programs must be restricted in support of the Medicare beneficiaries.**

I would ask what HHS's position in on this and would CMS support a legislative safe harbor to protect access of Medicare beneficiaries to these pharmacy assistance programs, particularly since the drug benefit only covers an estimated one-third of drug costs and many people with fixed incomes will find it extremely difficult to deal with such costs during the coverage gap?

A18. The decision to keep a patient assistance program is up to the pharmaceutical company, not the US government. The terms of the programs are determined by the company, without any government involvement.

There is nothing in the law that prohibits a pharmaceutical company patient assistance program from providing drug assistance to Medicare beneficiaries, even those enrolled in a Medicare prescription drug plan, but that help has to be outside the Medicare coverage – just as it has been until now.

Pharmaceutical company patient assistance programs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit. In these circumstances, the beneficiary obtains the patient assistance program drugs without using his or her Part D insurance benefit.

Q19. **Insufficient Funding for Counseling and Outreach: The complicated structure of the Medicare drug benefit necessities that Medicare beneficiaries by thoroughly educated and informed about the new program and the multiple choices available to them. However, groups providing personalized counseling, such as State Health Insurance Assistance Progams (SHIPs), have not been given sufficient resources. They have been understaffed and overwhelmed by calls. In a letter to the President dated December 15, 2005, Senator Max Baucus expressed concern that, of the $436 million it had for education and outreach, the Administration allocated just 7 percent to SHIPs.**

What is the Administration's budget request for funding to SHIPs in FY 2007? Also, would the Administration support legislation or funding to the SHIPs to help them work through the complexity and issues created by the new Medicare drug benefit?

A19. We are aware that SHIPs have experienced an increased demand for services with the start up of this important new drug benefit. As a result, we have placed heavy emphasis on building a more extensive network of partners to assist these programs in their education effort. The CMS Regional Offices have worked extensively to cultivate relationships with community-based organizations providing awareness, information, and enrollment assistance support at the community level. Furthermore, through join effort of CMS and the Administration on Aging (AoA), the Aging Network has enlisted the active support of 10,000 aging services community provider organizations in beneficiary education and enrollment activities.

Each year, the Administration requests funding for the State Health Insurance Assistance Programs (SHIPs) within the National Medicare & You Education Program (NMEP.) This program is part of CMS' Program Management account which is funded through the annual appropriation process. The SHIP funding is part of CMS' community-based outreach efforts. In CMS' FY 2007 budget request, the Administration included $43.6 million for all of the community-based outreach. In FY 2007, CMS will continue to build on its grant relationship with the SHIPs, which are located in all 50 States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. SHIPs provide one-on-one counseling to beneficiaries on complex Medicare-related topics, including enrollment in the new Medicare prescription drug benefit, entitlement, health plan options, Medigap, long-term care insurance, and Medicaid.

Q20. **Option for Medigap Coverage:** During consideration of the Medicare prescription drug bill, the House included a provision that allowed Medigap policies to wrap-around the drug benefit. The conference committee, however, failed to provide such an option and actually prohibited such policies.

Unfortunately, for Medicare beneficiaries with fixed incomes, the drug benefit is such that it is what some call a "rollcoaster" as coverage levels increase and drop many times. As a *Health Affairs* article notes, "...beneficiaries who sign up for the 'standard' benefit will face the full cost of medications for a month or two until meeting the required deductible ($250 in 2006). After that they will settle into a period of stable coverage, in which 75 percent of their prescription costs are paid by their drug plan. That phase ends for those with medication costs above $2,250 as they enter the "doughnut hole" – a $2,850 gap in coverage during which beneficiaries are responsible for paying for medications out of pocket. Beneficiaries with total drug spending in excess of $5,100 for the year will regain coverage and pay only 5 percent of their drug costs after reaching the catastrophic threshold. Then the calendar rolls over and the cycle begins anew" ("Riding the Rollercoaster: The Ups and Downs in Out-Of-Pocket Spending Under the Standard Medicare Drug Benefit," July/August 2005).

The best solution would be to fill the coverage gap, but I think that in lieu of such a result that we should at least allow Medicare beneficiaries the ability to buy a Medigap policy that would smooth out the "rollercoaster" effect of the benefit and give people with fixed incomes more certainty with their coverage. It is ironic and unfortunate that proponents of private sector health solutions would prohibit and ban such private sector options.

As such, would HHS to consider supporting legislation, as was included in the original House bill, to allow Medigap options to wrap-around the Medicare drug benefit, just as Medigap is allowed to do for the remainder of the Medicare program?

A20. The Administration is not supporting any legislative changes to the Part D program at this time.

Q21. **Beneficiary Information Regarding Health Plan Information:** The organizations that are participating in the Medicare Drug Plan have multiple reporting requirements that are due to CMS on May 31, 2006 and again on August 31, 2006. These reporting requirements include the following items:

* enrollment and disenrollment
* reversals
* medication therapy management
* generic dispensing rate
* prior authorization. step edits/ non-formulary exceptions
* appeals
* call center measures
* overpayment
* pharmaceutical manufacturer rebates
* discounts
* other price concessions
* licensure and solvency

This data should be helpful in evaluating how well plans are functioning and should also be useful to consumers in making decisions about which drug plans they would like to subscribe to. Thus, would like to know what mechanism CMS will have in place to make this information available to the public. How does CMS plan to make this information available to the beneficiaries, the public, and Congress?

A21. Once CMS receives the first set of required performance data from plans, we will validate it and begin making data publicly available.

Senator Lincoln

Q1. **Dr. McClellan, at last week's Aging Committee hearing, you and I discussed the prescription drug plans' payment cycle for pharmacies. You said that CMS would do all it could to enforce the contracts that pharmacies have with drug plans, which I assume includes specifics relating to payment terms. I have some follow-up questions for you on this:**

a. Does CMS include specific language in its contracts with drug plans that specify how often the plan has to pay pharmacies or how often it must update the pricing benchmarks used as the basis of pharmacy reimbursement?

b. Should such terms be included in the contracts that CMS has with plans?

c. What is your understanding of the general prescription drug plan contract terms relating to payment terms and cycles with pharmacies? Is there great variation from contract to contract in terms of how quickly pharmacists have to submit claims and how quickly pharmacists will be reimbursed? Is every two weeks typical?

d. Do you have any recommendations on how these terms could be changed to alleviate some of the economic pressure on pharmacies?

A1. **a.** No. This is between the plan and pharmacy to negotiate.

b. Payment levels and frequency are addressed through contract between a plan and a pharmacy. Plans are expected to comply with the terms of the contracts they have signed with pharmacies. If a pharmacy finds a plan is not compliant with the terms and conditions of its contract, they should contact the plan. They may also contact CMS via 1-800-MEDICARE. Such pharmacist complaints will be logged and sent to the appropriate CMS Regional Office. As part of our ongoing monitoring efforts, CMS will continue to track the pharmacy compensation process across plans, and will address pharmacist complaints related to failure to pay according to contract terms as such issues arise.

c. CMS intends to research these issues through a survey of plans later this year.

d. CMS establishes criteria for pharmacy networks and access that must be adhered to by the various Medicare prescription drug plan sponsors. In addition, plans must comply with any willing pharmacy requirements so that a pharmacy accepting the standard contractual terms and conditions becomes a network pharmacy. These requirements give pharmacists some amount of leverage when it comes to negotiating payment speed and amounts

CMS has been in continuous contact with the pharmacy community, providing information about the new program and accepting feedback. Payment cycles are contractual issues between plans and pharmacies. We understand that plans may follow a payment cycle that differs from that of the various Medicaid programs with which pharmacists are familiar and that shifting from one cycle to another will cause temporary interruptions in payment. We investigate all complaints about plans not paying pharmacists on time and we will seek remedial action against any plans that are not abiding by the terms of the contract that it has negotiated with its network pharmacies. Negotiations, however, are between the plans and the pharmacies.

Q2. **We also discussed Arkansas' state law allowing patients to choose their own pharmacy. We asked for guidance in our January 9th letter. Will CMS issue further guidance on this? We need you to clarify the intent of your policy on a patient's right to choose a pharmacy when such a right exits under state law.**

A2. Because state freedom of choice laws typically regulate the conduct of long-term care (LTC) facilities and do not affect the Part D sponsors, such as by forcing the sponsor to modify its plan coverage or the manner in which it administers its Part D plan, CMS believes these laws likely are not preempted under section 1860D-12(g) of the Social Security Act. If a state freedom of choice law placed requirements on a plan sponsor, then we would have to reevaluate the issue.

Our primary concern is ensuring plan sponsors have adequate pharmacy networks that meet our standards, including ensuring that plans provide convenient access to long-term care pharmacies for enrollees who are residents of long-term care facilities. CMS will continue to monitor Part D sponsors to ensure that they provide convenient access to their enrollees residing in LTC facilities.

Ultimately LTC beneficiaries will have the full array of prescription drug plans operating in their area available to them. We encourage LTC facilities to assist their residents in enrolling in prescription drug plans. I appreciate your efforts to ensure that we provide Medicare beneficiaries with the prescription drug coverage they expect and deserve.

Q3. **State Reimbursement: Last week my office received a copy of the template for the state reimbursement costs (Section 402 Demonstration Application Template) from CMS. In addition, CMS representatives indicated that the agency (CMS) will contract with "reconciliation intermediaries" to calculate and process the reimbursements. It seems as if the implementation of this reimbursement process is still in its early phases. As of Friday, your staff indicated that CMS had yet to contact with these so-called "reconciliation intermediaries."**

a. Can you give us an update on the timeline for this reimbursement process? Will you have to extend the February 15th deadline?

b. How is CMS intending to calculate the "administrative costs" that states have incurred over the past month and a half?

c. It is my understanding that drug costs will reimbursed for any drug costs incurred by February 15th. Yet, for administrative costs, such costs can be reimbursed even for those incurred beyond February 15th. Can you give us a sense of how long the window will remain open?

A3. **a.** CMS appreciates the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled beneficiaries receive the prescription medication they need. CMS will continue to work expeditiously with States in processing the claims for this demonstration to ensure that America's most vulnerable populations continue to receive the care they need. On Thursday, February 16, 2006, the Centers for Medicare & Medicaid Services (CMS) approved the applications of 45 States (including the District of Columbia) to participate in a Medicare demonstration project that will reimburse States for their efforts to assist dual eligible beneficiaries and

low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage. Under the demonstration, states will submit information to a CMS contractor, in a specified format, on costs that the State incurred relative to the provision of Part D drugs to dual eligible and low-income subsidy entitled beneficiaries. This information will include claims-level data on payments made to pharmacies, as well as information detailing administrative costs that are eligible for reimbursement under the demonstration. CMS will reimburse states directly based on eligible claims received. CMS's contractor will be responsible for submitting the state claims data to Part D plans in order to reconcile the state payments made for Part D drugs with claims that should have been paid by the Part D plan and determine the final payment due to States.

b. Administrative costs are defined in the state demonstration template as "costs directly related to the facilitation of correct enrollment and the development and processing of claims associated with the provision of Part D drugs, as dual eligible beneficiaries make the transition from Medicaid coverage to Medicare Part D coverage, or the provision of, or facilitation of access to, Part D drugs for low income subsidy entitled beneficiaries."

c. CMS extended the demonstration project in all 45 states through March 8, 2006 for claims.

The demonstration project in 12 states was extended beyond the March 8, 2006 deadline. Specifically, CMS has approved an extension of the demonstration for reimbursement of drug claims' costs until March 15, 2006 for Massachusetts and Wisconsin. CMS has approved an extension of the demonstration for reimbursement of drug claims' costs until March 17, 2006 for Arkansas. CMS has approved an extension of the demonstration for reimbursement of drug claims' costs until March 21, 2006 for New Hampshire. CMS has approved an extension of the demonstration for reimbursement of drug claims' costs until March 31, 2006 for the following states: Arizona, California, Maine, New Jersey, New York, Pennsylvania, Texas, and Vermont.

Medicare will pay for administrative costs incurred through May 5, 2006. Additionally, Medicare will continue to pay administrative costs incurred for activities specifically related to the creation, production, exchange and reconciliation of eligibility and claims files for the Section 402 State Reimbursement Demonstration Project through September 1, 2006. No Federal funding is available for any other administrative costs incurred after May 5, 2006 than those specified above.

Q4. If we look ahead to reimbursement process, I can imagine a situation where states come up with one figure regarding reimbursement and the reconciliation intermediary contracted by CMS comes up with a different – and perhaps lower – figure.

a. In the event of such a discrepancy, do you envision CMS establishing an appeals process?

b. If not, how will such differences between states and the reconciliation intermediary be resolved?

A4. **a.** As described in the demonstration template, under the demonstration, the State will submit beneficiary identification information to CMS for all beneficiaries for whom the State incurred eligible demonstration costs. States that have paid for Part D drugs will also submit to CMS information, in a specified format, on costs that the State incurred related to the provision of Part D drugs to dual eligible and low-income subsidy entitled beneficiaries for prescription drug provided. This information will include claim-level data on payments to pharmacies, as well as information detailing administrative costs eligible for reimbursement under the demonstration.

CMS will compute the total initial amount owed to the State, based on certain edit checks of the submitted claims data to verify that the beneficiary is a dual eligible beneficiary or a low-income subsidy entitled beneficiary and that the prescription drug is a Part D drug and will remit this amount to the State. CMS will then use information submitted by States to recover from each Part D plan the portion of CMS payment to the State that is the responsibility of the respective Part D plan, that is, the plan's contractual payment for the drugs. CMS will also reimburse the State for additional costs determined by CMS to be eligible under the demonstration.

CMS does not plan to establish a formal appeals process for the 402 state reimbursement demonstration.

b. We expect there may be some back and forth between the states and our contractor on some data issues. We expect to resolve issues without a formal appeals process. Discussion will be on a claim-by-claim basis, not on an aggregate dollar amount.

Q5. **<u>Formularies for Duals</u>: Dr. McClellan, the Inspector General of the Department of Health and Human Services recently issued a report to determine the extent to which Medicare prescription drug plan formularies include drugs commonly used by dual eligibles under Medicaid. In the report, they found that <u>only 8% of the dual eligibles in Arkansas</u> were randomly assigned to prescription drug plans that covered ALL of the most common drugs used by the dual eligible population. This was the lowest percentage of any state in the country. Compare that with our neighbor region of Missouri, where 25% of their dual eligibles were randomly assigned to PDPs that covered all of the most commonly used drugs, or Oklahoma, where 20% were assigned to plans that covered all of the most commonly used drugs. What is the reason for this discrepancy? How can we be sure that the 61,000 residents of Arkansas who are dual eligibles are getting access to the drugs they need through their PDPs?**

A5. All Medicare prescription drug plans are required to cover all Part D drugs when – under the regulations – the drugs are determined medically appropriate. Even if a Part D drugs is not on the plan's formulary, the plan must cover the drug through an exception process,

if the plan determines the formulary drug would (a) have adverse effects, (b) would not be effective for the particular beneficiary, or both. When a specific drug is not on the formulary, generic equivalents or other drugs used to treat the same condition should be covered, but the specific drugs used when an individual beneficiary joins the plan may differ from those included on the plan's formulary. For some conditions, such as mental illness, cancer and HIV/AIDS, all or substantially all of the drugs must be covered.

The OIG report has serious flaws and its conclusions are suspect, because rather than examine drugs that *individual* beneficiaries are taking, it merely examined a list of drugs. Medicare beneficiaries who are also on Medicaid take an average of eight prescriptions, not 200. The OIG report also fails to account for state-imposed Medicaid limits, which vary from state to state.

In contrast, CMS's own analysis, which through contact with clinicians and pharmacists examines actual prescriptions, found that on average about 93 percent of the medications dual eligible individuals used under Medicaid before their transition to the new Medicare drug coverage are on the prescription drug plan formularies available to them. CMS disagrees with OIG that the CMS study validates OIG's conclusions. CMS found that, on average, about 93 percent of drugs people actually use are on the formularies in contrast with the OIG which compared a list to a list.

In addition to covering all drugs determined medically appropriate, Part D plans are required to have a transition process in place to address the needs of new enrollees who are stabilized on certain drug regimens when they join a plan. An effective transition process ensures that new drug plan enrollees will have timely access to the drugs they need while allowing the flexibility necessary for plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. CMS reviews each plan sponsor's transition process as part of the plan benefit design review. Plan transition processes must address these situations for new enrollees, in addition to situations where new enrollees are stabilized on formulary drugs that require prior authorization or step therapy under a plan's utilization management rules.

In addition, the guidance for the transition process recognizes the needs of new full-benefit dual eligibles who may be auto-enrolled in a prescription drug plan and who, despite education and outreach efforts on the changing nature of their drug coverage under the Medicare drug benefit, may be unaware of the impact of the prescription drug plan's formulary or utilization management practices on their existing drug regimens.

Q6. **<u>Auto-enrolling Duals</u>: It is my understanding that, in auto-enrolling full dual eligibles, CMS relied on data from the Social Security Administration (like the resident's home of record) and used that data to randomly assign beneficiaries to plans. In some cases, long-term care residents were assigned to a plan outside of their region because their home of record was in a different state from their long-term care facility. How does CMS plan to address this problem?**

A6. CMS is committed to ensuring that Medicare beneficiaries in long-term care (LTC) facilities continue to receive the medications and pharmacy services they need without interruption. CMS established a standard operating procedure that caseworkers use to address the rare situation in which a beneficiary had been auto-enrolled by CMS into a plan outside of his or her region. The caseworker determines whether the PDP sponsor offers another PDP in the beneficiary's region with a premium at or below the low-income premium subsidy amount. If the PDP sponsor offers such a plan, then CMS instructs the PDP sponsor to move the beneficiary to that PDP. If the PDP sponsor does not offer such a plan but does have a national pharmacy network, CMS instructs the beneficiary to use that network to obtain his or her prescriptions at the appropriate copayment and join a plan in his her region with a prospective effective date. Finally, if the PDP sponsor does not have a national pharmacy network, then the caseworker is instructed to cancel the out-of-area auto-enrollment retroactively, and allow the beneficiary to access the Wellpoint POS system.

Q7. **<u>Duals with Mental Illness</u>: Dr. McClellan, there was a heart-breaking article in the *Washington Post* on Monday about the problems individuals with mental illness are having in accessing their medications under Part D. About 2 million mentally ill Americans are dual eligibles, and many of them have had to go without the drugs that keep their delusions, paranoia, or anxieties under control. The story told of how a mother of two was unable to get her prescription for her antidepressant because it was not covered under her new plan. Fortunately, her local community mental health center bought her a week's supply of her medication. They have done this for several other clients with a cost exceeding $2,400. How will community health centers be reimbursed for their extra costs that, frankly, the private plans in Part D should be covering? Also, did CMS do anything special as far as outreach and education for persons with mental illnesses?**

A7. Due to the unique needs of institutionalized beneficiaries and beneficiaries with cognitive impairments, CMS made special efforts to reach out to this vulnerable population. Among others, the Substance Abuse and Mental Health Services Administration (SAMSHA) has been a key CMS partner in these outreach efforts. Pursuant to an interagency agreement, CMS and SAMSHA worked together to develop materials and coordinate outreach activities. In addition, CMS has been working with state and local health agencies and disability organizations to reach institutionalized beneficiaries and those with cognitive impairments. Examples of organizations CMS has collaborated with include the National Mental Health Association, National Alliance for the Mentally Ill (NAMI), National Council for Community Behavioral Healthcare, and the National Association of State Mental Health Program Directors. CMS offered training and materials to these organizations to supplement the substantial outreach activities conducted by the CMS regional offices.

Q8. **<u>Educating Pharmacists</u>: Like Mr. Schule will testify later, many of my pharmacists did not know about the point-of-sale (Wellpoint plan) or about the E1 query and many other processes needed to do their jobs with Medicare Part D over the last 3-4**

weeks. Even a pharmacist at Wal-Mart in Mountain View didn't know what an E1 query was. How did you educate pharmacists, particularly independent pharmacists who don't belong to an association of any kind, on all these processes? It seems to me that this should have been a top priority leading up to January. Don't you have a list of all the pharmacists who contract with Medicaid? Couldn't you have used that?

A8. * CMS released several Medicare Rx Updates about the point-of-sale (POS) system, and also a national press release on 12/1/2005 (see http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1736). To view all Medicare Rx Updates, please visit http://www.cms.hhs.gov/Pharmacy/RX/list.asp#TopOfPage.

* CMS released several Medicare Rx Updates and presented information through our regional pharmacists and national speakers to thousands of pharmacists about the E1.

* Assuming the processes Senator Lincoln refers to are the E1 and POS, it is important to note the actual problem. Pharmacists are using the E1 system effectively by all accounts. There are two reasons that the E1 system might provide incomplete information. One reason could be that pharmacists are using poor search criteria to query the data. While CMS does not have significant evidence of this occurring on a frequent basis, we did release two separate fact sheets from Per-Se technologies which point to best practices for using their system. In addition, CMS held three conference calls to specifically discuss issues pharmacists might have using this system.

* There are dozens of software vendors whose systems vary widely. These vendors provide specific information to their pharmacy customers for systems use. CMS presented at the national conference for the American Society for Automation in Pharmacy (ASAP), the national association for the vast majority of software vendors. At this conference, we stressed the importance of outreach.

* The other reason the E1 might provide incomplete information is because the information loaded into that system is incomplete. This may occur due to a lag in processing enrollments or inaccurate information loaded from different systems; this information frequently originates at the state and in Long Term Care settings. The cascading effect of this incomplete data places pharmacists in the position of using this incomplete information to determine that beneficiaries are eligible for using the Wellpoint POS solution. CMS and Wellpoint have been explicit in their instructions to pharmacists that they verify dual eligibility as well as whether the patient has been enrolled into another plan prior to using the POS solution. Indeed, instructions clearly state "If the beneficiary is a full-benefit dual eligible individual, but already enrolled in a Part D plan, the POS Contractor will contact the pharmacy to reverse the claim, and the pharmacy will bill the appropriate Part D plan. Wellpoint will generally provide information on the other Part D plan to the pharmacy at the time contact is made to reverse the claim. If the beneficiary is Medicaid-eligible only, the POS Contractor will contact the pharmacy to reverse the claim, and the pharmacy will bill the appropriate

state agency. If the person is Medicare-eligible only, the Enrollment Contractor notifies the beneficiary that s/he is ineligible for facilitated enrollment, but may enroll in a Part D plan under normal enrollment rules. The POS Contractor will contact the pharmacy to reverse the claim, and the pharmacy will pursue collection." Unfortunately, in their frustration over lagging data, some pharmacists have made the affirmative decision that they will bill the Wellpoint contractor regardless of their assumed risk.

Q9. **Generic Drugs: Dr. McClellan, I read an article by Marc Kaufman in Saturday's *Washington Post* which reported that the FDA now has a backlog of over 800 generic drug applications. Since generic drugs are vital in helping to contain the costs to seniors participating in the new Medicare prescription drug program, I find this tremendous amount of backlogged applications to be both unbelievable and unacceptable. Generic drugs typically cost 60 to 90 percent less than the brand-name versions of the same drugs, so this backlog is essentially costing the federal government billions of dollars under the new program. It seems to me like this is a simple case where the Bush Administration is letting down the American people. My questions are:**

a. How can we justify that while the Administration is looking for ways to cut the Medicare program in its new budget proposal, at the same time it has allowed the backlog of generic drug applications to balloon to 800?

b. Is there anything the Administration can do to make generic drugs more available to our nation's seniors?

c. Does CMS have any cost projections regarding how much both Medicare beneficiaries in particular and American taxpayers in general could save as a result of using more generic drugs?

d. Do you support the use of a "user fee" for generic drug applications?

A9. **a.** CMS does not have a response to this question. This is a question for the FDA.

b. CMS supports the use of generics, where appropriate as determined in consultation with a health care provider. All Medicare Part D plans include coverage for generic drugs.

c. While CMS has not specifically projected cost savings associated with using more generic drugs, ongoing CMS analyses of the savings available to illustrative beneficiaries enrolled in Part D plans indicate that beneficiaries with common chronic conditions who are willing to switch to generic drugs can save even more on their prescription drug bills. These savings could amount to as much as 76 percent off of their annual prescription drug costs, with similarly large savings available through the 10th-ranked and mid-priced plans (74 percent and 65 percent, respectively). In sum, beneficiaries using generic drugs when available can get very large savings from a broad range of plans.

d. CMS does not have a position on this issue. This is a question for the FDA.

Q10. I'm sure you are familiar with the press that has occurred on SSA Deputy Commissioner McMahon's e-mail regarding the problems SSA is having with administering the Medicare Low Income Subsidy. It seems that SSA has been so overwhelmed with Medicare that their other services are starting to suffer. She says that SSA's "National 800 Number Network has been overwhelmed for weeks, with busy rates running above 35 percent many days" and they had "nearly 200,000 visitors a day" to their field offices. I'm concerned if we don't help SSA resolve these problems, the American people are going to lose their confidence in the SSA and the Medicare drug benefit. What are your thoughts on this? Do you feel that Congress should act quickly to provide the SSA with the resources they need?

A10. The Social Security Administration (SSA) is in the best position to answer your specific questions. SSA was given authority to process low-income subsidy applications and to make extra help eligibility determinations for individuals who were not automatically eligible. Section 1015 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Public Law 108-173) appropriated $500,000,000 for the Social Security Administration to carry out the changes made by MMA, including the processing of low-income subsidy applications.

Q11. How will CMS ensure that a beneficiary who changes plans on the 31st of the month get access to their prescriptions on the 1st of the next month? (This turnaround time certainly didn't work in January; how will it work in subsequent months?)

A11. CMS has been reaching out to beneficiaries and educating our partner network about the importance of enrolling in the first half of the month to maximize chances of a smooth transition to new Part D coverage. We also have taken steps to improve the regularity and consistency of data exchanges between plans and CMS to increase the likelihood that pharmacies will have enrollment and cost-sharing information available to them when new enrollees first try to fill a prescription using their new coverage. Transition-related issues such as those occurring in early January have declined considerably.

Q12. How long does CMS estimate it will take to address all these access problems dual eligibles and other low-income beneficiaries are experiencing?

A12. The Centers for Medicare & Medicaid Services is particularly concerned about ensuring that the new Medicare prescription drug benefit works effectively for all of our dually eligible beneficiaries. As you know, we experienced some problems in the Medicare prescription drug coverage early on, but we were able to find, fix and finish the unexpected problems quickly. For the vast majority of beneficiaries, the drug benefit is working well and beneficiaries are using their Medicare prescription drug coverage. CMS and state officials have now resolved the vast majority of billing and access issues, and most pharmacies are able to use Part D to ensure that low-income beneficiaries continue to get the drugs they need through the Medicare prescription drug plans. We

will work on a continual basis to solve any outstanding or new issues that inhibit beneficiaries from accessing necessary drugs.

Q13. What is the average wait time for beneficiaries calling 1-800-MEDICARE? What is the average wait time for beneficiaries calling the prescription drug plans, by plan?

A13. On average, from November 15, 2005 to April 12, 2006, callers to 1-800-MEDICARE experienced call wait times of less than 2 minutes. We are still collecting data on plan call center wait times but will release it publicly at a later date.

Q14. How many beneficiaries eligible for the Low Income Subsidy are still waiting for their Medicare letters and cards? How can they get their prescriptions filled while they wait?

A14. We believe that after initial start-up period, only a minimal number of low-income subsidy eligibles are still awaiting their Medicare letters and/or cards (although the time they wait for these documents may vary because of lags between file updates). We continue to emphasize to Part D plans on our weekly calls and in our published guidance that once eligibility is confirmed, enrollment packages must be sent quickly.

We are asking beneficiaries who have enrolled late in the month to take the following with them to the pharmacy to assist them in getting their prescriptions filled until they receive a membership card:

- An acknowledgement or confirmation letter until they receive a membership card.
- If they haven't received an enrollment letter yet, a welcome letter from the plan, or an enrollment confirmation number.

Q15. According to the Social Security Administration, 60% of those beneficiaries applying for the Low-Income Subsidy are denied, and over 60% of those are due to the assets test. Do you support eliminating the assets test?

A15. We do not believe legislation is needed at this time. CMS is committed to working hand-in-hand with other Federal agencies, such as the Social Security Administration, states, employers, unions, and national and community-based organizations to educate people with Medicare about the new Medicare prescription drug coverage and the low-income subsidy. CMS wants to ensure that all beneficiaries eligible for the extra help available through the low-income subsidy can take advantage of the generous benefit.

Q16. I have heard from my nursing home facilities in Arkansas that billing for prescription drugs has been complicated by delays in uploading data to the national database used by long-term care pharmacies. Beneficiary data has been incomplete or outdated. There are still significant numbers of beneficiaries whose plan information cannot be located or whose low-income subsidy information is not correct. How does CMS propose to remedy deficiencies in Part D enrollment data systems to enable pharmacies to determine the plan in which a Medicare beneficiary

is enrolled? When will all of the enrollment information, including the low-income subsidy data, be loaded into this system?

A16. CMS has taken a two-step approach to addressing this problem. First, we educated beneficiaries and our partner network about the importance of enrolling in the first half of the month to maximize chances of a smooth transition to new Part D coverage. We also have taken steps to improve the regularity and consistency of data exchanges between plans and CMS to increase the likelihood that pharmacies will have enrollment and cost-sharing information available to them when new enrollees first try to fill a prescription using their new coverage. Thanks to these strategies, transition-related issues such as those occurring in early January have declined considerably.

Q17. CMS sought to randomly auto-enroll all dual eligibles into Part D plans with premiums below a "benchmark amount". As a result, many nursing home residents were auto-enrolled in plans that did not cover the drugs they needed, or which subjected the drugs to cumbersome prior authorization requirements. (In some plans, up to 40 percent of all drugs had prior authorization requirements.) The Part D marketing guidelines prohibited nursing homes and pharmacies from helping dual eligibles choose a plan designed to meet their particular needs. Yet nursing homes remain responsible under federal and state regulations for providing prescription drug coverage to their residents. Will CMS consider revising its guidance to allow nursing home professionals or pharmacists to assist residents in selecting Part D plans designed to meet their needs?

A17. Nursing home staff are allowed to help beneficiaries compare plans objectively given the individual's needs. However, nursing home staff are not allowed to select plans for individuals, in order, to avoid allowing staff to steer patients to plans that contract with favored pharmacies rather than ones that are best for patients. The Part D benefit is a voluntary benefit, which means that all beneficiaries must be given a choice of plans - including the choice to decline coverage. Allowing nursing homes to select a plan for their patients could result in a beneficiary not having access to the benefit structure they prefer.

Q18. Pharmacies that have appropriately dispensed medications to meet their patients' needs during the transition to Part D are now facing massive amounts of rejected claims, resulting from confusion during the first month of implementation of the new drug benefit. CMS has given assurances to the states that it will assist them in reconciling claims against Part D plans and ensure they are "made whole" for their drug expenditures on behalf of Medicare beneficiaries. Will CMS provide that same assurance to pharmacies?

A18. CMS recognizes and applauds the heroic efforts made by pharmacists during implementation of Part D. Especially in the early days of the benefit, when pharmacists could not easily get coverage information on a number of people with Medicare and Medicaid, many phone calls resulted in long phone delays. We have seen most drug plans respond with enhanced customer and pharmacy service. Pharmacists tell us that

wait times for most of the individual drug plans are improving. CMS monitoring of the customer and pharmacy help lines is confirming this. Good service is a requirement in the Medicare drug benefit, and we are pleased that many plans are meeting and exceeding these expectations now. To help make sure that all drug plans are producing good service and are recognized for it, we have increased our monitoring and reporting of wait times. Any plan that does not meet its commitment to provide prompt service will be dealt with through the corrective actions that the Secretary has authority to take.

As you are aware, through a new Medicare demonstration project, developed in consultation with State Medicaid Directors, States that have assisted their dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage will be reimbursed for their efforts. Unlike states, however, pharmacies administering Part D drugs have preexisting contracts with prescription drug plans (PDPs). Payment between plans and pharmacies is a term and condition of the contract between those two parties. Plans are required to comply with the terms and conditions of their contracts, including paying pharmacies according to the terms outlined in such contracts. To the extent that a pharmacy believes that a plan is not making payments according to their contract, the pharmacy should notify CMS and we will investigate and take corrective action as necessary.

Q19. CMS has acted to enforce transition policies designed to ensure that beneficiaries receive the medications they need. However, complicated and cumbersome prior authorization requirements that vary by plan threaten to cause further problems in Part D once the "first-fill" transition phase of the program concludes. These requirements pose particular difficulties in the long-term care setting, where Medicare beneficiaries must have 24/7 access to medically necessary prescription drugs. To remedy this problem, will CMS require standardized prior authorization forms and processes for Part D plans?

A19. CMS' top priority is to ensure that Medicare beneficiaries have access to the prescription drugs they need. We have been working with Part D plans and the pharmacy community to facilitate the adoption of uniform codes at the pharmacy counter. In addition, CMS worked with industry partners to develop a standardized prior authorization and appeals form for providers, which plans are expected to accept.

Q20. Many of the Medicare beneficiaries residing in assisted living facilities are frail, elderly individuals who require the same specialized pharmacy services as residents of other long-term care facilities. Assisted living residents should therefore receive the same protections that CMS has extended to other long-term care residents, including special enrollment periods and exemption from cost-sharing requirements. Will CMS resolve this issue by interpreting the regulatory definition of "long-term care facilities" to include assisted living facilities?

A20. We understand your concerns regarding the imposition of cost sharing on the full benefit dual eligible population enrolled in home and community-based waiver programs.

However, based on the specific statutory language, we do not believe we have latitude to treat home and community-based recipients as institutionalized for the purpose of the cost sharing exemption. Section 1860D-14(a)(1)(D)(i) eliminates copayments for full-benefit dual eligible individuals who are institutionalized (as defined in section 1902(q)(1)(B) under the Medicare prescription drug benefit. Section 1902(q)(1)(B) of the statute defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility for which payments are made under the Medicaid program throughout a month, and who is determined to be eligible for medical assistance under the State plan. An inpatient is someone who is physically in a medical institution or nursing facility. Beneficiaries living in the community, assisted living facilities, boarding homes, residential care homes, etc do not meet the general definition of an institutionalized individual as defined in section 1902(q)(1)(B). This includes individuals receiving services under the waiver authority provided by section 1915(c) of the Act.

RESPONSES FROM DR. MARK McCLELLAN
TO QUESTIONS POSED DURING THE HEARING
SENATE FINANCE COMMITTEE
FEBRUARY 8, 2006

SENATOR BINGAMAN. Let me ask about one other issue, which is a little unrelated. There is a provision in the bill, the prescription drug bill, that allows Indian Health Service and Indian providers to get Medicare pricing for their contract health service dollars. That requires some implementation by you folks. It was supposed to be implemented over a year ago. Nothing has been done on it. This means a lot of money to the Indian Health Service. Is this something you could get people working on and get that implemented?

DR. McCLELLAN. On April 28, 2006, the Indian Health Service (IHS) Published a proposed rule in the *Federal Register* (71 FR 25124) to implement section 506 of the Medicare Modernization Act (MMA). Section 506 requires hospitals that furnish inpatient hospital services payable under Medicare to participate in the Contract Health Services (CHS) program of IHS. The rule proposed amending IHS regulations, by adding a new subpart D to describe the "Medicare-like rate" payment methodology and other requirements for Medicare-participating hospitals or critical access hospitals (CAHs) who furnish inpatient or outpatient services, either directly or under arrangement, to American Indians or Alaska Natives who are authorized to receive these services by the IHS, Tribe or Tribal organization, or Urban Indian organization. The rule also proposed amending Medicare regulations to require Medicare-participating hospitals or CAHs that furnish inpatient hospital services to American Indian or Alaska Native patients who are authorized for services by the IHS, Tribe or Tribal organization, or Urban Indian organization to accept the "Medicare-like rate" payment methodology.

The proposed rule provided interested persons until June 27, 2006 to submit written comments. IHS and the Centers for Medicare & Medicaid Services are currently in the process of addressing the comments received as they develop a joint final rule, which is expected to be issued next year.

SENATOR LINCOLN. Our attorney general came out with a ruling yesterday about being able to choose our State law. So, do you have any idea when we can expect that guidance from you? Maybe this week?

DR. McCLELLAN. Because State freedom of choice laws typically regulate the conduct of long-term care (LTC) facilities and do not affect the Part D sponsors, such as by forcing the sponsor to modify its plan coverage or the manner in which it administers its

Part D plan, CMS believes these laws likely are not preempted under section 1860D-12(g) of the Social Security Act. If a State freedom of choice law placed requirements on a plan sponsor, then we would have to reevaluate the issue.

Our primary concern is ensuring plan sponsors have adequate pharmacy networks that meet our standards, including ensuring that plans provide convenient access to long-term care pharmacies for enrollees who are residents of long-term care facilities. CMS will continue to monitor Part D sponsors to ensure that they provide convenient access to their enrollees residing in LTC facilities.

Ultimately LTC beneficiaries will have the full array of prescription drug plans operating in their area available to them. We encourage LTC facilities to assist their residents in enrolling in prescription drug plans. I appreciate your efforts to ensure that we provide Medicare beneficiaries with the prescription drug coverage they expect and deserve.

SENATOR BAUCUS. If you would also give us a little more breakdown on who the beneficiaries are. For example, what about Native Americans? We have a sizeable Indian population in Montana. We are a little concerned that they are not getting the same treatment, the same access as others.

DR. McCLELLAN. CMS is engaged in an ongoing effort to ensure that American Indians and Alaska Natives fully participate and fully enjoy the benefits of the Part D Medicare Benefit. CMS recognizes the particular needs for outreach and training at the local level for this population and the I/T/U system. CMS is fully committed to working with Indian Health Services (IHS) and tribal representatives to ensure that all Medicare eligibles receive the information they need to make informed choices and to reduce their prescription costs and that the I/T/U network is able to bill appropriately and accurately for Medicare services.

Those efforts began with the outreach and education activities Drug Discount Card and Transitional Assistance Program. CMS through an interagency agreement with the IHS conducted 14 training sessions in Indian Country and trained over 700 IHS and tribal staff on the benefit. CMS Central and Regional office staff, IHS staff, and representatives from the two card sponsors, CSC and Express Scripts that received special endorsements to administer the programs in Indian country, presented at each of the trainings. CMS outreach and training materials, including posters and brochures, were adapted to address the special circumstances of the I/T/U system and American Indian and Alaska Native beneficiaries. CMS has conducted, and continues to sponsor, several Open Door Forums for the AI/AN population and continues to work with the CMS Tribal Technical Advisory Group (TTAG). In addition, CMS maintains a website (*http://www.cros.hhs.gov/AIAN/*) for the American Indian/Alaska Native population. Information about Part D and links to materials and other resources are available on this site. CMS continues to sponsor open door forums on the drug benefit and has participated in several IHS national teleconferences with system users on the implementation process.

CMS is committed to ensuring that the I/T/U system will see the results of our efforts to assure accurate and up to date drug plan information, on dual eligibles, is available; data translation is improved between Medicare, health plans and States; there is responsive service through 1-800-MEDICARE, measuring and monitoring the plans' customer service and wait times; there is an extension of transitional coverage; and work with the States and the problem-solving process is continued.

CMS is developing guidance for tribes, identifying a process by which they can contact one key person within each Region to resolve problems, concerns, and barriers they face with beneficiary enrollment in the prescription drug benefit. This process will be similar to the process used for States. However, it will be tailored to address unique needs of Tribes and the Indian Health Service outreach and enrollment staff.

CMS has been fully engaged with the American Indian and Alaska Native population during both the preparation for and the initial phase of the enrollment period through coordinated outreach, education and enrollment activities. CMS is fully committed to continuing this relationship and is confident that the AIAN population will fully benefit from Part D.

At this point in time we do not have State-by-State information on the number of Native Americans who have enrolled in the Part D program. CMS is actively pursuing a data sharing agreement with IHS that will enable us to determine an unduplicated State-level count of AI/AN beneficiaries. When the data sharing agreement is established CMS will be able to compare IHS person level data from I/T/U pharmacies in 28 States to CMS Part D enrollment data.

SENATOR BAUCUS. Turning a little bit to education, or lack thereof, of pharmacists, you have stated you vigorously reached out to pharmacists. I must say, some of the independent pharmacists that I have talked to have not heard from you—not from you, personally, but not heard from CMS—at all.

The concern we have is that the treatment of pharmacists by CMS is substandard compared to, say, the treatment that CMS gives to doctors. That is, you educate doctors directly on Medicare benefits and all that is involved in Medicare. You do not go out and directly reach out to the pharmacists. Rather, it seems that you are relying on trade associations to get the information out to pharmacists. You would not do that with doctors. You would not reach out to the AMA and have the AMA educate doctors. Rather, you do it directly. Fifty percent of doctors do not belong to the AMA. Is that somewhat true with pharmacy trade associations too? We have a very strong impression in my State that there has been virtually no CMS education and outreach, at least to independent pharmacists.

DR McCLELLAN. CMS has conducted a number of outreach efforts focused on pharmacists in Montana. These efforts include:

June 28, 2005 - Train the Trainer Session, 8:30 a.m. to 5 p.m., Kalispell Center Mall;
October 27, 2005 - Train the Trainer Session, 8:30 a.m. to 5 p.m., Grouse Mountain Lodge; and
December 21, 2005 - CMS Conference call for Montana pharmacies.

The Denver regional Provider Relations office sent a mailing to 335 Montana Pharmacies. The mailing contained a one-page spreadsheet with information on all plans available in Montana, the most recent information on the point of sale process, and the long-term care convenient access statement. They also announced an upcoming free 1-800 conference call on December 21, 2005 at 7 p.m. specifically for Montana pharmacists. The call had 29 callers.

These efforts build on on-going, intensive outreach conducted through national pharmacy organizations. Many of these organizations worked with us to set up IT systems that would facilitate the work of their members.

CMS worked directly with Per-Se Technologies (formerly NDCHealth), pharmacy organizations, software vendors and the American Society for Automation in Pharmacy (ASAP) to design, develop and implement the eligibility and TrOOP processing systems. Pharmacies access these systems through dozens of software vendors. As a result, training and instruction for new functionality is system-specific and may have to be customized by individual software vendors. CMS and Per-Se Technologies initiated and have maintained contact with vendors to ensure that they have the necessary information to train on the new systems. CMS also designed and released a training CD for pharmacists. This training is available on the webpage CMS created specifically for pharmacists (*www.cms.hhs.gov/pharmacy*). In addition, CMS held three national conference calls on January 31, 2006 to provide information and answer questions about the El and POS systems.

CMS provided extensive direct outreach to pharmacists specifically about the Point of Sale Facilitated Enrollment (POS FE) solution. Specifically, we released several Medicare Rx Updates, a national press release and placed instructions for its use on *www.cms.hhs.gov/pharmacy.* Furthermore, CMS' regional pharmacists traveled the country, giving speeches, participating in panels and disseminating their contact information for any pharmacist with questions.

As the contracted plan, Wellpoint regularly communicates directly with pharmacies regarding the procedures for the POS FE. This communication includes detailed instructions for using the POS FE solution, payment information, an extensive list of FAQs, and more. This information is also available on their website (*www.anthem prescription.com*).

This new functionality allows pharmacists to save time coordinating Part D benefits.

SENATOR WYDEN. A lot of these small independents have really put themselves on the line here. And, I think we need to give them more leverage with the plans. Now, by your count, Dr. McClellan, how many seniors were wrongly denied drug coverage since January 1? Would you get back to me with an Agency report on how many seniors were wrongly denied? I want to know, for example, the kind of context you are talking about.

DR McCLELLAN. We do not have the data necessary to answer this question. However, CMS has been tracking beneficiary and pharmacist complaints, and we have established a comprehensive case work management system to address issues that might interfere with beneficiary access to their Medicare prescription drug coverage.

SENATOR LINCOLN. It seems that the implementation of the reimbursement process is still in a lot of early phases. We are one of those States with about 17,000 beneficiaries that have been dealt with by the State, to the tune of about $4 million. As of Friday, your staff indicated that CMS had yet to have contact with these so-called reconciliation intermediaries. Is that correct? Can you give us an update on the timeline for that reimbursement process? Will you have to extend the February 15th deadline, considering today is the 8th?

DR. McCLELLAN. CMS appreciates the efforts States have made during this transition period in ensuring that dual eligible beneficiaries and other low-income subsidy entitled beneficiaries receive the prescription medication they need. CMS will continue to work expeditiously with States in processing the claims for this demonstration to ensure that America's most vulnerable populations continue to receive the care they need.

On Thursday, February 16, 2006, the Centers for Medicare & Medicaid Services (CMS) approved the applications of 45 States (including the District of Columbia) to participate in a Medicare demonstration project that will reimburse States for their efforts to assist dual eligible beneficiaries and low-income subsidy entitled populations in obtaining and accessing Medicare Part D coverage.

Under the demonstration, States will submit information to a CMS contractor, in a specified format, on costs that the State incurred relative to the provision of Part D drugs to dual eligible and low-income subsidy entitled beneficiaries. This information will include claims-level data on payments made to pharmacies, as well as information detailing administrative costs that are eligible for reimbursement under the demonstration. CMS will reimburse States directly based on eligible claims received. CMS's contractor will be responsible for submitting the State claims data to Part D plans in order to reconcile the State payments made for Part D drugs with claims that should have been paid by the Part D plan and determine the final payment due to States.

SENATOR LINCOLN. I just have one more minute, and I have one more question to get on your mind. The Inspector General at the Department of Health and Human Services recently issued a report to determine the extent to which Medicare prescription drug formularies included drugs commonly used by dual eligibles under Medicaid.

In the report, they found that only 8 percent of the dual eligibles in Arkansas were randomly assigned to prescription drug plans that covered all of the most common drugs used by dual eligible populations. It was the lowest percentage of any State in the country. Compare that with our neighboring regional States like Missouri, where 25 percent of their dual eligibles had access as they were randomly assigned to PDPs.

Do you think there is any answer to why that discrepancy happened? How can we be sure that the 61,000 residents of Arkansas who are dual eligibles are going to get the access to the drugs that they need through their PDPs?

DR. McCLELLAN. All Medicare prescription drug plans are required to cover all Part D drugs, when under the regulations, the drugs are determined medically appropriate. Even if a Part D drug is not on the plan's formulary, the plan must cover the drug through an exception process if the plan determines the formulary drug would (a) have adverse effects, (b) would not be effective for the particular beneficiary, or both. When a specific drug is not on the formulary, generic equivalents or other drugs used to treat the same condition should be covered, but the specific drugs used when an individual beneficiary joins the plan may differ from those included on the plan's formulary. For some conditions, such as mental illness, cancer and HIV/AIDS, all or substantially all of the drugs must be covered.

CMS's own analysis, which through contact with clinicians and pharmacists examines actual prescriptions, found that on average about 93 percent of the medications dual eligible individuals used under Medicaid before their transition to the new Medicare drug coverage are on the prescription drug plan formularies available to them.

In addition to covering all drugs determined medically appropriate, Part D plans are required to have a transition process in place to address the needs of new enrollees who are stabilized on certain drug regimens when they join a plan. An effective transition process ensures that new drug plan enrollees will have timely access to the drugs they need while allowing the flexibility necessary for plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. CMS reviews each plan sponsor's transition process as part of the plan benefit design review. Plan transition processes must address these situations for new enrollees, in addition to situations where enrollees are stabilized on formulary drugs that require prior authorization or step therapy under a plan's utilization management rules.

Furthermore, the guidance for the transition process recognizes the needs of new full-benefit dual eligibles who may be auto-enrolled in a prescription drug plan and who, despite education and outreach efforts on the changing nature of their drug coverage under the Medicare drug benefit, may be unaware of the impact of the prescription drug plan's formulary or utilization management practices on their existing drug regimens.

Testimony of Joy Paeth, CEO
Area Agency on Aging of Southwestern Illinois
Before the U. S. Senate Committee on Finance

Thank you for the opportunity to speak about our experiences with the Medicare Prescription Drug Benefit. I am from an Area Agency on Aging in Southwestern Illinois. We are located just east of St. Louis, Missouri, and serve 115,000 older persons in a seven-county region in Illinois. Our primary purpose as an Area Agency on Aging is to build systems, coordinate services and provide answers on aging.

It was a very natural transition for us to go full speed ahead to assist with the Medicare Prescription Drug Coverage. We began by assisting older adults with the prescription drug cards in 2004, and are now working on Part D enrollment. Through the Transitional Assistance drug cards, we became familiar with the national Access to Benefits Coalition (ABC) and the tools they had to offer, such as BenefitsCheckUpRx (BCURx). We are the catalyst agency for the St. Louis Metropolitan Access to Benefits Coalition. We believe the resources, training, tools and new collaborators are what helped us to successfully assist older adults, caregivers and persons with disabilities with Medicare Prescription Drug Coverage.

Strong Coalitions

Building our coalition entailed bringing all willing and able to the table to better assist individuals. The coalition began with our traditional aging network providers and then extended to the advocate community for persons with disabilities. We began to recognize the importance of the Senior Health Insurance Program (SHIP) and the knowledge they brought to the table. SHIP then became a member, as did the Social Security Administration, the faith- based community, and we were so delighted when we had the large pharmacies join us around the table. This was our start. As an Area Agency on Aging we were always strong collaborators, but now we were communicating with organizations that were never a part of the traditional aging network.

Recognizing that the media played such a large role in this process, and that we shared the same media market with two Missouri Area Agencies on Aging (AAA), it

was critical that we all provide the same message to our communities. With all three AAA's in the Coalition, we were set. Our coalition had the ability to reach out to approximately 365,000 older adults with the assistance of financial resources from the national ABC for the region. These resources helped to do things that may seem simple to many but were critical to the aging network being able to accomplish this task. The coalition's members added high speed internet access, additional phone lines, temporary workers, laptops and wireless internet connections. More importantly, we were able to develop a marketing strategy to both educate and inform older adults and persons with disabilities about the new benefits and where to go to find answers to their many questions.

Clear Communications

Our strategy is to "Simplify the message." Although we have 42 members in our coalition, we offered only one phone number in all of our messages. Without having to dial another number we were able to transfer the caller to their local community for assistance. Whenever possible, a live person answered the call.

The real challenge was to assure that the person on the line could correctly answer the caller's questions. CMS was instrumental in providing training for the coalition. Members were able to attend trainings, use online modules and access materials that were helpful in sharing the message with individuals. Every conference, meeting or event focused on Medicare prescription drug coverage. CMS's embrace of the existing aging network made this daunting task doable. We also expanded our SHIP network of providers. We were fortunate to be able to use resources that flowed into our state from CMS to accomplish this task.

The tremendous amount of available information and training was helpful as the public began to gain more knowledge about the plans. We placed a great emphasis on training the small local pharmacies as well as the larger ones. Along with training, each pharmacy was given materials they could include, with customers prescriptions noting appropriate AAA's phone number to call should they have questions about Medicare prescription drug coverage.

Outreach

Outreach and education became more and more challenging as we approached the fall. A typical event that would bring in approximately 30-40 people prior to Medicare Prescription Drug Coverage would now bring in 200. The request for educational events was increasing every day. Since October, the Coalition hosted 360 educational sessions for 19,560 people.

There was a definite point in time when we knew the education and outreach was done and it was time to help people to enroll. This however happened prior to the plans being available. Everywhere we went, plan finder "worksheets" were distributed and mailed to the appropriate AAA. When the plan finder was accessible, we were one step ahead. We completed our own training on how to use the plan finder and in turn trained the coalition members.

At this point, we were able to access resources from the National Association of Area Agencies on Aging through the Administration on Aging and CMS to focus on the areas that had a high population of persons with low incomes. We continued to work closely with staff from the SSA. The AAA staff would answer initial questions and the SSA staff would be available to assist with the Low Income Subsidy application (LIS). This proved to be an effective strategy to when assisting people with the LIS application.

At the same time a team from NCOA's My Medicare Matters campaign was deployed to assist with the entire ABC region. Due to our earlier work, we were able to help those who had made inquires early in the process prior to being able to enroll, thus eliminating the backlog and permitting us to keep up with the incoming calls. Calls were not always related to enrolling, but rather reassuring the older adult that they were in the appropriate plan or already had credible coverage. To date we have assisted 26,321 people.

State Wrap-Around Programs

Illinois has wrap-around coverage, Illinois Cares Rx. Our challenge in Illinois has been that over 300,000 older adults and persons with disabilities that were using the state's plan were required to apply for Medicare prescription drug coverage. This required three steps: (1) applying for the Low Income Subsidy; (2) making sure the plan they were automatically enrolled in was appropriate; and (3) once again, continue to apply for the Illinois coverage.

"Why is it changing?" was the most common question and most difficult to answer. When the person finally got to the pharmacy after January 1st, we ran into the most challenges. Many times, software wasn't working from the PDP, or the person had not yet been assigned a plan. Illinois has two PDPs that coordinate with Illinois Cares Rx. Switching from one plan to another could not be done by the network but rather only through the state. The majority of the network's work in January has been assisting with the "switch" or finding out in which plan they have been enrolled. There were also regions in the state that had no coordinating PPO or HMO, which posed a challenge for those individuals. Currently, Illinois has eight coordinating HMOs and PPOs. This has increased by two since January.

Challenges

We have seen the CMS website improve since December with the addition of more comprehensive information on the formularies. The number of questions we are getting has decreased, however the ones we get now are more complicated. It is truly amazing to see the technology work as well as it has. Some general challenges we have had are:

- Customer service lines for the plans have long waits and many times the caller is disconnected. Simple questions could be answered electronically.
- There has been a delay entering a person's data in the system so we can assist them in finding which plan they are assigned.
- Medicaid problems have revolved around the individual not being automatically enrolled or knowing if they are LIS eligible. The communication to the network is limited; therefore, we are unable to assist with enrollment once we have the information. The State of Illinois Department of Public Aid

has not had the training to assist with the process. These are the most frustrating challenges because there is nothing that we can do to help a person and we are the entity with whom they have built trust.

- There have been challenges with insurance brokers enrolling people in plans that are not appropriate for them and using the person's one chance to switch plans. If a person could switch more often during this initial period, they could solve this challenge.
- Pharmacies have not been getting the appropriate information from the E1 Queries.

Results

Having financial resources in the aging network dedicated to supporting Medicare prescription drug outreach and enrollment activities has been the only way we have stayed educated and able to assist. The challenges have been minimal due to the systems we have been able to develop. As May 15, 2006 approaches, however, our resources go away, but the need to help seniors, particularly those with low incomes, with concerns regarding Medicare prescription drug coverage will remain. We hope we will be able to continue to provide the comprehensive training and assistance to both the network and older adults and persons with disabilities.

It is my hope that we will continue to hear stories such as a person with no drug coverage who was paying $2,830/month for lung cancer medication (Tarceva), this person is now paying $1,458 for the entire year, including premium. Another individual who is HIV positive was paying $1250.09/month for medication (Lexiva, Norvir, Epzicom). This person is on SSI and does not have drug coverage now will pay $180/year for medication and will have no premium. This is why we do the work we do. As a result of the prescription drug plans, the Area Agency on Aging has new collaborations and a stronger network with stronger systems than ever before.

Thank you again for the opportunity to share the experiences of the network. I am happy to answer any questions you might have.

Finance Committee Hearing
"Implementation of Medicare Part D"
Questions Submitted for the Record
Joy Paeth
March 13, 2006

Senator Baucus

1a. Do you feel you have the resources to meet demand for assistance to those who choose to enroll in a Part D Plan?

Response

Our Agency has been fortunate. We are very aggressive in seeking out resources and have been successful.

b. Will the need for funds continue after May 15th?

Response

Yes, we will still get questions from those who did not enroll initially, and will also need to assist when the enrollment period begins again. We have also been able to successfully answer people's questions, therefore they will come back to us.

c. What percentage of current funds would be needed on an ongoing basis?

Response

25 percent.

2. Do you have enough computers, wireless access, and field staff needed to reach out to eligible seniors?

Response

Yes, but no funds for the wireless connections.

3. In testimony, you noted that your Area Agency on Aging was "able to access resources from the National Association of Area Agencies on Aging [N4A] through the Administration on Aging and CMS…" to help fund their outreach and education efforts.

How much money was made available to assist your AAA? Are any of these funds contingent upon or connected with performance criteria, such as number or percent of enrollments completed? If so, might these funds be reduced if performance criteria are not met, even though your resources to attempt to meet them were expended?

Response

Approximately $300,000 in assistance was made available, and it was based on the number of persons assisted, not on percent of enrollments. We have never had a problem with performance, so I cannot answer the question about the reduction of funds.

Written Testimony of Susan E. Rawlings, Senior Vice President and President, Senior Services, WellPoint, Inc. Before the Senate Finance Committee

Hearing on Medicare Drug Benefit Implementation

Introduction

Chairman Grassley, Senator Baucus, and distinguished members of the Committee, thank you for the opportunity to discuss implementation of the Medicare Part D Prescription Drug Benefit and the unique role that WellPoint's Facilitated Enrollment process is playing to address the challenges related to the transition of full-benefit dual eligibles to the Part D program. Facilitated Enrollment is functioning as an additional layer of protection to help fulfill the nation's promise to Medicare beneficiaries with special needs.

I am Susan Rawlings, Senior Vice President and President in charge of Senior Services for WellPoint, Inc. I have been with WellPoint since November, 2004. WellPoint, Inc. is the largest publicly traded commercial health benefits company in terms of membership in the United States. WellPoint is an independent licensee of the Blue Cross Blue Shield Association and serves its members through Blue Cross and Blue Shield plans in fourteen states and UniCare.

In positions held prior to WellPoint, I focused on Medicare programs, retiree health and applying the principles of geriatric medicine. At WellPoint, I am building on my experience by developing products, programs and services that meet the needs of our senior and disabled populations; for example, a key focus of mine over the last year has been the planning and application processes associated with the participation of WellPoint companies in the new Medicare Part D program. I am also continuing my efforts to broaden the understanding about older adults among multiple stakeholders. I believe that greater insight will be required to ensure that the health care system and the Medicare program are well prepared as the baby boomers age.

WellPoint Participation in Part D Prescription Drug Benefit Program

WellPoint has a long history of providing services to Medicare beneficiaries, including offering Medicare supplemental insurance and Medicare Advantage programs. As of 12/31/05, we were serving over 1 million beneficiaries in these programs across the country. Prior to the launch of Part D, we offered the interim prescription drug card. We have continued that tradition with the new Medicare Part D program. We offer the prescription drug benefit through our Medicare Advantage-Prescription Drug Plans (MA-PDs) in several regions, including the newly available Regional Preferred Provider Organization (PPO) in three regions, as well as stand-alone Prescriptions Drug Plans (PDPs) in all 34 regions, encompassing the 50 states and the District of Columbia. WellPoint offers three benefit plan options, enabling Medicare beneficiaries to choose the benefit plan that best meets their individual medical and financial needs. The formularies that support these products are consistent across the country. Our formulary designs meet or exceed the minimum requirements established in the law. Our pharmacy network is made up of 51,000 pharmacies nationwide, representing 90% of available retail pharmacies.

WellPoint is pleased to report that we have an estimated 1.2 million Part D members, of which approximately 60% are auto-assigned dual eligibles. In January, we processed an estimated 3.5 million prescriptions of which approximately 575,000 were processed through the Facilitated Enrollment program.

WellPoint Commitment to Part D Success

WellPoint is committed to supporting the effective implementation of Part D for all Medicare beneficiaries. We are focused first on making sure that these people get the prescriptions they need filled timely, then resolving issues and problems so that all of our Part D members have a good experience when they go to the pharmacy. The transition to Part D for dual eligibles, and particularly those that were missed in the auto enrollment process, was not flawless and should have been easier for them. WellPoint shares the concern for the beneficiaries, and the frustration of pharmacists, elected officials, advocates, the States and CMS, *but we are not discouraged.* WellPoint's primary goal is to ensure that beneficiaries receive all the benefits of their health coverage, including

access to prescription drugs, in a timely and beneficiary-friendly manner. We are doing everything in our power to make the transition a success and believe that progress is being made.

As all of the stakeholders work to improve the transition and implementation of this program, we must all keep in mind the tremendous value of adding a comprehensive prescription drug benefit to the Medicare program. Millions of seniors will not only see cost savings, but true improvements in their quality of life. The mindset at WellPoint is to focus obsessively on enabling seniors and disabled beneficiaries to receive their prescriptions, even when they were not initially assigned a plan. The recent report that nearly 24 million now have prescription drug coverage is not just great news, but reminds us that we must keep our full attention on resolving barriers to service. As Part D members begin using their new prescription drug coverage, the confusion in the marketplace will abate and a solid foundation for the Part D program will begin to take hold.

Recognizing Dual Eligibles As a Vulnerable Population

Continuing to improve the enrollment process is especially critical for the 6.3 million dual eligibles which often have more health care needs than other Medicare beneficiaries. Many dual eligibles live with chronic conditions that require multiple medications. They may have physical or cognitive disabilities, including mental health illness and Alzheimer's disease. They may suffer from diabetes or HIV/AIDS, and they may live in a nursing home. We provide services to dual eligibles facing cultural, linguistic and literacy barriers.

A "Customer First" Approach to Problem-Solving

"Customer first" is a core value at WellPoint. Our number one priority for this new drug program is that each beneficiary leaves the pharmacy with their prescriptions filled at the appropriate cost to them. For this reason, WellPoint is committed to shielding beneficiaries from complex work-around solutions and shielding pharmacists from unavoidable back-end reconciliations.

The level of collaboration among CMS, plans, pharmacies and other stakeholders is unprecedented. Continuing to improve on the progress we've made requires maintaining

this collective effort. A shared approach to problem solving is the essential ingredient for making this new program work for all beneficiaries. Stakeholders are stepping up to the plate and accepting mutual accountability for meeting the challenges and ensuring the success of the Part D program. When all parties are bound by a common interest in putting the beneficiary first, an environment is created that allows for constructive criticism and open dialogue. The results being timelier implementation of the steps needed to achieve a smooth transition, faster identification of new issues, and smarter problem resolution.

Facilitated Enrollment Program: A Pharmacy Point of Service (POS) Solution

In early November, 2005, CMS approached WellPoint to develop a pharmacy-based solution to ensure that any dual eligible who was not auto enrolled would still get a needed prescription filled. WellPoint was ideally positioned for this role because we were the only company offering a plan with a premium below the low-income benchmark in all fifty states. On November 21, 2005, WellPoint signed the contract to become the "Facilitated Enrollment", or "Point-of-Service" (POS) vendor, for CMS. We agreed with CMS that no dual eligible, who are among Medicare's most vulnerable beneficiaries, should experience any gaps in coverage.

Once the contract was signed, WellPoint began a massive effort to operationalize the Facilitated Enrollment process in time for a January 1st effective date. A successfully designed safety net program would require executing many tasks related to claims administration, staff training, outreach and education, and other core areas of operation in both our health plans and our PBM. WellPoint was particularly focused on communication strategies, recognizing that working jointly with CMS to educate pharmacists would be critical to their use of this new process.

The Facilitated Enrollment process makes enrollment possible in those situations where a full benefit dual eligible visits the pharmacy and the pharmacist discovers that the individual has not been auto-enrolled into a Part D plan. With special facilitated enrollment, a dual eligible is enrolled into a WellPoint plan and can immediately access their Part D prescription drug benefits. A beneficiary can, however, also opt out and select a different Part D plan at any time. Pharmacy associations, chains and individual pharmacies have been provided information describing our Facilitated Enrollment solution.

The Facilitated Enrollment process is straightforward and consistent with putting the dual eligibles first: establishing a minimum threshold for proving Medicaid and Medicare eligibility in order to reduce the burden on the beneficiary. Let me describe the steps that a pharmacist can follow on behalf of a dual eligible that visits the pharmacy before he or she has been auto-enrolled but who has a Medicaid card:

1. The pharmacist bills Medicaid and the claim is denied.
2. Pharmacist checks for Medicare eligibility by one of the following:
    - Submitting an E1 query into the TROOP facilitator;
    - Calling 1-800-MEDICARE;
    - Requesting to see a Medicare card;
    - Requesting to see the Medicare Summary Notice (MSN); or
    - Requesting to see a letter from SSA stating that s/he may be eligible for Medicare.
3. If the pharmacist is unable to verify Medicare eligibility and/or enrollment in a Part D plan through these mechanisms, she/he provides the prescription drug to the beneficiary at the $1/$3 co-payment levels and bills a special WellPoint account which WellPoint has provided on its payer sheet to pharmacists.

At WellPoint, the claim is flagged as being outside its normal claims process in order to prevent it from being rejected and then the claim is paid. If the pharmacy is not contracted with WellPoint, the pharmacy is sent special instructions to establish the mechanism for payment. WellPoint also flags this individual for CMS's vendor, Z-Tech, to verify their full dual eligibility status. At this point in the process the dual eligible is enrolled in a WellPoint plan, (but can always opt out and choose a different plan later). If Z-Tech confirms the dual eligible was previously enrolled in another Part D plan, WellPoint still pays the pharmacy and works directly with that plan. This approach is consistent with our principle of shielding pharmacies from back-end reconciliations. The pharmacy is responsible for verifying the individual's eligibility for Medicare and Medicaid at the point of sale. As mentioned above, this is done through reviewing the Medicare and Medicaid cards or paperwork. This is a critical step in the process. The pharmacy is a key partner in caring for these duals, and drugs should be dispensed only to those eligible for the program. Although the pharmacy is responsible for verifying Medicaid and Medicare eligibility, the Facilitated Enrollment program only requires the

pharmacist to enter appropriate, minimal information such as name, address, birth date and a valid Medicare number into the processing system. This requirement, in effect, streamlines the electronic edits at retail and mail to facilitate more rapid prescription processing. At the same time, the minimal data provided acts as important safeguards that minimize risk exposure to pharmacists and potential abuse of the program.

Additional Proactive Steps To Support Implementation Goals

Based on our experience with launching new programs and serving seniors and disabled beneficiaries, we planned for a higher call volume and a longer average call length that we thought would be appropriate for this program. However, like other Part D plans, our estimates of the difference in magnitude fell short; for example, we experienced calls lasting more than twice as long and call volume nearly 50% higher than we predicted. Beneficiaries and pharmacists were negatively impacted, experiencing lengthy hold times and busy signals. Some abandoned their calls in frustration. Overall electronic eligibility challenges across the program, particularly in early January, also created additional volume as pharmacies wanted to discuss eligibility over the phone.

WellPoint staff has worked collaboratively with CMS, pharmacies, industry trade groups, etc. to resolve the issues facing the program. We have been working literally day and night to fix these problems as our first priority is that Medicare beneficiaries get the prescriptions they need on a timely basis. Many of the issues facing the program are systemic and data related and are being aggressively worked by industry and CMS workgroups. We must continue this collaborative work across the industry and with CMS – it is improving daily, but there is much more to do.

To improve our own service levels, some of the most effective mid-course corrections we have taken include:

- Increasing staffing as quickly as possible. We have already increased Part D staff from 455 people at January 1 to 545 at January 31. By end of February we will have nearly doubled staff, with 900 trained people serving Medicare beneficiaries and pharmacies.
- Extending the hours of operation daily and to seven days a week.
- Adding additional T-1 lines in the PBM to speed up phone service and reduce busy signals.

- Providing connectivity and availability to interface with CMS on a 24/7 basis.
- Implemented internal procedures to address urgent situations as they arise.

Recognizing that our rapid response must also include strategies that assist Medicare beneficiaries and our pharmacist partners, we have also implemented the following:

On Behalf of Beneficiaries

- Voluntarily extended our formulary transition rules from 30 days to 90 days beginning January 1st prior to CMS mandating such a change for all health plans.
- Extended the Facilitated Enrollment prescription quantities from an allowed 14 days to 30 days.
- Increased beneficiary education to inform them about any changes they may experience during the transitional drug period.
- Contracted with outside vendors to accelerate information gathering from Part D program applicants to complete applications. When possible, information is obtained from external data sources to expedite automatic completion in order to minimize contacting beneficiaries directly.

On Behalf of Pharmacists

- Adopted an inclusive network development strategy to contract with a range of pharmacies, including independent and rural pharmacies, to increase pharmacy access to network advantages and to enhance beneficiary access to affordable prescription drugs.
- Enhanced outreach by constantly communicating with pharmacies through fax blasts, weekly conference calls with independent pharmacy associations (e.g. National Association for Independent Pharmacies and other independent chain groups) and chain drug stores (e.g. National Association of Chain Drug Stores and smaller work groups formed from major chains), and individualized calls to reach as many pharmacists as possible about Facilitated Enrollment.
- Engaged in active training through our PBM on the Facilitated Enrollment process for pharmacists when they call in.

- Provided direct technical assistance to pharmacies and their vendors if necessary to address software issues.

In brief, WellPoint has developed multiple mechanisms to eliminate the obstacles that interfere with dual eligibles receiving their medications and to ensure that pharmacists can serve their Medicare customers according to their own high service standards, while receiving timely and accurate reimbursement.

Customer Service Improvements: Progress To Date

Improvements Benefiting All Members and Pharmacies. Our customer phone service has not yet reached normal levels, but it is improving. Our average speed-of-answer has improved by 20-25 percent as compared to early January. Busy signals, dropped calls and abandoned calls have been reduced by 50 percent.

Facilitated Enrollment Results. As noted previously, WellPoint's Facilitated Enrollment program, has processed approximately 575,000 claims, enabling an estimated 120,000 beneficiaries to receive their prescriptions. As we monitor Facilitated Enrollment, we are finding that the process truly operated as a "safety net" in response to data and transaction issues. The good faith behind this program has also created an incentive for non-network pharmacists to join our network and enjoy faster payment through electronic reimbursement. Overall, early skepticism regarding receiving payment seems to be yielding to an increased comfort level among pharmacists as evidenced by the increased claims volume.

Remaining Challenges and Recommendations

A number of challenges remain that require all stakeholders to work in partnership to establish a high performance Medicare Part D program that will make a difference in the lives of so many older and disabled Americans. With enrollment growing daily, we must not only invest our time and energy, but capitalize on the new relationships and knowledge gained from this experience. Addressing issues related to dual eligibles and the Facilitated Enrollment process is a top priority for WellPoint. These more vulnerable Medicare beneficiaries are also at the forefront of CMS's efforts as well. For this reason, I would like to take this opportunity to recommend some additional administrative strategies that

CMS, as our partner, might take to further optimize the Part D implementation process, benefiting all constituencies – beneficiaries, pharmacists, CMS and health plans. Our recommendations include:

1. ***Intensify efforts to provide correct, accurate eligibility information***. Many of the current challenges associated with Part D implementation stem from the need for clean, accurate eligibility data. Resolving this single issue will accelerate the pace at which the overall program is functioning smoothly. Improving data accuracy and the process for updating and validating the CMS eligibility file will ensure claims are paid by the correct plan and the beneficiary is charged the correct cost sharing amount, as well as eliminate the incentive for pharmacists to substitute the phone or the Facilitated Enrollment process for the more appropriate E1 transaction.

2. ***In order to avoid confusion and frustration for beneficiaries, CMS should clarify that beneficiaries who choose to switch plans and enroll after the 15th of the month may not have their enrollment materials before the first day of the following month.*** Allowing those beneficiaries that enroll in or switch their Part D plan prior to the 15th of the month to be enrolled with their new plan on the first day of the following month would help address this issue. CMS should likewise educate beneficiaries accordingly about the importance of enrolling prior to the 15th of the month. It is important to note that most states already use a similar approach with respect to dual eligibles applying for Medicaid eligibility. This recommendation would go a long way towards avoiding disruption for those Medicare beneficiaries for whom the data files may not yet correctly indicate their eligibility for the low-income subsidy.

3. ***Increase Pharmacy Outreach to Create One-Stop Shopping For Help.*** CMS has been conducting educational outreach to pharmacies and we commend the efforts – and we recommend it continue in earnest. Additionally, we recommend that CMS train their call centers to handle additional pharmacy related calls, particularly when pharmacies call about the Facilitated Enrollment process. Currently, CMS refers pharmacists to our call centers when contacted about the Facilitated Enrollment process or edit questions. Since the process is not complicated, we would suggest

that CMS directly provide instruction to pharmacies on how to process a Facilitated Enrollment (FE) claim during the initial call or, as we add the editing of the Health Insurance Claim Number (HICN), share the reason for the FE edit. Pharmacists would appreciate the timely assistance and many would use the information to trigger the FE enrollment process without having to make a second call to WellPoint. We would be pleased to work with CMS to train their staff.

Conclusion

The January 1st effective date for the launch of the Medicare Part D program brought with it a surge of business operations activity and customer service requests. In preparation, WellPoint did extensive advanced implementation planning and outreach, knowing that the program was complex, with many moving parts that had to work in synchrony. Our hope was that we had anticipated the major barriers that might arise as seniors navigated the enrollment system and pharmacists attempted to fill prescriptions. While it was not possible to foresee all the challenges that this enormous undertaking would pose, it is in WellPoint's DNA to be a part of the solution. We will continue to strive to get past the hurdles because the Medicare Part D prescription drug program is worth it.

Thank you for your time. I would be happy to answer any questions you may have.

Finance Committee Hearing
"Implementation of Medicare Part D"
Questions Submitted for the Record
Ms. Susan Rawlings
February 16, 2006

Senator Baucus

1. When did your firms realize or suspect that there could be the magnitude of data systems problems experienced in the first few weeks of delivering the Medicare Part D benefit? Did you warn CMS? If so, when?

   WellPoint realized that there could be data systems problems in the first few weeks of delivering the Medicare Part D benefit in early January. Given the scope and magnitude of the program, there was no way to know what would happen until the program started. During this time we were in daily contact with CMS regarding identified issues.

2. What is the health insurance industry's standard for customer service wait and response times for pharmacists and for people enrolled in health insurance plans? Did your firm meet those standards through its Part D plans the first 2 weeks of January? Are you meeting them in your Part D plans now? If not, when do you expect your Part D plans to meet them? What are the customer service standards that your firm included in its Part D contracts with CMS? If it varies by region, please provide the contract details for each region.

   Standard customer service wait times are 80% of all calls answered within 30 seconds, less than 5% abandoned, 0% blocked. CMS contracts for Part D requirements are consistent with these standards. We did not meet these standards in the first two weeks of January. We are meeting some of these standards now. We are committed to returning to our standards as soon as possible and are making progress every day towards achieving this goal.

3. Did you directly contact ALL pharmacists that you signed contracts with about how to bill and how to meet your "first fills" policies under your Part D plans? Please provide an example of the information you used to inform/educate pharmacists contracting with your Part D plans. Did you provide the same number of contacts and information to your "non-preferred" pharmacies as you did to your "preferred" pharmacies? If not, how did they differ?

   WellPoint directly contacted all pharmacies to join our Part D network and provided the necessary payor sheets to inform them of plan set up and how to bill claims under the Part D benefit. Additionally, WellPoint has communicated to all

network pharmacies on multiple occasions via blast-faxes, conference calls with chain consortiums, individualized calls, and on January 31st CMS hosted an industry call related to POS FE in which WellPoint provided education and hosted a Q&A session. WellPoint currently contracts with 56,437 pharmacies nationwide, representing 98% of available retail pharmacies. WellPoint does not have a preferred and non-preferred network. We do not contact non-participating pharmacies.

4. Does your firm include language in its agreements or contracts with Part D plans that specify how often WellPoint has to pay pharmacies or how often it must update the pricing benchmarks (*i.e.*, AWP, WAC) used as the basis of pharmacy reimbursement? If so, were these terms included because of the contract WellPoint has with CMS or for other reasons?

   WellPoint includes payment terms and payment schedule in all pharmacy agreements/contracts. We have language in our agreements/contracts that outlines the terms of payment between the PBM and the health plans and the PBM and the pharmacies. Terms include the basis of pricing determinations, but not how often those pricing determinations are updated. These are not included exclusively because of the contract WellPoint has with CMS; we would provide this to any pharmacy as it is standard operating procedure and has no relation to Part D or CMS.

5. Does your firm include language in its contracts with Part D plans that specify how often it will pay pharmacies or how often it must update the pricing benchmarks (*i.e.*, AWP, WAC) used as the basis of pharmacy reimbursement? If so, were these terms included because of a requirement in the contract your firm has with CMS or for other reasons?

   WellPoint includes payment terms and payment schedule in all pharmacy agreements/contracts. We have language in our agreements/contracts that outlines the terms of payment between the PBM and the health plans and the PBM and the pharmacies. Terms include the basis of pricing determinations, but not how often those pricing determinations are updated. These are not included exclusively because of the contract WellPoint has with CMS; we would provide this to any pharmacy as it is standard operating procedure and has no relation to Part D or CMS.

Senator Rockefeller

Ms. Rawlings, as you are aware, I am extremely concerned about dual-eligibles getting their prescription drugs through Medicare. And, I'm hoping you can clear up a few questions I have.

1. CMS has indicated that they require all plans to provide a 30-day transitional supply of all medications beneficiaries were previously taking. However, I've been told that WellPoint was providing only 14 days of transitional medications. Why was WellPoint out of compliance with the CMS guidance?

   WellPoint was never out of compliance with CMS guidance. The CMS 30-day (now 90-day) rule applies only to Part D plan members. WellPoint voluntarily extended our formulary transition rules for Part D members from 30 to 90 days beginning January 1st, before CMS mandated such a change. The 14-day fill policy was initially applied to non-members who were potentially eligible for the dual-eligible facilitated enrollment process. The 14-day window was set to allow WellPoint and Z-tech, a CMS contractor engaged to provide Medicaid eligibility data, to verify dual-eligibility. As it became clear that the eligibility verification process would take longer, we revised our systems to allow for a 30-day fill. This change was made in mid January and we were never out of compliance with CMS guidance.

2. I hope you will be able to clarify some other conflicting information for me. Once a beneficiary is enrolled in WellPoint through the pharmacy point-of-sale system and receives the transition supply of medications, what happens? Do these beneficiaries stay in the WellPoint plans until they make a decision to change plans? Or does WellPoint work with CMS to reassign them to another plan that meets their need for continuing coverage? How long should this process take?

   WellPoint will provide a one-time 30-day supply of medication until dual-eligibility can be confirmed. If dual-eligibility can be confirmed by CMS or Z-tech, WellPoint enrolls the individual in a WellPoint Part D plan with a retroactive effective date back to the first of the month in which the first point of service claim was processed. If individual is not eligible for the point-of-sale enrollment process, he/she will receive a notice from both Z-tech and WellPoint confirming instructions for enrolling in a Part D plan. For those enrolled in a WellPoint Part D plan, they will stay in the WellPoint plan until they make a decision to change plans and we are notified by CMS that the beneficiary has been reassigned.

Senator Lincoln

1. How many beneficiaries have been enrolled in the WellPoint Facilitated Enrollment process? Can I also please have this number for Arkansas only?

As of February 22nd, we have enrolled 9,082 beneficiaries through the WellPoint Facilitated Enrollment process nationwide. Forty of these beneficiaries are from Arkansas.

2. Why have some dual eligibles, including those with proof of enrollment in both Medicare and Medicaid, been turned away from pharmacies without their prescriptions even though the "Facilitated Enrollment" process is in place? Many states, like Arkansas, have stepped in to pay pharmacists because this process wasn't working.

   WellPoint and CMS have made considerable effort to educate pharmacies regarding the proper steps to utilize the Facilitated Enrollment process. To recognize the unique challenges facing full duals and remove obstacles to pharmacists filling prescriptions at the pharmacy counter WellPoint has taken the following steps:

   - Electronic edits at retail and mail have been streamlined to facilitate more rapid processing of prescriptions.
     - WellPoint is committed to shielding beneficiaries and pharmacies from back-end functions and will reconcile with appropriate parties as necessary
   - 14-day facilitated enrollment prescription expanded to 30-days
   - Active training of pharmacists for facilitated enrollment
     - Fax blasts to pharmacies
     - Weekly conference calls with industry associations
     - Individual calls with pharmacies and switch companies as necessary to work through issues
   - Increased staffing for call centers, including PBM, health plan and outside vendors
   - PBM adding T-1 lines to improve phone service and reduce busy signals

U.S. Senator Rick Santorum
Opening Statement
Senate Finance Committee Hearing on Medicare Part D Implementation
February 8, 2006

Good morning, I would like to thank the Chairman for holding today's hearing on implementation of Medicare Part D and providing an opportunity to build upon last week's Special Committee on Aging hearing on this important topic. As I emphasized in last week's hearing, Medicare prescription drug coverage holds enormous potential for our nation's seniors, and we cannot lose sight of this potential and the lengthy, hard-fought process it took for Medicare drug coverage to be realized. However, the potential of this benefit cannot be fulfilled until problems that have arisen during implementation of Part D are permanently resolved. As a member who represents a state with one of our nation's largest senior populations, which stands to gain tremendously from Medicare drug coverage, I remain committed to ensuring that my constituents have access to medically necessary prescription drugs through this program, and that implementation problems are resolved immediately. Input from today's panelists will be critical in identifying what work still needs to be done as we move forward in the implementation process.

Since this benefit began, constituents have shared their positive experiences with me. Pennsylvanians, and seniors across our nation, are thankful for the savings they are experiencing and for the peace of mind of knowing that they are protected against catastrophic prescription drug costs. We must make sure that problems are resolved to ensure that all seniors have the same positive experience as those that have not encountered problems getting prescription drugs through Medicare.

The addition of prescription drug coverage is an important step in ensuring that the Medicare program reflects high-quality health care in the 21st century. In the years to come, the Medicare program will reap the benefits of investing now in our nation's seniors' health through affordable prescription drug coverage. I was pleased to hear of the projections in the one-month progress report released last week by the Secretary, which highlighted that taxpayers will also save—at least 10 percent over the next five years—and that premiums are now projected to average only $25 a month. Despite criticisms, these findings illustrate that the competitive framework built into Medicare drug coverage is paying off.

Just as Congress has strengthened and improved the Medicare program since its inception in 1966, I am confident that Congress will continue to work with CMS to act as necessary to strengthen and improve Medicare Part D. During the early weeks of this legislative session, we have already seen efforts to advance reactionary legislation. Political posturing does nothing to fix the problems that CMS has identified and does not benefit our nation's seniors. Instead, honest discussions such as today's are an important step in ensuring that improvements to Medicare Part D are the culmination of a policy

driven process, not politicking. Any legislative efforts that are not the result of a policy-driven process hold little potential for improving the current situation, but tremendous potential for unforeseen consequences that could complicate efforts already underway by CMS to remedy problems that have been identified.

Quantifiable metrics from CMS are essential. Without such measures, Congress will be unable to accurately gauge the progress of implementation of Part D, and determine what, if any, legislative actions are necessary.

Everyone that has a role to play in the implementation Medicare Part D must be held accountable because this program is an investment of significant taxpayer dollars into America's seniors' health. I look forward to hearing Dr. McClellan's testimony on what progress CMS has made to address problems and concerns I have raised on behalf of Pennsylvanians.

Written Testimony of Tobey Schule, RPh
Sykes Pharmacy, Kalispell, MT
Before the Senate Committee on Finance
Medicare Drug Benefit Implementation Hearing
February 8th, 2006

Chairman Grassley, Senator Baucus, members of the Committee, I appreciate the privilege and opportunity to speak about Medicare Part D and how it is affecting my patients and pharmacy.

I am the co-owner of a small independent pharmacy in Kalispell, Montana that was established in 1981. There are about 32,000 people in Kalispell and the surrounding areas; we are 200 miles from the state capitol in Helena. Our pharmacy employs two pharmacists, my son and me, and two pharmacy technicians. There are five senior apartment buildings within three blocks of the pharmacy, and we serve primarily geriatric patients. In addition, we provide weekly medication box exchange for three assisted living facilities and the mental health center in our community. About ninety percent of our walk-in patients are elderly.

Medicare Part D has become a major factor in my pharmacy. I contracted with every company offering drug plans in Montana, so I could continue to serve my patients. I would like to address my concerns with this new benefit, in the following four areas: confusion among patients and pharmacists, education and outreach, coverage of dual-eligibles, and burden on pharmacists.

CONFUSION

The implementation of Part D has caused confusion and frustration for my patients. And it has caused confusion and frustration for me. This program doesn't need to be so complicated.

The frustration and confusion for my patients began last summer, when they started receiving information from insurance companies offering Medicare Part D coverage. With over 40 plans to choose from in Montana, my patients said they were scared and intimidated by all of the options. Many of my patients were not fortunate enough to have a family member help them through the process of deciding which plan was best for them. I work with the elderly every day, and this has been overwhelming for them. Bewildered by the complexity, some patients are choosing not to enroll.

Those patients who could make sense of the Medicare mailings faced new obstacles. They were instructed to check the internet to see if the coverage was appropriate for their individual situation. I question this approach, since the vast majority of my elderly patients do not have computers and cannot use the internet. Access to the information through the 1-800 Medicare number was not much better. The phone systems are automated, and many of my elderly patients are unable to navigate through them. Others had the ability to use the phone system but gave up because of long hold times.

EDUCATION AND OUTREACH

Despite this enormous confusion, there were few opportunities for Kalispell patients and pharmacists to get answers. Several meetings were sponsored by the state of Montana, by insurance companies and by senior citizen advocates to help the elderly make their choices and explain Medicare Part D. After attending these sessions, many patients came back to my pharmacy saying they were even more confused. Patients received different answers from different people. They had trouble understanding the literature that they received, and felt a lawyer was necessary to make heads or tails out of it.

On top of this complexity, elderly patients feared they would select the wrong plan. At educational events, patients were instructed to focus on the formularies and pick one that had their medications on the list. But patients found only some of their drugs listed on formularies, requiring patients to choose between medications.

Education for pharmacists wasn't much better. I heard of only one event sponsored by CMS to educate pharmacists, and that was in Billings, nearly 500 miles from my store. I could not attend this meeting, although I did send a pharmacy technician to a local educational event sponsored by an insurance counselor. This seminar did not help us serve our patients enrolling in Part D. But it did help us understand why our patients were so frustrated.

With little information coming from CMS or the insurance plans, I relied on my drug wholesaler to learn how to handle patient in Part D. For instance, in mid-December I called my software vendor to ask how I would determine patients' Part D drug coverage. It was only though this call that I learned about the E-1 transaction, which shows patient plan eligibility. I now use this system many times a day when trying to figure out a patient's coverage, but I had to learn about it on my own.

Over the last few weeks, drug plans have been my only source of information describing the administrative procedures that I must follow to provide drugs and submit claims. But this information is often incomplete. I recently received a notice that patients enrolling in Part D in late January wouldn't be in the system on February 1st. So the problems we heard about at the beginning of January are happening again.

PATIENTS WITH MEDICAID AND MEDICARE

Many of my patients have both Medicaid and Medicare . These "dual-eligibles" were automatically enrolled into the new drug plans as their drug coverage was shifted from Medicaid to Medicare. Unfortunately, these plans did not always meet patients' medical needs. I found many patients' medications were not covered by their plans.

Further complicating matters, information systems did not recognize these patients as dually-eligible. They could not afford the high co-pays that the system said they should be charged. I handled each patient on a case-by-case basis, and it required a huge time

commitment to sort out problems in drug plan data and information systems. Fortunately, we are a small pharmacy and we know all of our patients. So we were able to give them their medications on the spot. I cannot help but think of how many patients across the country must have gone without their medications. Now we are working through billing issues, trying to determine how we will be reimbursed.

FORMULARIES AND MAIL ORDER

I am very concerned for my patients because we are being forced to change their medications to match the formulary for their plan. By changing medication, I expect to see increases in physician visits, labs, and hospitalizations. This will increase costs to the program. Medicare should have a plan to track the costs associated with medication changes.

Some of the plans are offering the mail-order pharmacy, and I do not think that mail-order should even be an option for Medicare Part D. If patients are getting some medications from mail-order and others from local pharmacies there is no continuity of care. This lack of coordination between mail-order and bricks-and-mortar pharmacies increases the likelihood of adverse events and noncompliance. If a patient using mail-order pharmacy is hospitalized, it is very difficult for doctors at the hospital to get drug information when prescriptions are not filled locally. If patients need drug information about a medication and are using mail order, they must attempt to use automated phone systems. In contrast, local pharmacists are readily available to answer questions. The ordering process of mail-order is also difficult for the elderly. These patients have trouble remembering to order a medication before they run out, but if they order too soon the script will not be processed.

As a pharmacist I want to know how certain medications were picked for the formularies. An example is why is one plan using Zocor and another is using Lipitor. I would like to know why some formularies use a branded drug when a generic is available. This appears costly to the program.

PHARMACIES

As the program began on January 1st, it became apparent that the insurance companies were not prepared for the start. Patients had not received their cards or enrollment letters. When this documentation had been received, the information was often incomplete. Missing data included BIN numbers, group numbers, ID numbers and processor control numbers. When I tried to access through the E-1 system, patients would come back as not enrolled. I was not able to bill the appropriate plan

We have spent a tremendous amount of time on the phones with the different companies getting patient billing information or prior authorization to fill. We have been on hold to talk to a representative for as long as four hours before we were able to get through. In other cases, we were simply disconnected after hours on the phone. This is unacceptable.

Drug plans are sending out lists of the pharmacies associated with their plan. While I have contracted with every plan offered in Montana, my pharmacy is not on every company's list. As a result, several of my patients have come in very upset because they think they will have to change pharmacies. I tell my patients that I can fill for them even though I am not on the list. Insurance companies should not send only a partial list of in-network pharmacies. It should be all or nothing. Also, I think that it is totally unacceptable for the drug plans to co-brand patient insurance cards with Wal-Mart, Walgreens, or other chain drug stores. It is confusing to the patient, leading them to think that they can only go to those pharmacies.

The insurance companies have created problems on the business side of my practice. There is no "negotiation" between pharmacists and drug plans on reimbursement rates. If I am going to continue serving my patients, I am forced to accept the low rates offered by insurance companies. Plans are slow to pay claims, and my drug wholesaler requires that I pay for drugs much more quickly than the plans pay me. My pharmacy has over $45,000 in unpaid claims from Medicare Part D.

Pharmacist and pharmacy technician salaries are climbing because of the shortage of available personnel. I am not sure how long independent pharmacies will be able to stay in business with the low reimbursement rates.

CONCLUSION

I wish that before this program started on January 1st that Medicare and the insurance companies would have taken the time to truly consider the elderly. If the people setting up the program had thought about the needs of their own elderly parents, I am sure this plan would be different.

Chairman Grassley, Senator Baucus and Members of the Committee, thank you again for inviting me to appear before you here today. I will now answer any questions you may have.

Finance Committee Hearing
"Implementation of Medicare Part D"
Questions Submitted for the Record
Tobey Schule, RPh
February 16, 2006

Senator Rockefeller

Mr. Bernauer and Mr. Schule, pharmacies have been put in the middle of all of this, and as a group have done a commendable job trying to help beneficiaries get their drugs while dealing with long telephone waits, system glitches and other difficulties. I want to thank you for your efforts.

1. I have heard many complaints from pharmacists about not being able to access eligibility data that will allow them to bill plans at the time of the sale. This breakdown seems to be the main cause of frustration among pharmacists and beneficiaries in determining what plan to bill and what co-payments to charge. What is your view on how this program is working and what can be done to address this situation? How adequately do you think you were prepared to use the new pharmacy billing system prior to the start of the benefit?

Response

At the beginning, the system was working very poorly. Patients were told that they had coverage but were not provided with the proper information from the companies to bill for their prescriptions. When we tried to utilize the E 1 system, patients just came up as not covered. Apparently there was not enough time to get the patients entered into the system. I feel as time goes on and patients get entered into the systems, these problems will lessen. Unless something is done to improve the data entry of new patients coming into the system, these problems are going to continue. When patients are enrolled by the insurance companies, there should be a temporary card given with all of the billing information, so if there is a problem that company could be contacted. We are now over forty-five days into the program and we are still having difficulty receiving patient information through the E 1 system.

My pharmacy staff was prepared to access the E 1 system. Our software company had our software up-to-date and ready. We had all the insurance companies billing data entered into our computers.

2. I would also like to hear about your experiences calling the plans and actually being able to talk with a customer service representative. When you are able to get through to somebody, how helpful are they? Can you also talk about your experiences with the prior authorization process and whether or not you feel that process is helping or hindering beneficiary access to their medications?

Response

Our pharmacy staff is very frustrated calling the plans. We have been on hold up to four hours and then sometimes after long hold times we were just disconnected. Even now after a month and a half, I feel that our wait time is too long. We are still on hold ten to twenty minutes at times before we can get through to a representative. Once we are able to reach a representative, the problems are dealt with very rapidly.

The prior authorization process creates other problems for our patients and pharmacy staff. When a drug is not on formulary, we have to call for prior authorization to get a temporary fill for the patient. Then the physician must be contacted so that a medication change can be made. All of this process takes a great deal of time. In some cases, I expect increase cost to the Medicare system because it could require another office visit, labs and if the patient doesn't respond to the change, a possible hospitalization. This is especially true when you are referring to a mental health patient on psychotropic medication. I feel that in many cases that requiring a medication change is not in the best interest of the patient. The prior authorization is only for thirty days of medication before a patient's medication has to be changed. Again, not only are we on long phone times, now the physician has to deal with it as well. As pharmacists, we are not able to bill for all time is takes to complete this process.

3. I have heard that many pharmacists have provided drugs to patients without knowing who would reimburse them. Some have even taken out lines of credit to make sure their customers are able to get their medications while this all gets straightened out. Would you tell us about your experiences in this area? What are your recommendations to Congress on how to reimburse pharmacists for unexpected prescription drug costs?

Response

I stated in my testimony that we filled many of our patients' prescriptions without knowing who we were going to bill. It was important for us to know that our patients were not going to be without medication. The prescriptions were then billed at a later time when we could determine which company was to be billed. We also encountered prior authorization problems because of the delay in billing. Our budgets were previously set up around the payment schedule of Medicaid and the majority of our patients on Medicare Part D were previously on that program. This process, however, put our receivables with delayed payment. We are still required to pay our payables on time. We still currently do not know when to expect payment from some of companies and those receivables have created cash flow problems for us. I will have to take out a short term line of credit until we see how the cash flow will be from the insurance companies.

I am not sure what I would recommend to Congress for reimbursement of unexpected prescription drug costs. I became aware that some of these prescriptions could have been billed through WellPoint. I was not aware of this in the beginning. I contacted several

pharmacists in my area to see if they were aware of the temporary billing of WellPoint and they were not familiar with this either. I, however, would hope that Congress would look out for pharmacies' reimbursement to make sure that they are fair and payments are timely so that we can stay in business for our patients.

Senator Lincoln

1. Mr. Schule, after listening to your testimony, I feel like I've been listening to one of my pharmacists in Arkansas. You have experienced the same problems and frustrations they have, and I'm glad you've shared your experiences today. Can you elaborate on the problems with timely reimbursement from the prescription drug plans? What efforts, if any, have you taken to ensure you are paid appropriately?

Response

At the end of the first month, we had not seen payments coming in on a timely manner. We were still trying to get some of the initial patients' prescriptions billing information, so the plans could be billed. When payments did start to come in, we were finding that some of the claims were being adjusted from the adjudicated (online) amounts. In some cases, we were not being paid for what was billed and accepted on the initial billing process. What we are receiving is a lesser amount. I do not see how the insurance companies can pay a different amount from what they approved and adjudicated online. We have not been able to actually determine what the pay cycle is going to be. We are now seeing claims being paid that were billed the early part of January. Previous to the start of Medicare Part D, many of these patients were on Medicaid. We would be paid promptly twice a month. Since the start of the Medicare Part D, and with the multiple companies involved, we are not seeing a clear payment schedule. This has caused us some difficult cash flow problems.

I am finding that it is very time consuming to check all claims being paid and calling the companies for payment. I am currently looking at a program with our switching company that would reconcile the claims with the insurance companies. This program will check for claims being paid under adjudicated amounts and that the claims do not go beyond thirty days without payment. This will be an added expense to my pharmacy.

Testimony of Pamela Willoughby
Hearing on Implementation of Medicare Part D
February 8, 2006

It is my privilege to be invited to speak here today.

I am the Parish Nurse at St. John's Episcopal Church and Bedford Presbyterian Church in Bedford, Virginia. I work with the members of the Catholic, Baptist, and Methodist Churches in our community service outreach program.

Because of this unique position, I was called by David Edwards of the Central Virginia Area Agency on Aging. He met with me and Tom Mustard, the Rector of St. John's, on Tuesday, September 27, 2005, and he explained in general the Medicare Part D program. Would I be interested in becoming a Tier I Partner since there was no one in Bedford City/County to sign up those eligible for Medicare Part D?

Nine volunteers met at St. John's with Margaret Moon, Health Insurance Specialist from Philadelphia, on Friday, October 28, 2005. She explained the program in general and referred us to medicare.gov on the web. We knew the big picture, but none of the "how to" details. I made a Medicare Part D flyer for the weekly newspaper and the Bedford County Ministerial Association to reach the target population through the church bulletins and newsletters. We began enrolling clients in the program on Thursday, November 17, 2005, in the computer lab at Main Street United Methodist Church. The volunteers work every Thursday 3 or 4 hours and I work an extra 15 hours per week. Throughout the week, clients call my cell and appointments are made. It is important to match the volunteer's expertise with the individual client. Each appointment requires at least an hour, more or less, to enter the prescription data and compare the top three plans. It is not unusual for clients to take upwards to 17 prescriptions and we have to refer to the Epocrates software in my palm pilot and/or call the pharmacist on many occasions. The drugs are not always easy to find (example sublingual NTG 0.04 mg.) Oftentimes, the clients take the printouts home to study them and then come back the following week to sign up.

Approximately 252 clients have been signed up in the computer lab. We learn something new about the program every week and this is shared among us which makes it easier to answer the many questions. This program is not easy and requires study, dedication and commitment by the volunteers who make our program possible. But, we absolutely think it is a worthwhile program. The feedback is very positive and people are most grateful. I try and give each client my business card so they will have a contact person for positive and negative feedback, and the upcoming open season November 15 to December 31, 2006 if their health should change and they need to choose a different plan.

Many of the volunteers sign up clients at their home. According to the 2000 census for Bedford City/County, there were 9,160 eligible clients and we have only signed up about 3 per cent as of February 6, 2006. Some have come on crutches, in wheelchairs, been mentally challenged, blind, or deaf. It is a broad spectrum of people: well educated with doctorates and computer literate to those who are educated or not and with or without computer skills. Children come for their parents and neighbors bring friends. The common denominator is "It is so confusing, can you help me?" After four months working with the program, I finally think I understand it and feel comfortable answering questions. Margaret Moon continues to be a resource person. There is a website in Virginia for questions or to identify problems, but with no feedback, it has not been useful.

There are a few problem areas I feel should be addressed:

- Lagging data entry
- The client must activate their own letter of confirmation if they qualify for additional assistance.
- Benzodiazepines are excluded from coverage.
- Insurance plans which refuse to give over rides for prior authorization.
- Clients have the annual cost but need to know the monthly cost for prescriptions where there is a deductible.

❖ Designers must look critically at the May 15th deadline. It's not that people do not want the coverage; it's just that it's terribly complicated and many do not know where to turn for help.

❖ A major effort must be made by federal, state, and local groups to assist those eligible and it must be done one-on-one. We have basically communicated that this is an issue for the elderly; it is, in fact, a societal issue.

❖ The "doughnut hole" needs to be filled. Many of those eligible cannot afford the increased monthly premiums for "gap" insurance. Monthly premiums are higher as the number of prescriptions increases; this hits those in their 80's and 90's and beyond hardest.

❖ Major advertising by private-pay insurers should make it clearer about options.

❖ Some people are deeply skeptical about what they will get for their money and are fearful that the program will be discarded by a subsequent administration and/or congress.

In conclusion, this plan is a "compassionate idea, written by career politicians, insurance and pharmaceutical executives, implemented by bureaucrats, administered by special interests, enrollment designed by the computer savvy, aimed at folks who are largely technologically challenged." This is the definition of Medicare Part D from an elderly woman who was being helped to sign up.

COMMUNICATIONS

STATEMENT FOR THE

SENATE COMMITTEE ON FINANCE

ON

IMPLEMENTATION OF THE NEW MEDICARE DRUG BENEFIT

February 8, 2006

WASHINGTON, D. C.

For further information, contact:
Kirsten Sloan/Anna Schwamlein
Federal Affairs Department
AARP
601 E Street, NW
Washington, DC 20049
(202) 434-3770

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.

amda
American Medical Directors Association

Statement of the American Medical Directors Association on the Medicare Part D Prescription Drug Benefit February 7, 2006

A national organization of long term care physicians committed to quality care

American Medical Directors Association

10480 Little Patuxent Parkway
Suite 760
Columbia, MD 21044
410/740-9743

Washington, DC
301/596-5774

Toll Free
800/876-AMDA

FAX
410/740-4572

www.amda.com

The American Medical Directors Association (AMDA) represents more than 7,000 medical directors, attending physicians, and others who practice in nursing facilities. On average, AMDA physicians see 100 nursing facility patients per month (which constituted approximately 8.5 million visits in 2000, or 42 percent of the total number of nursing facility visits that year). AMDA physicians also care for patients in other venues in the long term care continuum, which includes home health care, assisted living settings, hospice and other sites of care for the frail elderly. The majority of members (59 percent) also maintain a private practice outside of their long term care responsibilities. Our comments reflect that experience, as well as the commitment to provide the best quality of care to our patients.

Since Part D implementation on January 1, AMDA has been relaying member problems and concerns regarding the new Part D drug benefit to the Centers for Medicare and Medicaid Services (CMS) in weekly conference calls and frequent e-mails. Despite CMS efforts, we are still seeing significant problems for physicians in obtaining medically necessary drugs for their patients.

The problems are exacerbated by the myriad drug plans and drug plan options with which physicians must deal. Each drug plan maintains its own formulary, policies and procedures, with no uniformity among them. Event absent transition problems, it will continue to be extremely difficult for physicians to work with so many individual drug plans.

We are pleased that CMS has extended the transition period for enrollees to change to the new drug plan formularies, and we hope that drug plans will comply with the extended transition period to a far greater degree than they did with earlier transition guidelines issued by CMS.

Recurrent problems our members report include:

Transition Process

- Many plans are not honoring the 90-180 day transition period that CMS recommended for long term care patients. Despite CMS reminders, some plans have provided only 3-5 day transition supply of current medications, while some plans have provided drugs for 30 or 60 days.
- Drug plan transition time frames and procedures are not generally available on plans' web sites. This results in considerable confusion for physicians and providers.
- A gradual transition is important for long term care patients with multiple co-morbidities, as well as multiple medications. Typically the nursing facility population today has 6 to 10 active medical problems and 9 or more prescription drugs. Changes in drug regimens for these patients must be both cautious and gradual to avoid adverse effects.

Lack of Critical Information about the Drug Plan

- The drug plans have often distributed incorrect information regarding contacts and policies.
- Drug plans have not provided clear information regarding procedures for exceptions and appeals, as well as prior authorizations. Likewise, there is a lack of access to drug plan forms that physicians must complete for exceptions and appeals, as well as for prior authorizations.
- Each plan develops its own procedures and forms. There are no uniform forms and procedures, which would reduce confusion and ease administration.
- Drug plan front-line workers do not seem to understand their plan formularies and procedures.

Lack of Access for Emergency Medications

- In at least some instances, drug plans have not been available on a 24-hour basis for coverage determinations on emergency medications. In such cases, CMS is advising physicians and pharmacists to rely on the 1-800-Medicare number for emergency access, but problems have been reported with that system as well.
- We have received reports of lack of access to influenza medications that may be required on an emergency basis to prevent influenza outbreak in long term care facilities. The Centers for Disease Control have approved antivirals oseltamivir (TamiFlu) and zanamivir (Relenza) to treat influenza this year. Some physicians report having difficulty obtaining oseltamivir because it is not on some plan formularies, while some drugs that are on formularies to treat influenza are contraindicated for patients with seizures or Alzheimer's disease.
- We have also received reports of drug plans that require prior authorization for all drugs to treat influenza. This is a special problem in long term care, where prompt treatment and prophylaxis is crucial to prevent an influenza outbreak.

Lack of Access to the Drug Plan

- Our members report lengthy delays in telephone access; frequent problems getting through to plans at all (e.g., busy signals, referred to other numbers; frequent hang-ups on calls). We receive frequent reports of delays of 30 to 45 minutes, after which the call is simply terminated by the drug plan. These problems seem to continue despite an increase in operators to handle calls.
- CMS has required drug plans to have special telephone numbers for access by pharmacists, but not for physicians or nursing facilities.

Onerous Administrative Requirements

Members are reporting a wide array of requirements imposed on physicians by Part D plans in order to have prescriptions honored. Many requirements entail personal contact by the physician with the drug plan, or access to the enrollee's health record, which is often not accessible to the physician, as it remains at the long term care facility. Drug plan communications with the physician sometimes leave the nursing facility completely out of the loop. Some requirements seem designed simply to deter physicians from requesting prior approvals or exceptions.

Specific problems our members have encountered include but are not limited to:

- Requiring personal telephone calls from physicians by some plans, rather than accepting faxes or e-mails for prior authorizations or exceptions requests.
- Requiring prior authorization for all drugs in a class (e.g., drugs to treat Alzheimer's disease and influenza).
- Requiring additional documentation as part of prior authorization (e.g., requiring a mini-mental status score for drugs for Alzheimer's).
- Requiring prior authorizations for inexpensive drugs.

Additional problems:

Some additional problems include:

- Lack of recommendations by the drug plan for alternative drugs when a prescribed drug is not on the formulary. Physicians often do not have access to patient records or drug plan formularies when they are called regarding adverse coverage determinations, and the suggestion of appropriate alternative drugs that are on formularies could expedite the prescribing process.
- Omission of all forms and doses of formulary drugs from drug plan formularies. Long term care patients may require alternative strength doses or alternative delivery system (sustained release, intravenous, etc.), but physicians must pursue exceptions for such different forms and dosages of drugs that are on the plan formulary.

There seems to be little understanding on the part of drug plans of the requirements regarding unnecessary drugs contained in the Conditions of Participation for nursing facilities (42 CFR 483.25(1)(1), 483.25(1)(2)(i)), or of

the extensive related guidance to surveyors regarding unnecessary drugs and drugs whose use may be contraindicated in elderly patients. We have heard anecdotes of drug plans requiring use of medications that are considered potentially inappropriate in the elderly.

Finally, we are extremely concerned with the incredible burdens the new drug benefit is imposing on physicians. Physicians are reporting spending up to an hour trying to obtain just one drug for just one of their patients. One physician last week reported that her nursing facility worked with the drug plan for more than four hours and still could not obtain the drug the patient needed. Sometimes it sometimes seems that if physicians pursue problems high enough up the drug plan chain of command, problems are resolved, but our current system for providing and paying for care does not support that level of physician involvement. In at least one instance, when a physician could not obtain emergency authorization for drugs to treat an outbreak of influenza in a nursing facility and prevent the transmission to other patients, the physician had to argue for one day and discuss his willingness to speak to the press about need to obtain the medications to prevent patient deaths in order to obtain the necessary drugs. Physicians simply should not have to go to such lengths to obtain medically necessary medications for their patients. Nor do Medicare physician payments encompass such an increased amount of work. One of our physicians advised us, "Medicare Part D is not a workable system for long term care", because the program is "tying up inordinate amounts of time that is taking away from patient care."

AMDA Recommendations

Congress should consider how to reshape the Medicare drug benefit to simplify the program for Medicare beneficiaries and for administration. Simplification could make the program more attractive to beneficiaries, ease the administrative burden on physicians and health care providers, and reduce the cost of the program.

In the meanwhile, several steps could be taken that would immediately improve implementation of the drug benefit, including:

Implementation Issues

- Require all drug plans to have a web page link to a page for physicians and pharmacists that includes:
    1. Telephone and e-mail contacts for questions; prior authorization; exceptions and appeals; and emergency access to medications.
    2. Procedures for prior authorization, exceptions, and appeals;
    3. Forms for prior authorization, exceptions, and appeals.
    4. Formulary, with notations of which drugs are subject to prior authorization, step therapy, or other utilization tools; and
    5. Transition process of the drug plan.
- Require drug plans and participating pharmacies to have telephone lines dedicated to the exclusive use of physicians and long term care facilities as well as the lines currently dedicated to use by pharmacists.

- Require drug plans and participating pharmacies to staff telephone lines so that physicians and long term care facilities are not kept waiting more than 5 minutes on a call.
- Require additional training by front line drug plan staff.
- Require drug plan use of uniform procedures and forms (to be developed by CMS) for prior authorizations, exceptions and appeals.
- Require drug plans to immediately honor e-mail and fax transmissions of physician justifications for prior authorizations and exceptions and appeals.
- Require that all drug plans must offer as formulary drugs those that have been recommended by the Center for Disease Control to treat the current year's strain of influenza (oseltamivir and zanamivir in 2006).
- Require drug plans to include in their formularies all doses and drug forms of formulary drugs.
- Require drug plans and pharmacies to recommend formulary alternatives to non-formulary medications or those requiring prior authorizations.
- Require drug plans to provide information on the exceptions and appeals processes when drug coverage is denied.
- Extend the period for enrollment without penalty until December 31, 2006.

Ongoing Issues

Once the implementation phase is passed, there will still be significant ongoing issues that will need to be addressed. We are already seeing signs that drug plans will use management controls to deter access to medically appropriate drugs, including, in some instances, drugs on plans' own formularies.

- Prohibit inappropriate and onerous requirements for prior authorizations, such as requiring prior authorizations for all drugs in a class; requiring prior authorization for all drugs to treat certain conditions (such as Alzheimer's Disease and influenza); requiring additional burdensome documentation, etc.
- Prohibit inappropriate and onerous requirements for other utilization programs, such as step therapy and quantity limits.
- Require drug plan policies to recognize the clinical implications of changing drug regimens for frail, elderly enrollees on multiple medications, particularly those who have been stabilized after many medication adjustments.
- Require drug plans to recognize the interplay of the requirements of the Medicare Conditions of Participation for nursing facilities with the Medicare drug benefit. In particular, plans should recognize requirements regarding unnecessary drugs as well as drugs whose use may be contraindicated in elderly patients.
- Impose sanctions against drug plans that:
  + Fail to maintain sufficient staffing to respond in a timely manner 24 hours a day to inquiries by physicians, pharmacists, and beneficiaries;
  + Failed to provide a transition supply of medicine of 90 to 180 days for long term care patients;
  + Provide incorrect formulary information to pharmacies, physicians or beneficiaries;

+ Fail to provide information about the exceptions and appeals process;
+ Fail to maintain a system to respond immediately to requests for prior authorization, exceptions or appeals; or
+ Fail to adequately front-line and intermediate-line staff in the above.

Monitoring the Part D Drug Benefit

It is crucial that CMS and Congress track key elements of the Medicare Part D drug program, in order to monitor implementation and to assess the need for corrections. We believe that these critical issues should be tracked on a monthly basis for the first year of the program. Elements that should be monitored for each plan include but are not limited to:

- Number of prior authorization requests and the outcome of those requests.
- Analysis of drug plan procedures for prior authorization, including additional documentation requirements.
- Number of requests for exceptions (including both requests for exceptions for non-formulary drugs and requests for exceptions from tiring requirements).
- Outcome of exceptions requests.
- Number of appeals.
- Outcome of appeals.
- Changes in formularies, including how often drug plans change formularies, and what drugs are added or deleted.
- Drugs that are appearing most often as the subjects of exception requests/appeals.
- Analysis of the impact of the Medicare drug benefit on dual-eligible, and on the quality of care in long term care facilities.

Thank you for the opportunity to share our experiences with you.

Statement of the American Pharmacists Association
To the Senate Committee on Finance

On "Implementation of the New Medicare Drug Benefit"

February 8, 2006

The American Pharmacists Association (APhA) welcomes the opportunity to present the pharmacist's 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 to 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' efforts to implement Part D highlight the fact that they are the health care professional most important to successful implementation of the Medicare drug benefit. Pharmacists' heroic efforts minimized the chance that the challenges of this benefit disrupted patient care. The Medicare program must include coverage for prescription drugs — one of the primary tools in health care's kit. It is imperative that we make this benefit work.

Pharmacists: Unsung Heroes

The start of the new Medicare prescription drug benefit was more challenging than many anticipated, and pharmacists involved in direct patient care bore the brunt of implementing the new benefit. New financial and administrative burdens were placed on pharmacists who were required, as the access point for the benefit, to explain and defend the benefit to hundreds of thousands of patients. The 'choice' Congress required in the benefit led to a cumbersome number of plans that met the 'choice' goal but also increased the amount of beneficiary confusion. Additionally, while some plans were well-prepared to implement the benefit or worked quickly to address issues as they arose, others were unprepared or appeared to have a blatant disregard for making the benefit a success.

Consequently, pharmacies became eligibility verification centers and insurance benefits manager facilities rather than health care facilities. As has been widely reported, pharmacists encountered: patients who had been auto-enrolled into plans whose network didn't include their pharmacy; being on hold for hours with prescription drug plans and then being hung up on; incorrect or insufficient data making claims processing impossible; too few CMS customer service representatives many of whom were often unable to answer pharmacist questions; wide variation in plan procedures; long eligibility query response times; and other challenges.

But regardless of the chaos, pharmacists answered the call and patients were served. Many more patients would have gone without their medications during this implementation phase without a concerted effort by pharmacists. The humanitarian response of pharmacy was similar to pharmacy's response to the hurricane crises. Patient care trumped red tape. 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. CMS' efforts prior to implementation were also helpful, such as the 'E1'system that allows pharmacists to

request information about a patient's eligibility. In fact, it is something from which the private market would benefit. APhA continues to partner with CMS to make improvements to the system. While problems remain, we commend CMS for their efforts.

Taking Advantage of Lessons Learned

As we look into the future of the benefit it is important to take advantage of what these first weeks taught us and address the program's weaknesses. Requiring pharmacists to provide free medications or face hours of telephone calls to secure insurance information or authorization for a month's supply of medications should not be considered a viable option. Such system flaws are not sustainable on the backs of pharmacy and inappropriately remove pharmacists from their primary role of helping patients make the best use of their medication. Ultimately, it is patients who suffer from these flaws. If patients are unable to get their prescribed medications 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? We must have greater assurances that the benefit is working.

To ensure the benefit is working requires evaluating and improving the system. One of the elements we suggest be reviewed is the timing of the payor's involvement in what a patient receives for medications. It is something that distinguishes pharmacy from other parts of our health care system. For example, although physician services may require a second opinion before a procedure is 'covered', that evaluation is completed before the point of service. We don't debate what will be covered – anesthesia or cesarean sections – in the delivery room. Drug coverage decisions, however, are rarely addressed until the patient is facing the pharmacist, and the red tape clouds patient care.

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. As we have moved to more outpatient care that relies heavily upon medications and patients' ability to manage 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 the source of those savings should not be denial of necessary therapy. And simply because these disruptions also occur in the private market does not make them appropriate.

Recommendations

To better ensure that we receive the greatest return on our investment in this important benefit, we recommend addressing the following problems. We draw the Committee's attention to the immediate problem of formulary management. We are pleased that CMS decided to extend the 30-day transition period to up to a 90-day transition period. 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 Committee must consider ways to standardize the program. Such standardization will provide plans the opportunity to be competitive while not being ineffectively disparate. Our complete list of issues to date follows:

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.

Solutions:

- Clearly define enrollment periods and cutoff dates. 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 as well as 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. The recently created CMS flyer addressing this issue may not be enough.
- 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.
- Monitor and establish minimum standards for plan data match rates. Suspend E1 transaction fees when the match rate is sub-standard.
- Compensate pharmacists for their enrollment and eligibility verification efforts.

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 only some pharmacies in their network often referred to as 'co-branding'. 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 for 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: Formulary Compliance

We are pleased that CMS decided to extend the 30-day transition period to a 90-day transition period. 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. Current postings are sporadic, difficult to find (nearly impossible without Internet access) and confusing.
- 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.
- Standardize the formulary compliance mechanisms across plans. At least one plan is requiring the use of medication-specific prior authorization forms and has as many as 37 forms for pharmacists and prescribers to use. That sort of variability is time consuming and unnecessarily burdensome.
- Standardize formulary parameters. The Plan Finder may report that a plan's formulary covers a specific medication. However, the information may be misleading if the patient or health care provider is unaware that the medication has a higher co-pay (could be up to a 100% co-pay) or requires step therapy and therefore requires prior-authorization. When such information is available on the Plan Finder, it is not readily apparent and requires a saavy consumer who knows to 'click' through several layers of web pages.
- Standardize tier processes. There is wide variability amongst the plans regarding their use of tiers within their formulary. CMS should standardize this drug benefit management tool.
- Standardize messages to pharmacists to better enable pharmacists and prescribers to implement formulary management procedures.
- 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. CMS has reflected the burden associated with these tasks in their recent decision to compensate states for not only the medications they covered during the transition period but also an administrative fee. Only through pharmacists' 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.

Immediate: Part B vs. Part D Payment

- Provide plans additional information on what medications should be covered by Medicare Part B versus Medicare Part D.
- Monitor plan compliance with B/D directives to ensure only minimally necessary procedures are required of pharmacists and prescribers and that coverage decisions are not unnecessarily delayed.

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, such as those serving community health centers and/or authorized in the 340-B program, create plan incentives 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.

However, the recognized role of pharmacists to implement and sustain the new benefit makes recently enacted and newly proposed Medicaid cuts to pharmacy reimbursement absurd. They undercut the very infrastructure responsible for making the Medicare drug benefit work. Congress' cuts to pharmacy in the Medicaid program 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— making a drug benefit moot . Policymakers must begin reflecting that reality in their decisions.

To fulfill the promise made to Medicare beneficiaries to provide them a prescription drug benefit requires continuous quality improvement. Plans that are unable to meet their contractual obligations should face stiff penalties. Pharmacies should no longer be forced to carry the burden

of implementing the benefit; ignoring this problem will damage pharmacy's economic viability and result in limited patient access to community pharmacists. This market-based program is reliant upon the market for success, and to date, some elements of that market have failed. It is time to address those failures.

Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to improve the program and provide a more effective system of providing prescription medications to Medicare beneficiaries.

American Psychiatric Association
1000 Wilson Blvd, Suite 1825
Arlington, VA 22209
Press contact: Jason Young (703) 907-8640
Government Relations: Tom Leibfried (703) 907-8646

Statement of the

American Psychiatric Association

for the

Senate Committee on Finance

on

Implementation of the New Medicare Drug Benefit

February 8, 2006

The American Psychiatric Association (APA) thanks Chairman Grassley, Ranking Member Baucus, and members of the Finance Committee 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. The 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. We too are committed to the success of Medicare Part D.

INITIAL IMPLEMENTATION PROBLEMS

Unfortunately, widespread problems persist as the Medicare Part D program is being implemented. Many of these problems concern the transition of Medicare/Medicaid dual eligibles to Part D drug plans, and 27 states have spent millions of dollars covering the medication costs of these beneficiaries on an emergency basis. Common problems include 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 are 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. In Minnesota and Florida, plans failed to comply with the transition policy of the Centers for Medicare and Medicaid Services (CMS), barring access to vital medications that had been covered under previous drug coverage. In some cases, plans claimed they were unaware of this transition policy. 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 implementation 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, customer service, and formulary policy 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:

- **Emergency one-time fills.** CMS's transition guidance to drug plans articulated an expectation that Part D beneficiaries experiencing difficulty in having prescription refills covered would be provided with an emergency supply of medications until administrative concerns are resolved. Many plans did not comply with this policy and there are many reports that plans persist in non-compliance even after problems are reported to CMS. It is important that CMS actively enforce the transition policies that have been extended for 60 days.

- **Continuity of care for patients with serious medical conditions.** Guidance issued by CMS in June 2005 requires "all or substantially all" drugs to be covered by the plans in six categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and drugs for HIV/AIDS. The guidance was based on the complexity and high cost of the diseases these drugs treat as well as evidence-based practice. CMS also stated that plans must presume that new enrollees submitting refills for drugs in these categories are stabilized on these medications. CMS directed the plans to have transition policies in place to ensure that patients are able to fill these prescriptions without being subject to prior authorization or restrictive formulary policies – and they should be able to continue doing so. Unfortunately, many drug plans do not have effective transition policies in place and complaints to CMS have not improved performance. Improved enforcement is also needed in this area during the extension of transition policies.

- **Ongoing continuity of care issues.** The "all or substantially all" guidance 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, and it should be continued as an ongoing policy after the implementation period is over.

- **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.

- **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 be developed to assist patients with these activities and physicians should be compensated for clinical decision making.

PART D COVERAGE FOR IMPORTANT MEDICATIONS

In addition to addressing ongoing implementation problems, the Committee is urged to develop legislation that will clarify CMS formulary policies and expand Medicare Part D coverage to ensure that patients have access to the full range medications used in the treatment of mental illnesses and substance use disorders. Unfortunately, for a number of clinically important medications for the treatment of these disorders, the Part D program fails to provide adequate coverage, and for some categories of medications, provides no coverage at all. Access problems exist for a number of addiction treatment medications because they are inappropriately classified in formulary guidelines. Other medications are excluded from statute governing the Part D program. Legislative action should address several issues:

- **Re-classification of addiction treatment medications.** The model formulary guidelines developed by U.S. Pharmacopeia (USP) for Medicare Part D mis-classify medications used to treat substance use disorders. As a result, drug plans may fail to include these medications in their formularies or may apply inappropriate utilization review procedures in making coverage determinations. Specifically, two drugs proven clinically effective in the treatment of opioid dependence, methadone and buprenorphine, are listed as analgesics as opposed to addiction treatment medications. Naltrexone is included in the USP guidelines for the treatment of opioid dependence, but it is also used as an alcohol deterrent, and should be covered for this use as well. Congress should pass legislation to instruct CMS to fix this problem by working with USP to change the model formulary guidelines or by issuing guidance to drug plans.

- **Adding coverage of benzodiazepines.** Benzodiazapines are sedative agents that have significant clinical value in treating a number of medical conditions, including anxiety disorders, panic disorders, seizure disorders, skeletal muscle spasticity, and the nausea and

vomiting associated with cancer chemotherapy. Congress should amend the Part D statute to include coverage of these medications.

- **Adding coverage of barbiturates.** Barbiturates are sedative agents that are clinically effective in treating seizures associated with epilepsy and head injuries. In addition, they effectively treat insomnia. Legislation should require the Part D program to cover this category of medications.

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:

- Require CMS to report on drug plans' progress in implementing effective transition policies. It is important that CMS enforce requirements that plans provide emergency prescription fills or waive formulary policies as necessary to ensure that drug therapies are not abruptly interrupted.

- 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) beyond the initial transition period. In addition, CMS should be provided with adequate statutory authority to enforce this policy with plans.

- 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.

- Pass legislation to address inadequate Part D coverage of important categories of medications, including addiction treatment medications, benzodiazepines, and barbiturates.

- 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.

###

Senate Finance Committee

hearing on

Implementation of the New Medicare Drug Benefit

February 8, 2006

Statement for the Record
Submitted by the

American Society of Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda, MD 20814
Email: gad@ashp.org
Phone: 301-664-8692

The American Society of Health-System Pharmacists (ASHP) respectfully submits the following statement for the record of the Senate Finance Committee hearing on the implementation of the new Medicare drug benefit.

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 senior 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 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 contract 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 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 considerable time contacting

CMS or plans for information or to dispense emergency medications to beneficiaries in need;

- 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;

- Difficulty transitioning certain community mental health patients who received Medicaid benefits previously, but who did not qualify for auto-enrollment in a Medicare plan and who have not proactively enrolled in a Part D plan;

- Potential continuity of care issues resulting from the auto-enrollment of dual-eligible beneficiaries in plans that do not match their 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.

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;

- Provide ongoing education to beneficiaries about the need to enroll early in the month or to leave a few weeks for their enrollment to be processed prior to filling a prescription. CMS and Congress should also continue to closely monitor this situation and consider implementing a monthly enrollment deadline of the 15th for coverage to begin on the first of the following month;

- 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

ASHP commends CMS for issuing the much-needed request to plans to extend their transition policies. This extension is critical to allowing sufficient time for the health care team to work with plan sponsors and beneficiaries to make appropriate adjustments to beneficiaries' medication regimens.

It is important however, that CMS continue to work with plans to simplify the administration of this transition period and to ensure appropriate steps are taken to resolve formulary issues during the transition.

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. Moreover, the messaging the pharmacist receives back from a plan on a specific claim does not provide sufficient or consistent information to help the pharmacist understand a non-formulary message. As a result, pharmacists have had to contact plans to verify their policy or to get further information to process the claim. In some cases, pharmacists have experienced difficulty contacting the appropriate person at the plan who has the information necessary to answer the question. ASHP recommends CMS continue to work with plans to develop more consistency between transition policies and to develop a uniform messaging system to convey coverage decisions back to the pharmacist.

In addition, plans should honor transition policies that provide access to both formulary and non-formulary medications. Requiring prior authorization or step therapy on formulary drugs during the transition period potentially affects continuity of care, particularly for patients on a large number of medications.

Formulary/Coverage Issues

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 ongoing monitoring 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 for certain covered drugs. CMS has provided guidance and educational sessions in this area, but the issue continues to cause confusion in the field. ASHP is making CMS resources and other educational tools available to our members to clarify the appropriate billing mechanism. CMS and the Congress must consider ways avoid this confusion in the future.
ASHP members have also 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 Medicare Part B. This can result in a delay in treatment and

unnecessary paperwork for the pharmacy and the Medicare program. CMS has advised plans against this practice, but must continue to enforce such policy. To facilitate coverage decisions, Medicare Part B claims will need to be processed on a real-time basis.

Home Infusion Drugs

While some home infusion drugs are covered under the new Part D benefit, the pharmacist-provided clinical services, supplies, and equipment necessary to ensure the safe and appropriate use of these medications are not covered. Home infusion therapies generally require services beyond those both needed and provided for drugs dispensed in the traditional community retail pharmacy setting. Covered home infusion therapies involve the administration of medications using intravenous, subcutaneous, and epidural routes. This includes, for example, certain antibiotics, chemotherapy, pain management, parenteral nutrition, and immune globulin therapies. The cost of providing this care far exceeds the average dispensing fee used in the community retail setting.

Under the Medicare Part D benefit, some beneficiaries who previously received home infusion therapies as part of their state Medicaid or Medicare supplemental coverage, lost the service and supplies component of that benefit. These beneficiaries are now being asked to pay out of pocket for the expenses related to the administration of these medications, or are being shifted to nursing home or hospital settings to receive their medications, or are receiving complex medications at their home without necessary support services to ensure their safe administration.

Failure to cover related overhead and administration services for home infusion therapies may result in an increased risk of medication-related complications, beneficiaries not receiving care in the optimal care setting, and greater expense accrued to Medicare for patients shifted to nursing home or hospital settings to ensure safe medication use.

Congress needs to investigate ways to separately and appropriately cover patient care services and supply expenses related to ensuring the safe and appropriate use of these medications, since CMS may have limited authority to broaden the scope of this coverage. For example, the Congress should recognize pharmacists as health care providers in a similar manner as nurse practitioners, physician assistants, and other non-physician provider services are covered.

In the interim, ongoing oversight is necessary to ensure plans' networks include an adequate supply of pharmacies that can meet beneficiaries' home care needs while meeting the well-established standard of care in home care settings.

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 and negotiating appropriate terms. ASHP suggests CMS put in place and enforce some minimum reimbursement rates to ensure access for beneficiaries when receiving care in these settings.

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

Pharmaceutical manufacturers' prescription assistance programs (PAPs) provide a significant benefit and will continue to be important to certain Medicare beneficiaries enrolled in the Part D benefit, particularly those who do not qualify for the low-income subsidy but who cannot readily afford their medications. ASHP appreciates CMS' guidance to PAPs, defining the means by which PAPs can continue to operate within the new Part D benefit. ASHP encourages CMS and the Congress to continue to closely monitor the impact of the Part D benefit on these programs to ensure they are not unnecessarily restricted, either due to increased administrative burden or negative incentives, thereby limiting the extra assistance some beneficiaries will 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. However, several obstacles currently exist that could limit the impact of these important programs.

Policymakers must reassess the financial incentives provided to plans for medication therapy management programs. Currently, medication therapy management programs are

considered part of the plans' administrative costs. Particularly for drug-only prescription drug plan sponsors, this may provide limited economic incentive to offer meaningful medication therapy management programs. ASHP therefore suggests creating a distinct revenue stream for medication therapy management programs, allowing for performance-based measures.

ASHP supports CMS's ongoing efforts to develop uniform measures to evaluate plans' medication therapy management programs. The Society has significant experience in medication safety and quality and hopes to continue to work with CMS on this effort. ASHP would like to see quality measures that evolve from a quantitative to a qualitative analysis of medication therapy management programs. In order to do so, policymakers will need to assess how to integrate multiple data sources.

To facilitate the evolution of these programs, and increase Medicare's return on investment, more information about plans' medication therapy management programs will also need to be made available to beneficiaries and providers. ASHP encourages CMS to make information describing plans' eligibility criteria and the medication therapy management services offered available to the public, and to incorporate this information into future plan selection tools to help beneficiaries make informed decisions when assessing plan offerings. This is particularly important for high-risk beneficiaries who are at greatest need for assistance in managing their medication use, but who now may find themselves enrolled in a plan for which they do not meet plan-specific eligibility criteria.

ASHP is disappointed by many of the medication therapy management programs that are being offered by plans this year. We understand these programs are expected to evolve over time, but some of the plan-specific eligibility criteria seem to be too narrowly drawn even for the first year of the program. For example, some plans used the criteria of multiple chronic conditions to limit their program to beneficiaries who have two out of a set of four specific chronic conditions, a small cross-section of the high-risk population. In addition, some plans have also limited the scope of their program to only the lowest-level services that CMS recognized as falling within the definition of a medication therapy management program.

Appropriate financial incentives, uniform quality measures, and public information will be essential to meeting the medication management needs of high-risk patients.

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.

Implementation of the New Medicare Drug Benefit

Testimony of

Kenneth E. Goodman, Chief Operating Officer
Forest Laboratories

Submitted to the Senate Committee on Finance

Mr. Chairman, Ranking Member Baucus, and distinguished members of the Senate Committee on Finance, as President and Chief Operating Officer of Forest Laboratories, Inc., I welcome the opportunity to submit a formal statement for the record regarding 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.

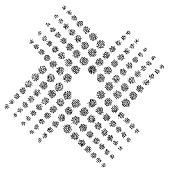
- A psychiatrist from Missouri reported that he authorized a switch from Lexapro® to citalopram after receiving a call from a pharmacist indicating the patient had requested the change to save money. Within less than three months, the patient destabilized and became depressed, affecting both her marriage 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.



LTCPA

Long Term Care
Pharmacy Alliance

Testimony for the Senate Finance Committee Hearing on Implementation of the Medicare Drug Benefit
February 8, 2006

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

1776 Massachusetts Ave., NW, Suite 410 Washington, DC 20036
Phone: (202) 386-7559 Fax: (202) 386-7560www.ltcpa.org

problems. Clearly, the long experience in healthcare demonstrates that variation across small populations does not enhance quality.

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

Implementation of the New Medicare Drug Benefit

U.S. Senate Committee on Finance
Wednesday, February 8, 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)
"Implementation of the New Medicare Drug Benefit"
February 8, 2006

Chairman Grassley, Ranking Member Baucus, and Members of the U.S. Senate Committee on Finance: 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.