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DOES CMS HAVE THE RIGHT PRESCRIPTION? IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM

HEARING

BEFORE THE

OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

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DOES CMS HAVE THE RIGHT PRESCRIPTION? IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM

THURSDAY, APRIL 8, 2004

U.S. SENATE,
OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA SUBCOMMITTEE,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:42 a.m., in room SD–342, Dirksen Senate Office Building, Hon. George V. Voinovich, Chairman of the Subcommittee, presiding.

Present: Senators Voinovich, Durbin, Lautenberg, and Pryor.

OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. The hearing will come to order.

I do apologize to the witnesses for being late but the Members of the Senate were being briefed by the Secretary of Defense and the Chair of the Joint Chiefs of Staff about what is going on in Iraq today. So we stuck around a little bit longer just to get a real flavor for what is happening there. I apologize for being late.

The Subcommittee on Oversight of Government Management, the Federal Workforce and the District of Columbia will come to order and we welcome you.

Today's hearing is entitled, "Does CMS Have the Right Prescription: Implementing the Medicare Prescription Drug Program." I thank all of you for coming today and hope that the hearing will provide an opportunity to have a forthright discussion about the management challenges facing the Centers for Medicare and Medicaid Services.

The existence of these challenges should not detract from the agency's significant accomplishments. Medicare has been and continues to be a successful program for the American public, providing vital health care to our Nation seniors. Yet the agency currently has more on its plate than it has since the creation of Medicare and Medicaid in 1965.

While Medicare and Medicaid have been essential for our Nation's seniors by providing coverage for the cost of doctor's visits and hospital stays, prior to enactment of the Medicare Prescription Drug Improvement and Modernization Act on December 8, 2003, it was structured for a 1960's health care system. Unfortunately, the system did not evolve with the new developments in science that

allows physicians to treat diseases that once required surgery with modern prescription medications.

Thanks to Congress' action last year, our Nation's seniors will now have access to a prescription drug program through Medicare. It is now our responsibility to make sure that CMS has the means to implement this new benefit in an efficient and effective manner. While the task ahead of CMS is enormous, the agency has faced similar challenges in the past.

In fact, implementation of this new benefit is similar to the previous administration's implementation challenge with Medicare Plus Choice. When Medicare Plus Choice was ready to be rolled out nationwide, I was serving as Governor of Ohio. I recall after reviewing the implementation plan I was concerned that the agency was not ready to handle all of the phone calls they were going to get after a massive advertising campaign.

Ms. DeParle will remember my concerns at the time. She was the head of the agency preceeding CMS—HCFA. I approached her and then-Health and Human Services Secretary Donna Shalala. I told them that I felt that before they rolled it out nationwide they ought to do some pilot projects to see how it would work.

To their credit, they adjusted the program. My State became one of the five test States and the program was implemented smoothly. I think that just like Medicare Plus Choice, CMS has a lot of work to do before it will be ready to roll out this benefit in 2006.

Remembering this experience will help us keep in perspective the administrative challenges facing CMS, which we will learn more about today. I believe that when we begin to discuss the details involved in implementing such dramatic changes the perception will shift from why is it taking 2 years to provide the benefit to amazement that CMS intends to provide it in 2 years.

I am encouraged to see that CMS already has taken substantial steps to offer a temporary drug discount card. On February 5, CMS announced that over 100 separate entities submitted applications to offer Medicare approved cards to beneficiaries.

By March 25, CMS was able to announce that they had reviewed the applications and, I understand, awarded 28 private card sponsors. This is the first step, and we have to make sure that this progress continues, particularly as the mailings go out and beneficiaries are going to be asked a lot of questions about how to take advantage of the card.

I understand Ms. McMullan will talk about the discount card but neither the details nor the merits of the program are the topic of this hearing. Understand that. I do not want to get into a debate about the program. There have been numerous Congressional hearings about that issue.

The purpose of this hearing today is to discuss the capacity of CMS to respond to the challenge of implementing the drug benefit program by 2006 and to establish a baseline of where the agency is today.

Even before passage of the Medicare Modernization Act, CMS was coping with administrative challenges. For example, a 2002 report by the National Academy of Social Insurance highlighted the fact that between fiscal years 1992 and 2002 benefit outlays increased 97 percent and claims grew by 50 percent, however pro-

gram management funds increased by only 26 percent and authorized full time equivalent positions only 12 percent. So the workload increased, but there was a question about whether the dollars were there to provide for the management that was needed to deal with the increases.

One of the challenges facing CMS in moving forward with implementation of the prescription drug benefit is the agency's human capital resources. In general, governmentwide strategic human capital management remains on the General Accounting Office's high-risk list. Currently 18 percent of CMS workforce is eligible to retire. The number is significantly higher, 30 percent, in the career Senior Executive Service. We are not talking about early retirement.

In addition, over the past 3 years, CMS has lost a quarter of its career executives to retirement. If that does not seem like a daunting challenge, 46 percent of the existing CMS workforce will be eligible for regular retirement by 2009.

These statistics leave me asking the question will CMS have the expertise and the leadership it needs to get the job done?

During my time as Mayor of Cleveland and Governor of Ohio, I worked to address the workforce challenges within our local and State governments. Working with a wide range of stakeholders, we successfully empowered our employees while establishing a culture of quality management.

Since coming to the Senate in 1999, I have stressed to my colleagues the urgency of the Federal Government's human capital challenges, the need to get the right people with the right skills and knowledge at the right place at the right time, something that has been ignored by this government for as long as I remember. And before I came here I lobbied this place for 18 years as a mayor and governor on this same issue.

So the question is, do we have the people to get the job done?

Human capital management is but one of the many management challenges we are going to touch upon today. For example, the Medicare program has been on GAO's high-risk list since 1990. I look forward to discussing what the future looks like for CMS.

Testifying before the Subcommittee today are three individuals with significant expertise and insight into CMS. While I have highlighted what I see as some of the challenges facing CMS, I look forward to hearing from CMS about the challenges they have identified and the steps the agency has taken to address them.

At this time I would like to welcome Michael McMullan.

Ms. McMullan is the principal career executive in charge of the Center for Beneficiary Choices. She has been with the agency for 31 years and I certainly hope you are not considering retiring, Ms. McMullan.

The Center is a focal point for innovation in the Medicare program, including clinical quality measurement and assessment, the Medicare Plus Choice program and beneficiary education.

In addition, we are privileged of have testifying today before us two past administrators of the Health Care Financing Administration, Gail Wilensky, who served from 1990 to 1992, and Nancy-Ann Min DeParle, who served from 1997 to 2000. I have had the privi-

lege of working with both Ms. Wilensky and Ms. DeParle during my time as governor.

More recently it was their presentation at the John F. Kennedy Commonwealth Health Policy Conference in January that highlighted for me the tremendous management task before CMS.

I look forward to their assessment of CMS's ability to manage the new drug program and what they would do if they were in charge of CMS today.

I would now like to recognize Senator Lautenberg for an opening statement. Senator, thank you for being here.

OPENING STATEMENT OF SENATOR LAUTENBERG

Senator LAUTENBERG. Thank you, Mr. Chairman.

You know that I think that Ohio had chosen wisely when they sent someone with the experience and the commitment that you have, Mr. Chairman, and I enjoy our chances to get together.

I am sure that some of our meetings are not quite as pleasant as some of the others, but we always have the same mission in mind, Mr. Chairman. And so I look forward to this hearing and commend you for calling it.

The Medicare Modernization Act is being closely scrutinized by all sides. We are not here to debate the merits of the new law, but rather to review how the Centers for Medicare and Medicaid Services will implement the most significant changes to Medicare since its inception. It is not going to be an easy job. It is precisely the implementation of this law that I have some serious concerns about.

As you would expect, the view of the law where the class is half-full or half-empty is where we are. The Chairman sees it as half-full. I see it as half-empty. His interest in getting the program underway is one certainly that I think we all would like to see in place.

Questions are raised about why the year 2006 was chosen, I think. I came out of the computer business and the Chairman has long studied Medicare and the health care problem. But I know that our recordkeeping is a lot better today than it was in 1965 when Medicare was created and it took us only 11 months, I think, to get the Medicare program up and running. With the computer technology and the recordkeeping that we have today, I think it could take a lot less time. I am rather suspicious about deferring the date until 2006.

I have repeatedly asked the Administration to stop producing misleading Medicare advertisements that have a political tone. The reality is that the recent print and television ads promoting the law do really little to inform the Medicare beneficiaries. Rather, they are thinly veiled political ads paid for with taxpayer funds.

At my request, the General Accounting Office reviewed these ads and found that they contained "notable omissions and other weaknesses" such as misleading seniors about the prescription drug program's premiums, which will very likely exceed the Administration's estimate of $35 a month. These ads sugar coat the description of the Medicare drug discount card program by failing to note that the cards require the payment of annual fees and that the discounts will vary greatly. The ads promise the same Medicare

when the law contains new structural incentives for the gradual privatization of Medicare.

In a similar vein, false news reports scripted by the Administration repeat the litany of intentional errors and misleading statements. Masquerading as journalism, video news releases, VNRs, produced by the Administration tout the new legislation. In a video produced by HHS, the cheering crowd stands there applauding the President as he signs the Medicare Modernization Act into law. It is fairly obvious that this had to be staged.

And even the government's official 1–800–Medicare help line extols the new law, literally forcing callers to describe the changes as Medicare improvement before permitting them to access a counselor. Once a caller submits to say Medicare improvement, he or she is led to an automated voice with a familiar misleading message. It says it is the same Medicare you have always counted on with more benefits. You can keep it as it is and you do not have to change a thing. The Administration's obligation is to educate and not spin.

The legislation is now law and understanding its many changes, including some which will offer legitimate help to people with low incomes or high drug needs, is daunting enough for people without being misled by Administration ads or video news releases.

If the Administration's primary interest truly lies in getting Medicare beneficiaries and their families to understand the changes under this law, we insist that it remove bias and distortion from its so-called educational efforts.

Mr. Chairman, I would like to be as cooperative as I can to get the program underway, but I just have a concern about how this is being presented to the American public.

Senator VOINOVICH. Thank you.

It is the tradition of this Subcommittee to swear in the witnesses. Will the witnesses please stand as I administer the oath?

[Witnesses sworn.]

Senator VOINOVICH. The record should reflect that the witnesses responded in the affirmative.

Ms. McMullan, I want to thank you very much for being here today. I want to also publicly thank you for your 31 years of service to our government and the people that you have come in contact with over the years. We look forward to your testimony.

TESTIMONY OF MICHAEL McMULLAN,[1] DEPUTY DIRECTOR, CENTER FOR BENEFICIARY CHOICES, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Ms. MCMULLAN. Chairman Voinovich, distinguished Members the Subcommittee, thank you for inviting me today to discuss implementation of the Medicare Prescription Drug Improvement and Medicare Modernization Act or MMA for short.

The Centers for Medicare and Medicaid Services is very proud——

[1] The prepared statement of Ms. McMullan with attachments appears in the Appendix on page 41.

Senator VOINOVICH. Ms. McMullan, I usually ask people to speak for 5 minutes, but I do not want you to rush through this. We have three witnesses today and I want to make sure that we hear you.

If you could just move up closer to the mike, too, so that we can hear what you have to say.

Ms. MCMULLAN. The Centers for Medicare and Medicaid Services is very proud to have a significant role in implementing this historic legislation and is working diligently to meet the numerous and aggressive deadlines outlined in the Act.

The MMA represents a fundamental change in the Medicare program by offering our beneficiaries more choices in how they receive their care and by establishing a responsive relationship with providers of that care.

This will begin with the Medicare-sponsored discount card and will continue as the full prescription drug benefit is implemented in 2006, and represents a lasting change in how CMS and the Medicare program will operate.

CMS is unique among government agencies in that it accomplishes its mission principally through contractors and other government entities. The agency employes about 4,500 people in locations across the country. However, these employers are only a small portion of a very large, complex network of people and groups that make our programs work successfully.

The chart that I have attached to my testimony gives an idea of the scope of this contracted work.[1] For example, in 2003, it is expected that CMS contractors will have provided claims processing services to about 33 million beneficiaries, worked with approximately 1.1 million health care providers, processed more than 1 billion Medicare claims, paid more than $236 billion for beneficiary services, and handled more than 7.3 million review requests and other kinds of appeals.

CMS' MMA implementation challenges can be categorized into a number of broad categories, including a prescription drug discount card and transitional assistance program, a new voluntary Medicare prescription drug benefit, modification of the existing Medicare Plus Choice program now renamed as Medicare Advantage, and contractor and regulatory reform.

The MMA also modified numerous payment systems under Medicare and Medicaid, particularly those affecting rural providers. It established new preventive benefits, established a number of demonstration programs, provided for administrative improvements and regulatory process changes and numerous other provisions.

Given the nature of the work before the agency and the need for effective steady leadership, we appreciate the Senate's swift confirmation of Dr. McClellan as our new Administrator.

As an example of what we have already done to implement MMA, on December 15, 2003, just 1 week after the law was signed, CMS published a regulation establishing a new prescription drug discount card program. We solicited applications from organizations interested in sponsoring such a program, and on March 25 announced the approved applications.

[1] The chart referred to appears in the Appendix on page 50.

On April 1, CMS announced the actual drug discount cards that the sponsors will offer. And on April 29 we expect to post on our Web site specific discount prices available through these programs. Beneficiaries will be able to sign up for the cards in May and begin realizing the associated discounts on their drug purchases effective June 1.

In addition, qualified low income beneficiaries will receive a significant additional benefit of a $600 credit applied toward their drug purchases.

Establishing the drug discount card program, although a major effort, is not the only work that CMS has accomplished in the past 5 months when it comes to MMA implementation. The second attachment to my testimony details more than 100 tasks that CMS has completed to date. It is obvious from this list of accomplishments that CMS is making good headway in meeting the ambitious timeline within the MMA.

The MMA provides CMS with about $1 billion to spend over 2 years for implementation. This money will be spent on hiring additional personnel, upgrading and adding new information systems for operations and analysis, educating and providing information services to beneficiaries and providers. CMS has already made important funding decisions related to the implementation of the drug card and to hiring new employees. CMS continues to develop and implement the budget plan as it moves toward implementation of the remaining provisions.

To implement the MMA, CMS will need to hire individuals with expertise in pharmacy benefit management, clinical professionals such as pharmacist and physicians, individuals experienced with disease management and prevention, health economists, public policy analysts, and individuals who know how employers structure their retiree benefit practice. CMS will also need additional IT professionals experienced in building systems and telecommunication infrastructure contemplated by the law. Finally, CMS will need to hire individuals experienced with government contracting, as much of the work under MMA, as with other Medicare operations, will be contracted out. We have begun staffing a number of these new positions.

Once contracts have been established for the administration of the program set up by CMS, the work of the contractors must be monitored and supervised to ensure program integrity and effectiveness. The main oversight work of CMS is to see that contractors and providers implement these new programs as directed by statute and established by the agency.

For example, CMS will need to monitor pricing of drugs and benefits provided under the drug discount card program, by the drug benefit plans, and the Medicare Advantage plans. The new programs must be studied for their effectiveness, to see whether they have carried out the statute as Congress intended, and if they have provided appropriate benefits and assistance to Medicare beneficiaries. Error rates in payment will need to be established and education made available to providers to help them avoid billing errors.

CMS must also monitor for fraud and abuse. The agency needs to be able to address any inappropriate behavior, either through remedial education or punitive measures.

The implementation of Part D and the new and revised payment systems require substantial IT development and changes. The agency will need to develop and manage plan enrollment and management systems, systems to process beneficiary eligibility requests and enroll beneficiaries in the new benefits, track utilization of services, and measure and track clinical quality.

Revised and new IT systems will need to interact with systems supporting MMA managed by other Federal agencies such as the Social Security Administration and the Internal Revenue Service, States, and private insurers who contract for the new benefits under MMA and those offering Medigap plans.

CMS recognizes that opportunities for beneficiaries to choose new benefits and how these benefits will be delivered represent a change for Medicare beneficiaries. Therefore, CMS has begun a substantial and varied education campaign to assist beneficiaries as they take advantage of these new benefits.

The timelines required under MMA are ambitious and will require prudent planning and wise use of resources. Although there are many decisions left to make with respect to budget and personnel, CMS is committed to informing Congress about these issues as they progress.

I thank you for your invitation to testify this morning and I welcome your questions.

Senator VOINOVICH. Thank you, Ms. McMullan.

I would like you to go back to about the last 2 minutes of your testimony. I would like you to repeat for us that last part about all the things that you have to do, that is a mouthful and you went quite rapidly through it. Just go through it real slow.

It is right at the end of your testimony, you were discussing bringing IT people on board.

Ms. MCMULLAN. The types of people that we need to administer the programs?

Senator VOINOVICH. That is right, could you repeat that again?

Ms. MCMULLAN. In order to implement MMA, we are going to need people who understand pharmacy benefit management, a principal task under the new Part D, clinical professionals such as pharmacists and physicians, individuals experienced with disease management and prevention, health economists, public policy analysts and individuals who understand how employers structure their employee benefit packages.

We will also need IT specialists who understand how to structure the systems and the telecommunication infrastructure contemplated by the statute in implementing both Part D and the other programs under the statute.

Senator VOINOVICH. That is a mouthful.

Ms. McMullan, you have been in the agency a while. What lessons has CMS learned from the twin challenges passed by the Medicare reforms mandated by the Balanced Budget Act of 1997 and the Y2K computer migration, in terms of prioritizing and implementing a lengthy list of important and complicated program changes?

Just listening to what you have said, what have you learned from past experience that will help you now?

Second, these people with specific expertise that you need to hire, are they available today to be hired? Is the budget that has been made available to the agency adequate enough to get the job done?

And, finally, but not least, what I am most interested in is do you think that you need some additional workforce flexibilities in order to get the job done?

For the last several years, I have been working on the issue of human capital management. One of the concerns I have had is that some agencies have been unable to keep people they need. And then, more important than that, agencies have been challenged in attracting new people into the agencies. I have worked to ensure agenceis have the flexibilities and the tools and the other things that are needed.

You have been at CMS a long time. So if you would talk through these issues for me, I would appreciate it.

Ms. MCMULLAN. To start with the lessons learned, I think that the most important thing that we learned in both doing the implementation of the Balanced Budget Act and in Y2K is the need to think through the plan for each of the activities that is contemplated in the statute for us to implement and understand what the business requirements are for the task, and the critical path to implementing the different activities.

And so, we are in a very careful planning and prioritizing stage now for many of the parts of the statute that have implementation dates in 2006 through 2011.

So that is a critical task and activity that proved to be very useful and important in our implementation of the Balanced Budget Act (BBA) and in the Y2K management. So we are actively doing that, reporting on a regular basis on our accomplishment against those plans and working with our colleagues and other Federal agencies and the States to coordinate the activities that have to be implemented against the plan.

So that is probably the greatest learning that we have done over time; understanding the importance of that first task of planning.

Having said that, then you take those business requirements in the plan and look at what the tasks are ahead of us that are the most important for us to accomplish in implementing the statute. And for Part D, that is substantially information systems and contract development and management because we will be contracting out for the management of the Part D benefit to private drug plans as well as Medicare Advantage plans. The private drug plans is a new entity in the marketplace and so we are going to be working through and thinking about having to do that.

Medicare Advantage offers a new option with the PPOs, so we are working to think through and understand how best to organize that and to be able to contract for it.

The business requirements for the systems deal with how do you add to our already existing plan management and monitoring capacity that we have now for the Medicare Advantage plans? How do we expand out those systems that already exist? And then, for Part D, establishing new systems to manage eligibility and pay-

ment. It is a different program. So that we have to think through those requirements and put the systems in place.

As far as the human capital aspect of that, significantly to accomplish the work done to implement those programs we will rely on contractors. And so the human capital that we need within CMS are the people who can define the requirements and manage the contractors. So it is very important that we have expertise inside of CMS and the Department.

Senator VOINOVICH. An important part of this program, and I have been through it as a governor, will be putting requests for proposals together for private contracting. It takes some really good people to do that.

Once it is done, it is important to have the people to review the proposals. Do you have that capacity now to do that?

Ms. MCMULLAN. We have the capacity now to do part of the work that we are doing now, and then we will build up the capacity over time to do the work that we will have to do between now and 2006. And then eventually, with contractor reform, through 2011.

So we need to increase capacity both for people who understand government contracting and in the IT systems, as well as the expertise that we need in understanding how to manage the pharmacy benefit and the clinical staff that can help us understand the coverage and rules. We also have disease management and prevention, so we need more clinical staff in that area as well.

So we do understand we have to build out the staff within CMS in order to manage the program. The significant human capital though, will be acquired through contracts as we do now.

Senator VOINOVICH. Do you feel confident that the people you need to bring in to CMS to do the RFPs, request for proposals, are available to be hired?

Ms. MCMULLAN. We have had significant success hiring expertise in government contracting. We often acquire people from other government agencies that do contracting. There are significant resources out there in trained resources.

So I think that on managing government contracts we probably do have a sufficient supply available to us within the existing government contracting world.

We are also using ways to attract scarce resources by offering recruitment bonuses as well as for our clinical staff, special pay provisions for physicians and others that qualify for those provisions.

Senator VOINOVICH. Do you have those flexibilities right now?

Ms. MCMULLAN. We have them and we are interested in employing some additional ones that can be made available to us through the direct hiring authority available through the Office of Personnel Management, as well as the hiring potential that is available through the statute itself. So we are interested in using those additional hiring authorities.

Senator VOINOVICH. We are going to have a couple of rounds of questions. Senator Lautenberg.

Senator LAUTENBERG. Thank you, Mr. Chairman.

May I have your permission to show a short video just to clarify what was said and when, that kind of thing?

Senator VOINOVICH. That is fine.

[Videotape played.]

Senator LAUTENBERG. Thanks, Mr. Chairman.

This news story, fake news story, was produced by CMS. It was distributed to TV stations around the country, run as if it were just an unbiased news clip. The video did not identify that it was produced by the government. The GAO has launched an investigation concerning the legality of this video.

And I thank you, Ms. McMullan, for your testimony. I know how arduous the task has been to get all these things into shape and I respect it greatly.

I just have some questions that I think need clarification. Do you know who Karen Ryan is, the reporter in this video?

Ms. MCMULLAN. It was a name used in developing the video.

We produce video news releases, audio news releases, and paper press releases that we give to the press in order to give them information. The way that the press stations use these, the VNR in particular, is to cut and paste certain portions of them.

The use of a voice in going through the VNR from beginning to end is meant to provide context in ways that news stations may use them. Most news stations just use pieces of the VNRs. Very few of them use any of them from start to finish, and that is really the decision of the news director. But most of them, as I say, use them as just little snippets.

And along with the information you show, we also include other kinds of materials that they can use called B-roll. I do not know what the B stands for, but it is called B-roll. That is added to the VNR just to provide them with other information that they can use.

So it is very much like a paper press release that newscasters and others use at their discretion.

Senator LAUTENBERG. But it does not identify anyplace that this was put out by CMS because it portrays what one would normally think of as a news report, "today thus and so happened." The President signed the bill, and here is what the law is going to be.

Usually that would carry a legend that says this is produced by, paid for by or otherwise.

But I think what comes across is, as you have just confirmed, is that you use voices and people to portray things that usually always, I think, are required to identify the fact that this is produced by the government. This certainly did not have that character.

How many stations played this so-called new report? Do you know?

Ms. MCMULLAN. No, I do not know but we will be happy to provide that for the record. We do have the information.

INFORMATION PROVIDED FOR THE RECORD FOLLOWS:

The video news release (VNR) was aired on 40 different stations in 33 local markets throughout the country.

Senator LAUTENBERG. I think the number was about 40, but I would appreciate your confirmation.

Should CMS be in the business of covertly distributing news stories that are not really representative of just the issue, but rather, in my view, certainly has a political overtone here? Do you think that is appropriate to pitch, cut, and paste, and do that kind of

thing, presented as if it was pure news without saying that this is a program that still has some way to go, and things to do?

We talk about senior citizens being able to get all kinds of drugs, everything they want. But the fact of the matter is they cannot get the health savings account if they are a Medicare beneficiary. That was pulled, Mr. Chairman, from the first circular that was printed because it is not a benefit that is available to those who are beneficiaries of the Medicare program.

The General Accounting Office found that the Medicare flyer and the ad campaign that the Centers for CMS produced contained notable omissions, had a political tone, and overstated the new drug law's benefits. These are tough criticism by a nonpartisan organization, GAO. And will CMS revise these materials in response to GAO's criticisms?

Ms. MCMULLAN. The materials that GAO reviewed were ads that had been on the air. We will be airing additional new ads on the drug discount card. We use the power of television to reach the maximum audience that we can.

The information that we include in ads, and note that ads are 30-second ads, so that there is not a significant possibility to include all information about all parts of the program. So we try to target it on one or two messages to make sure that people understand, particularly where do they go to get additional information on any of these.

When we do the ads, we substantiate the information in the ads to make sure that it is accurate and presented correctly. So we do intend to continue to use television advertising to help people understand Medicare.

Senator LAUTENBERG. So you dismiss the commentary, the response by GAO that said that there were notable omissions, the ads had a political tone, and overstated the new drug law benefits? You dismiss those as not being meritorious in this case?

Ms. MCMULLAN. I would never dismiss any good advice that we get from anyone. In looking at what they had to say, we take all of that into consideration in moving forward. But I would just note, in providing a 30-second ad, we have to limit the number of messages just because of the time. And we want to make sure that people understand what they are getting.

Senator LAUTENBERG. But that does not mean that you would change the facts.

Ms. MCMULLAN. We do not change the facts. They are fact-based.

Senator LAUTENBERG. Then what is the 30-second relevance, in terms of when I say over——

Ms. MCMULLAN. Well, when you mention that there are significant omissions, it is hard to include a complete analysis of anything in a 30-second ad, so we target it to just a few facts.

Senator LAUTENBERG. How about overstating the benefits and the political tone? Will those ads in the future say produced by the CMS and so forth? Should that legend be on there, do you think at all? Or is it appropriate to just have this out there and let us say pretend that it is a news story? Because it is not basically a news story.

Ms. MCMULLAN. You have two different issues here. One is that the ads are always attributed to the Department of Health and Human Services.

Senator LAUTENBERG. This was not.

Ms. MCMULLAN. The television ads. The video news release is much like a press release. The video news release, when we send it out, we send it out from the Department of Health and Human Services. So it is attributed to the Department of Health and Human Services when it goes out to the new stations, just like the press releases and fact sheet include our information.

What news stations choose to use is at their discretion, just like a newspaper reporter would not necessarily attribute a paragraph in a news story to a fact sheet that he gets from Health and Human Services. So it is much more akin to a press release than it is to the television advertisement, which on the television ads we do include an attribution.

Senator LAUTENBERG. How do you differentiate, who makes the decision that this one is supposed to create the impression that it is a news release, that it is a discovery by the reporter or the station? As opposed to an ad? Why was this not an ad? Because to me it looks like one.

Ms. MCMULLAN. For the ads, we buy time on television to present them to the public. The VNRs we produce and send out to the news stations and they make the choice as to whether they use any of it or not. We do not pay for the release of that information.

Senator LAUTENBERG. Did any other networks, the larger stations, use this, that you are aware of?

Ms. MCMULLAN. I do not know but I will be happy to provide that for the record.

INFORMATION PROVIDED FOR THE RECORD FOLLOWS:

The VNR was not aired on national network newscasts but was aired only by local affiliate stations of all four major networks (ABC, NBC, CBS and Fox), as well as Telemundo and some independent stations.

Senator LAUTENBERG. We did some checking because we take heed to what GAO said.

The VNR did not go out from CMS. It went out from HHS public relations firm, a professional firm. So there was no ID on the videos as to the source from whence they came.

And to me, Ms. McMullan, as we discuss this I am more convinced than ever that there was something out there that was deceptive, misleading and ought to be reviewed very seriously by CMS and by HHS.

And I am going to go further with this and see if we cannot insist that all of these carry the legend that this is sent out by either CMS or HHS to make sure that people understand that this is not just some news story that you go ahead and run, because it is misleading in character.

Mr. Chairman, what is your preference on time?

Senator VOINOVICH. I would like to ask some questions and then return to you.

Senator LAUTENBERG. Thank you.

Senator VOINOVICH. I would just like to comment, this is not the purpose of this hearing. But let me clarify.

The ad that we have seen was sent out as a news release, a television news release. When it was sent to the stations, they knew that it came from CMS and HHS; is that correct?

Ms. MCMULLAN. Yes.

Senator VOINOVICH. The point you were making is when they got it, stations could use the whole thing or a snippet of it. It was their decision to make, in terms of what they were going to use; is that right.

Ms. MCMULLAN. Correct.

Senator VOINOVICH. Sometimes I sent a news release out when I was governor. We would do a TV spot, put it together, and send it to the stations. And most of the time they did not use it but sometimes they did. But rarely did they ever run the whole piece. They just took parts of it. OK, that is one thing.

The other thing, you are guaranteeing to us that for any 30-second commercial that you paid for will notify everyone that it has been paid for by the Department or the government, so that there is no question about where it is coming from; is that correct?

Ms. MCMULLAN. Yes.

Senator VOINOVICH. OK, clear.

One of the things I am really worried about is the advertising of the 1–800–Medicare number. I had a little experience last night. I called the company that takes care of my drugs with a question about whether one drug that I was getting was cheaper or more expensive than another one that supposedly is the same thing.

I am writing to the president of this company. I waited for 15 minutes before I got a pharmacist, 15 minutes. And then, when I got the pharmacist, I could not understand the pharmacist.

I do not know where this person was, but I was really upset. Finally, after 5 or 6 minutes, I got what I needed, but it was unbelievable.

What testing have you done on the 1–800 number? How much time are you going to be giving the individuals that are making the call? And the people answering going to be U.S. citizens, who can enunciate their words? And I have nothing wrong with accents. My grandmother and grandfather on both sides, they learned to speak English.

My concern is that you are dealing with senior citizens. You must have people answering questions that have good diction, understand callers, and can communicate.

How much testing have you done on this 1–800–Medicare number. Once people start calling that number, if they are not happy with it, they are calling my office. They are going to call Senator Lautenberg's office. They are going to call our Department of Aging in Ohio.

So I would like to know, what testing have you done to make sure that thing really works.

Ms. MCMULLAN. At our 1–800–Medicare number, we have increased the number of customer service representatives from 352 to 1,400 people. To answer your question about volume, will we be able to handle the volume.

They are scripted with answers to questions that we carefully develop and test with both the customer service representatives and with Medicare beneficiaries.

We also provide a quality assurance activity within the call centers where their managers listen in on the calls to make sure that people are following the direction carefully and answering the questions with the right kind of consideration to the caller.

We have another tool that we use where we can offline watch the calls being answered and how people are navigating through the scripts to make sure that they are using the right answers to the scripts.

And we also have something called mystery shopping where we have contractors who call, ask questions as if they are a Medicare beneficiary, and tell us whether or not they are getting the appropriate answers in return.

Senator VOINOVICH. How long have you had the 1,400 people on? Are they all hired?

Ms. MCMULLAN. They are being hired and will all be available by May. So they are being hired and trained now.

Senator VOINOVICH. But people are already calling 1–800–Medicare.

Ms. MCMULLAN. And we are able to answer the questions now. The people there are being trained and scripted as we speak. So as we started with the marketing and advertising campaigns, we had the ability to answer those calls.

The calls are answered within a very short wait time, almost immediately. If there is a period of the day when there is a heavy call volume and they have to wait more that 2 minutes, we let them know that they can either wait or call back another time when there is less volume. But no one waits 15 minutes.

Our call center is operated 24 hours a day, 7 days a week with English and Spanish speaking customer service representatives. And all of the call centers are in the continental United States.

Senator VOINOVICH. Good. Senator Lautenberg.

Senator LAUTENBERG. Thanks again, Mr. Chairman.

Ms. McMullan, is Homefront Communications a division of government, do you know?

Ms. MCMULLAN. Homefront Communication is one of our contractors who developed the VNR on our behalf.

Senator LAUTENBERG. You said that they would know that this came as a news release from CMS. But here is the script and it says the address for this is Homefront Communications at 1620 I Street, and the phone number is definitely not a government phone number.

So is this not a little deceptive to have this released as if it was fresh news without saying hey, this is put out by our Department in the interests of selling this program? Because it has a political bias to it that is, I think, almost impossible to challenge.

We have seen a few things, Ms. McMullan, that are disturbing. You know the claim that there will be a $35 premium for the Medicare drug plan. It is only an estimate of what the actual premiums are going to be in 2006. And you know what happens with estimates, invariably they go up. The CMS materials give the misleading impression that the premium will be about $35 when, in reality, it could be substantially higher.

Would you stake your family farm on the fact that this is a $35 charge and nothing more?

Ms. MCMULLAN. Like many things we estimate prospectively what we anticipate it will be and that is our current estimate. That is our best knowledge at this time.

Senator LAUTENBERG. How long do you think the $35 premium will last, Ms. McMullan?

Ms. MCMULLAN. I do not know. I do not know what our analysis showed as far as how long we thought that would be $35. The estimates are done by people who do these kinds of estimates all of the time based on the information that they have. So I expect that they do the best that they can.

Senator LAUTENBERG. Do you know what the cost of this new program will take over the next 10 years? How much it will cost to do, to put this program into place?

Ms. MCMULLAN. Those estimates are available. I do not know them off the top of my head, I am sorry.

Senator LAUTENBERG. Do you recall the number $400 billion over a 10-year period?

Ms. MCMULLAN. The CBO estimate was close to that, $395 billion was the CBO estimate.

Senator LAUTENBERG. Are you aware of the contest that emerged with a re-estimate of that by Mr. Foster, whose name I am sure you have heard, suggesting that it might be 30 percent higher than was originally, 30 or 40 percent than originally estimated? You are aware that there was a challenge to that?

Ms. MCMULLAN. I am aware that the CMS actuaries had a different estimate based on a different set of assumptions that went into those estimates.

Senator LAUTENBERG. But you are satisfied that the $35 is an estimate that we can live with?

You are aware of the flyer, familiar with the flyer that was sent out, that was prepared for mailing, 36 million, I think, of these pieces; am I correct?

Ms. MCMULLAN. It was mailed to every Medicare beneficiary household, which is about 36 million.

Senator LAUTENBERG. When this was examined, we challenged the section called News for All Americans that talked about starting immediately so Americans would be able to set aside money, in the health savings accounts.

This was stricken from the later production because it was challenged. The GAO looked at this. Are you aware that there was a section removed in this?

Ms. MCMULLAN. Yes.

Senator LAUTENBERG. So was that a mistake or was that as a result, if I may suggest, that this was kind of a knuckle rap by GAO and some review of this?

Ms. MCMULLAN. In the initial development of the flyer, we were responding to the fact that we were getting lots of inquiries from people with Medicare trying to understand what was in the new Medicare Modernization Act. The health savings account information is in the Medicare Modernization Act. So in developing the first version of it we thought that we should explain that important attribute.

Since people with Medicare can, before they become Medicare eligible, have an HSA we thought we should explain it. However, you

are right. Once you are Medicare aged, you can apply for a Medicare savings account but not an HSA. So upon further review, we decided that we needed to remove it.

Senator LAUTENBERG. Thank you, very much.

Senator VOINOVICH. One of the questions that I had was the same as Senator Lautenberg, in terms of the cost. And I had it explained to me by the Secretary.

CBO still claims it is going to cost $395 billion over 10 years. It is OMB that came back and said that it is going to cost, I think, $530 billion or $540 billion, a substantial increase from the $395 billion.

It is my understanding that the difference is the estimate of how many people will take advantage of Part D. And I think CBO based their estimate on the percentage of people that are currently taking advantage of Part B of Medicare. Do you know what that percentage is?

Ms. MCMULLAN. It is about 90 percent.

Senator VOINOVICH. It is my understanding that when OMB looked at it they said that they thought a larger percentage. In other words, when CBO did its analysis, it said 90 percent participate in Part B. I think the Secretary gave me a larger number. Are you sure that number is right, 90 percent for Part B?

Ms. MCMULLAN. We are pretty sure that that is correct, but we will also provide that for the record if it is not.

INFORMATION PROVIDED FOR THE RECORD FOLLOWS:

Generally, 91 percent of those beneficiaries eligible participate in Medicare Part B. We assume that about 94 percent of those eligible for Part D will choose to participate.

Senator VOINOVICH. If you could do that.

But the fact is that there is a difference of opinion about how many people are going to take advantage of this Part D that will be offered to them in 2006. And that is the reason why we have different numbers. But CBO, at this stage of the game, has not backed off the $395 billion and there is a difference.

Quite frankly, if we are being honest about it, we are not really sure. It may be between $395 billion and $540 billion. Hopefully, it is not going to be more than $540 billion, but only time will tell because we just do not know how many people are going to take advantage of the program.

In line with having people take advantage of the program, you are going to have a Web site; is that correct?

Ms. MCMULLAN. Yes.

Senator VOINOVICH. One of my concerns is that you have a lot of vulnerable people out there. The ones that I am really concerned about in this country are the least of our brothers and sisters, the people who today are poor and are unable to buy prescription drugs or, in the alternative, buy them and ration them.

One of the things that this program is aimed at is that vast number of people, particularly those under 150 percent of poverty. They are most vulnerable people in this country today because they do not have prescription drug benefits.

How can somebody that is in this vulnerable position, that does not have a computer, or maybe like this Senator, is not computer

literate—thank god that my wife is—going to get the information so they can intelligently decide which card they should receive? What efforts are going to be made to help them take advantage of this program?

Ms. MCMULLAN. We are making a significant commitment to reach out to the low income population. We have several strategies that we are using. In fact, we have 700 people in Washington yesterday and for half a day today, that come from States and other organizations that assist people with Medicare, and understanding how to take advantage of the drug discount card program, particularly those people who qualify for the $600 credit. So we are training people, through this approach, with the conference.

We have put additional resources into our regional offices to work with State and local organizations to train additional community-based organizations to reach out to the low income population.

We have our State Health Insurance and Assistance programs which are grants to States that we have added money to so that they can also assist the low income individuals and find those opportunities to engage the low income population.

We are putting additional resources into establishing longer term partnerships with organizations that reach low income beneficiaries because that is also a very important aspect of Part D. So we have a significant amount of resources going to exactly the population that you are speaking about.

Additionally, anyone calling 1–800–Medicare can be walked through the Web site and helped to narrow the choices of drug cards that are available to them and also get additional information about other drug discount programs that may be available to them such as State pharmacy assistance programs in those States that offer those programs.

Senator VOINOVICH. I will close on this one comment. I have really worked with our governor and our Office on Aging and the Department of Insurance to expand OSHIIP. We started that aggressive program when I was governor. This has been very helpful and it seems to me that you ought to be encouraging the States to really go out and recruit more people in the OSHIIP program.

It seems to me that you ought to have an expert at every senior citizen club, every senior facility, living facility, so that there is somebody there that can help these individuals take advantage of it.

I just want to, for the record, say I had a staff member call 1–800–Medicare. For the record, there was approximately 90 seconds of recorded information. After that an agent picked up immediately. So far, so good, Ms. McMullan.

Senator Lautenberg.

Senator LAUTENBERG. That is better than you get from the telephone company if you call for a service call.

I would just ask one other thing, Ms. McMullan. I thank you for your cooperation and your patience in this, but we want to get to the bottom of it and we will be sending you additional questions for response to the record.

But the subject of the pharmacy assistance program was brought up. There is automatic enrollment for those who are presently in Medicare, in the discount drug program. Why are we prohibiting

the pharmacy assisted program beneficiaries from automatically being enrolled?

Ms. MCMULLAN. There is no automatic enrollment in the drug card. We have been working closely with the States that offer pharmacy assistance programs to look at the opportunities to allow automatic enrollment for their pharmacy assistance members, and we will do that. It is an interesting combination of both Federal issues and State law issues. But we have worked out a mechanism where we can provide the opportunity for automatic enrollment.

The one issue that we need to have, because it is stated in the rules around the drug card, is that we have to have a signature. So we are working with those programs to offer their members to make sure that they understand that they are being enrolled in this benefit. But we will allow the States that have pharmacy assistance programs to automatically enroll, given the fact they ask for a signature of those members.

Senator LAUTENBERG. Thanks, Mr. Chairman. Thank you again, Ms. McMullan.

Senator VOINOVICH. Ms. McMullan, I have several other questions I would like to ask you, but I am going to submit them to you in writing and would appreciate your responding to me in regard to those questions.

You have been very gracious to come here this morning. We really appreciate your testimony. You have a very formidable task ahead of you. I have been involved in implementing programs, and god bless.

Ms. MCMULLAN. Thank you.

Senator VOINOVICH. I would now like to call Gail Wilensky and Nancy-Ann Min DeParle to come forward.

As I mentioned earlier, Ms. Wilensky and Ms. DeParle are former administrators of HCFA, CMS's predecessor. I look forward to hearing what they believe are the major challenges facing CMS as the agency moves forward with this benefit.

Ms. Wilensky, if you could start. Again, I really am grateful that the two of you are here today and I am so glad that I was with you at the John F. Kennedy School of Government's 2-day health seminar. Had I not been there and heard from you, we would not be having this hearing, and I would not have been on the phone and working so aggressively to make sure that Mr. McClellan was confirmed to take Mr. Scully's position. A lack of leadership by CMS at this time would have been a disaster.

Ms. Wilensky.

TESTIMONY OF GAIL R. WILENSKY, Ph.D.,[1] SENIOR FELLOW, PROJECT HOPE

Ms. WILENSKY. I agree with your assessment. I believe the people running the January meeting, sponsored by the Commonwealth Fund and the Kennedy School, should feel this is a signal of the success of that meeting. And Senator Lautenberg, I hope sometime you will join us, as well. It is open to all Members of Congress.

Mr. Chairman, Members of the Subcommittee, thank you for inviting me to appear before you.

[1] The prepared statement of Ms. Wilensky appears in the Appendix on page 58.

I am currently a Senior Fellow at Project Hope, an international health education foundation. As you have indicated, I am a former administrator of the Health Care Financing Administration from 1990 to 1992.

I also served as the first chair of the Medicare Payment Advisory Commission, MedPAC, from 1997 to 2001, and chaired the Physician Payment Review Commission from 1995 to 1997.

I say that because it has given me a very broad perspective of issues both from an operational and administrative point of view, running the program but also advising the Congress on issues of payment and change.

Additionally, I have spent 8½ years in the Federal Government as a senior researcher and career staff person and that allows me to have a somewhat better understanding of the issues that career people have faced.

What I would like to do is review some of the challenges that I believe are present with regard to the regulation and implementation phase of the Medicare prescription drug program, to consider the adequacy of resources available, and also to provide some suggestions about how Congress might be helpful.

Before I start, I would like to make a comment in regard to a statement Senator Lautenberg had made about the timing, because I agree with the statement you made earlier, that having the full drug benefit occur January 2006 is going to require a Herculean task. I appreciate the assessment from somebody who has had a very successful career in the private sector in the computer industry that it seems like a long time to get a new benefit implemented.

But the computer industry and the rest of corporate America do not have to go through the APA process. It truly is not just a question of making the decisions and of implementing them. Although there are many discussions to be made, I am just going to hint at some of them. Nancy-Ann DeParle, because she was present to implement the Balanced Budget Act, can give you more of them.

But I have had the experience of having controversial regulations have to go through the APA process, including the process of proposing the regulation, of putting it out for comment, of having hearings and dealing with comments, particularly for controversial regulations. And some aspects of the regulations included in this bill will indeed be controversial, either with the provider community, industry or with senior citizens.

That process, along with the decisions and the implementation, will in my mind make 2006 a very difficult date to meet, although one that I think is possible.

It is not just the series of benefit changes. Although these will also be challenging. We have, as one of the specific challenges, the provision of a new benefit, the Part D benefit, using a new delivery system or, if it is not done as Part D benefit directly, it will be done as part of the Medicare Advantage program.

Initially these are just payment increases, but by 2006 there also are a number of specific new issues involved in the Medicare Advantage program in terms of bids, regions, appeals processes, etc., that will also have to occur for the Medicare Advantage program to hit full force in 2006.

There are, in addition, a series of changes to the outpatient drug program that is currently covered under Part B. I am just going to mention them briefly, as well as the usual host of payment changes and adjustments and modifications to all of the other Medicare providers.

I thought I understood the Medicare payment system rather well after spending 2½ years at HCFA, but I was constantly astounded at PPRC and MedPAC about the enormity of the changes and detail that is involved in the Medicare program. I had not, when I was at HCFA, focused on post-acute care in the way that MedPAC and the Congress has focused on what goes on in both home care and long-term care.

Let me just remind the Senators about a few of the issues that will need to get taken care of regarding Part B drug coverage. Then I would like to comment about the early results of implementation. And more importantly, I have a few suggestions to make about how to proceed over the next period that I hope you will find useful.

With regard to Part B drugs, and I am assuming that Nancy-Ann DeParle is going to comment more on some of the Part D drug issues as she did down in Florida, at the Kennedy School/Commonwealth meeting.

But let me remind you, while all the effort is being directed for the introduction of the drug discount card, which appears to be going well, and the Part D benefit for January 2006, Part B drugs will continue as Part B drugs at least for now. These are the drugs, outpatient drugs, mostly chemotherapy or other related drugs, that have to be provided by a physician and have previously been covered by Medicare.

Up until now, the reimbursement mechanism has been a percentage of the average wholesale price or AWP. The Congress has noted, the GAO has noted, the IG has noted that average wholesale price is not a very satisfactory measure to use. Initially reimbursement will be a lower percentage of AWP. But starting in 2005 the basis will be average selling price, a different measure that will become the basis of reimbursing Part B drugs.

And then, in 2006, physicians will have the choice either of continuing with the ASP or going to a competitive acquisition process, a very different process, one that they may or may not choose. We will have to see what happens.

In order to have that in place for 2006, a lot of decisions will have to be made and regulations issued about the competitive acquisition process. The number of regions, the kind of appeals process, what happens if there are not two contractors, etc. And it will have to be done by 2005 so that it can be in place for 2006.

None of this is impossible. It is just a lot of work, given all of the work that will be going on to get the Part D benefit to start in January 2006.

Early results are looking good. The regulations about the discount card got out in December. Of course, we need to remember this was a strategy or a plan that the program, that the Administration had been thinking about for at least 2 years. So in some ways it is not surprising that they could respond so quickly. There appear to be a large number of sponsors. There appears to be good response in terms of trying to make the adjustment from the State

pharmacy assistance programs for low income populations, as you mentioned and as Ms. McMullan mentioned, to the low income support program. It appears to be going well and those are good signs.

The fact that Mark McClellan was able to be confirmed within one quarter, one calendar quarter, from the time that his predecessor left is something I do not remember ever happening. I applaud the Senate for helping that to occur so rapidly. It would have been very bad to have had a leaderless CMS during this period. Not that the acting people are not capable, but for all the reasons that you need to have presidential appointees in place to lead their agencies, to deal with the Congress, to make decisionmaking, it would have been an awful time to have not had a leader in place. I am astounded it happened so quickly.

The Congress also wisely recognized the burden that was being put on the agency by making $1 billion available from the trust fund through September 2005, and $500 million available to Social Security. That is the good news.

Let me give you a few thoughts about what I think might help to have this all happen. First, recognize the Herculean task that has been put on CMS' plate.

Second, remember that if the Congress chooses to make any significant changes to the legislation between now and January 2006 that affect the decisionmaking, the implementation or the rulemaking process, this will seriously jeopardize the ability of the agency to meet the January 2006 deadline, which really is October 2005. That is when the materials have to be out to the seniors so they can enroll in November 2005.

You are, of course, entitled to make those changes as you wish. It is just important to make sure the consequences are known.

The third is that it may be useful for relevant Congressional committees to have occasional briefings on the progress that is being made to implement the legislation. It should not occur too frequently or it will become another burden to the agency. But if there is a problem either in the way the legislation is written or in the adequacy of CMS funding, knowing sooner rather than later would improve the likelihood of a successful resolution to the problem.

I had a problem with legislative language, implementing the relative value scale for physician payment. It caused a lot of internal frustration and some time could have been saved perhaps if that had been vetted with the Congress.

I would consider, if there is a problem, allowing the agency to use temporary hires, such as IPAs from other parts of government or universities, and other flexible hiring strategies in order to try to help solve what may be a temporary problem with a temporary solution.

It will be very difficult to hire people who have experience in rulemaking. If you can have them come in in a temporary way, that would help.

The agency will need more people with private sector experience than they have had. I assume that should be relatively easier to find. I do not know whether the salaries will be competitive.

Finding people who know how to write rules for Medicare, rules from any regulatory agency, and to work the process is difficult to find. It is not a skill you need in the private sector.

CMS and HCFA have had a long history of having a disconnect between funding and the responsibilities that are given the agency. This disconnect was recognized in an open bipartisan letter that was published in Health Affairs several years ago. I was a signatory to it. There are a number of individuals who have been both directly involved and who worked for the Congress, Republicans and Democrats, as well as public policy analysts who signed this letter. It was reaffirmed in a MedPAC report while I was chair to the Congress, just reminding the Congress that either it needs to make sure there are adequate resources to match the increasing responsibilities that it puts on the agency or the Congress should turn to other agencies that it is more willing to fund.

It is in this vein that I commend the $1 billion that was made available.

And finally, the new CMS Administrator Dr. McClellan will have his own vision of how the agency can best function to meet the needs of the people that receive its benefits, the providers that provide the services, and of course the taxpayers that fund these services. Congress should pay serious attention to what he thinks needs to be done in order to have this new legislation implemented on time.

Thank you for inviting me and I would be glad to answer any questions.

Senator VOINOVICH. Thank you very much. We really appreciate your testimony. Ms. DeParle.

TESTIMONY OF NANCY-ANN MIN DePARLE,[1] SENIOR ADVISOR, J.P. MORGAN PARTNERS, LLC

Ms. DEPARLE. Thank you, Chairman Voinovich, Senator Durbin, and Members of the Subcommittee.

As you know, I served as the Administrator of the predecessor agency to CMS, HCFA, from 1997 to 2000. It was my honor to work with many of you on the Subcommittee and I appreciate your having this hearing today to focus on the real management challenges that I think face the agency as it undertakes probably its biggest mission ever, which is to provide a prescription drug benefit to some 42 million beneficiaries.

I want to begin by noting that Michael McMullan, who testified here on behalf of the agency this morning, is one of the finest public servants that I have ever had the honor of working with.

In fact, Senator Voinovich, you referenced the meeting in Florida, the Kennedy School meeting at which Dr. Wilensky and I talked about CMS. And I think you asked a question there about whether I thought CMS could get the Medicare prescription drug benefit implemented by January 2006. And I answered you, in part, by saying there is one person that I have in mind. And if she is there, and if she is allowed the flexibility to get the job done, I think that it can be done.

[1] The prepared statement of Ms. DeParle appears in the Appendix on page 70.

Michael McMullan was the person I had in mind. She has, as you heard, served at the agency for 30 years and is a tremendous asset to the government. I want to thank her for everything she did while I was there.

So I do think that CMS can get the job done but I also think that there are some significant execution risks. And there are some particular things that this Subcommittee can help CMS with.

I think, if you look back at the record of the past few years, you will see a couple of things. One is that the agency Dr. Wilensky just alluded to, has been asked over a decade or more to do more and more with less and less, fewer and fewer people, fewer and fewer resources. That is something that has to change or we are going to be facing some real near-term problems as both we try to implement this prescription drug benefit and CMS tries to do all the other things that it needs to do to improve the health care services that we are offering to millions of Americans.

I think the record shows, though, that when CMS has a major project and it has adequate resources and flexibility, focused and stable leadership, and the support of Congress that it can get the job done. In my written testimony I gave you a number of examples of where I think the agency has been successful there.

Let me focus this morning, though, just on the execution risks because I know you have a tight agenda. The first risk I think that exists is one that I would characterize as a leadership risk. When we were in Florida I spoke about my concern that the agency was left without an administrator who had been confirmed as soon as the bill was signed. A number of other key political appointees had left as well. And the agency does not have that much depth in terms of political leadership. It is a relatively small agency.

As Dr. Wilensky said, the career people are terrific. They are focused. But you need a clear point of view, you need a leader who can be depended on. For the first few months of the implementation of this drug bill they did not have one. That is beginning to be corrected with Dr. McClellan having been sworn in a week or so ago.

I think there is still some risk around this, though, because, as I pointed out in Florida, Secretary Thompson said more than a year ago that he would be leaving HHS soon after the election. He has confirmed that recently, saying that he would not be there for the launch of the prescription drug benefit in January 2006.

So given the difficulty of working within the Department of Health and Human Services just to get regulations issued and things like that, I do think there is a political instability that should continue to be focused on.

But the more troubling concern that I have about leadership is one that is, in some ways, highlighted by Michael McMullan's presence here today. As I pointed out to you, I looked back at my redimentary list of the senior staff when I was there. There are a number of ways you can look at this, but I looked at the Senior Executive Service (SES), the most senior career folks in the agency, the real leadership that you depend on. And there has been a real brain drain of those people over the past few years.

In the Spring of 2001 there were 43 SES staff members. Since that time more than half of those people have left the agency.

These are people who were working shoulder to shoulder with Michael McMullan. These are presidential rank award winners. These are people who I depended on when I was implementing the Balanced Budget Act.

It is an unprecedented loss. You highlighted, Chairman Voinovich, some of the additional losses that we may be facing in the future. And I think that is something for this Subcommittee to really grapple with as you look at the importance of these programs and the unfortunate timing of the departures of these staff. Because I would not have wanted to be trying to do this without them.

The administrative complexity is the other big execution risk.

Senator VOINOVICH. To clarify for Senator Durbin, the number I used was 30 percent of the Senior Executive Service currently are eligible to retire. So they could walk out the door tomorrow.

Ms. DEPARLE. That is on top of the more than half who have left since the Spring of 2001. As I said, these are the people with the experience, the knowledge, and the history to get the job done. And that is what concerns me.

But to talk about the other execution risk, that is, I think, administrative complexity. Dr. Wilensky alluded to that in her testimony, as well.

The BBA, which we went through together, as you all know, was complex and contentious. We had to design new payment systems for virtually every provider. Virtually every hospital and doctor in the country, as well as almost every other health care provider, had their reimbursements cut. I think I heard from just about every one of them. I know all of you did and you told me about them. So it was a very difficult and contentious period.

That said, in the BBA, CMS was dealing with a familiar set of providers and a familiar benefit. And we knew a lot of the providers. We knew the trade associations. We kind of had an established process of working with them.

The difference here, and I think Michael McMullan talked about this, this morning, is that the Medicare prescription drug benefit poses a different kind of a challenge because CMS is being asked to build a whole new delivery system for a product it has never offered before with a whole new set of partners that it has never worked with before. Now it is getting some experience with those partners, with some of them, with the prescription drug cards that it is doing now. But the fact remains that CMS needs not only human capital but, along with that, intellectual capital around things like how to manage prescription drugs in a smart way.

And frankly, the severe time constraints that are built into the law pose a really huge execution risk. We have already had some discussion about that this morning, but I agree with Dr. Wilensky that the notion that on January 1, 2006 your 4 million—how many beneficiaries are in Ohio? I do not even know exactly any more.

Senator VOINOVICH. We have 1.7 million.

Ms. DEPARLE. One-point-seven million Medicare beneficaries in Ohio are going to be expecting to have a prescription drug benefit available to them 20 months from today. And really I think even that is unrealistic when you think about what CMS has to get done in order to have the open enrollment as the law mandates start in

November 2005. Beneficiary education is supposed to start October 1, 2005.

Chairman Voinovich, you recalled our interaction over the beneficiary education campaign in the BBA, and one can wonder whether starting the beneficiary education campaign, as far as telling beneficiaries how much the premiums are going to be, what the drugs are going to be that are available in October, is really sufficient time to allow them to understand it without being confused.

But if you just stick to the deadlines in the law, CMS basically has 18 months to build a brand new delivery system. And I think that is going to be a big challenge, notwithstanding what Senator Lautenberg said about computer systems. In fact, I think computer systems are a big part of the issue. Michael McMullan talked about that, as well.

I attached to my testimony a very high-level, abstract list of the steps that CMS has got to take between now and basically November 1, 2005 to get open enrollment going. And Michael McMullan alluded to the list they have, and I am sure their list has much greater detail than what I put forward. But just looking at my list, I think you can get an idea that these are not easy little things you can just check off the box on.

For example, how is CMS going to design an information system to keep track of what each beneficiary spends on drugs? They have to be able to do that: To make the deductibles, the catastrophic limits that you put in the bill, the so-called "doughnut hole," to make all those details work, they have to be able to keep track of what beneficiaries are spending on drugs.

Now the law stipulates certain ways that the spending is to be counted. For example, spending in the "doughnut hole" is supposed to count. I apologize for using that terminology but that is what you all are familiar with, I think.

But it does not count if you buy drugs in the doughnut hole that are not on the formulary of the plan that you were in, even if your plan is not contributing during that time.

And it does not count if it is for a drug in the beginning if it was not on your plan's formulary. And if it is paid by a family member it can count, but if it is paid by a third party it cannot count.

All of those are things that we could sit here and write the rules for but then somebody has to program computers to keep track of that. I believe CMS will have to modify the massive database that it maintains what is known as the Common Working File, which is a repository of all the claims that come in on each beneficiary, in order to keep track of this.

That is not going to be a simple task and it is a high-risk task as well. I know this from my experience with Y2K, which you alluded to, Mr. Chairman. We were successful there in remediating all the computer systems but that was a terribly high-risk and difficult chore.

Senator VOINOVICH. Senator Durbin has to go to another meeting. Would you mind if he asked some questions here before he leaves?

Ms. DEPARLE. Of course not.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you very much. Thank you, Mr. Chairman, for that. Senator Pryor, thank you, as well.

I was happy to vote for Dr. McClellan because I have a lot of confidence in him. I think he has done a fine job at the FDA and I believe he has an extraordinary challenge here and I hope that he can meet that challenge, for his sake and for all the people who will depend on him.

I told him when I met with him that I think this whole program is fatally flawed. As you describe the complexity of this law, it was an effort to superimpose a new system of reimbursement instead of turning to the obvious. And that is using the Medicare system to create a prescription drug option for seniors. We decided we were going to invent something new. And we put in rules that are unintelligible to the senators and to the seniors. And now, this agency is going to have to try to make something intelligent out of them.

I bet there are not too many survivors, but it would be great some time to have some people who were in on the implementation of Medicare to come and explain to us how, before computers, they established a Medicare program for America 8 months after the bill passed and was signed by the President. How did that happen? Miracle of miracles.

Well, it could have been that the concept, as big as it was, was very basic and simple in its approach. We have, instead, taken off on an opposite course. We have built into this so much complexity and we have given a 2-year opportunity to implement it.

And when I read statements by Mr. Scully, they really relate to, I think, the reason for this hearing and the passion of Senator Voinovich here. Mr. Scully said, in January of this year to a group, and I will read this from the Pink Sheet, which is probably the best place to turn. It is the Prescription Pharmaceuticals and Biotechnology Newsletter. Here is what they said: CMS itself has "no idea how they are going to do it, he declared. They do not have a staff so they are probably looking to quit like I did, he joked." And then he goes on to say, "Congress gave them about $1 billion in new funding to hire more people but there is going to be complete chaos in this whole area brought in from the outside world and at CMS in the next couple of years."

He went on to say, when he was asked about how they were going to deal with coverage decisions, which you have just referred to "this is something CMS has no clue how to do, by the way. It is completely new for them and they are not particularly well set up to do it."

Thank you, Mr. Scully, for your observations. So a law that I think is fundamentally flawed and extremely complex and has avoided the obvious of using Medicare to deliver a prescription drug benefit, is now going to be implemented by an agency that Mr. Scully announced in his sayonara is totally unprepared for the job. Well, there is good news for America. Anything more we can tell them, in terms of what we are doing to help them here?

Ms. DeParle, what you have said here, when you start describing how to deal with the computer program, you can imagine how much fun it is for me to stand in front of a group of seniors and

explain how this is going to work in their real lives. And Ms. Wilensky, there is an assumption in your testimony and others that all seniors are going to sign up for this. We have to at least prepare for that eventuality.

I think there is more skepticism out there at this point, when you are told you cannot buy a Medigap policy and the like. And the skepticism is built on this same complexity.

I guess the horse is out of the barn here, but do you conclude as I do that we have created the mess that we now find ourselves in with this legislation?

Ms. WILENSKY. It is a complex program, there is no question. Let me try to guess at the answer as to how did it happened in 1965? The original Medicare looked exactly like BlueCross BlueShield, which was the predominant financing system in the private sector. It is an interesting question about how did they pull it off. My guess is the government made Medicare look like what everybody else had.

The problems of turning to Medicare, and this is clearly a discussion for a different committee, and putting the drug benefit in traditional Medicare had to do with whether having Medicare use its usual administered pricing was the best way to provide this new drug. This has been subject to a lot of controversy in the Clinton Administration and in the current Bush Administration. I believe it was the majority consensus that that was not going to happen.

The question of whether this is the right answer, whether it is workable, is something else. I think it can be done but it is a complex issue.

Senator DURBIN. But you have admonished—admonished is not the right word. You have warned us, make any changes here and all bets are off. And I am sitting back here and saying well first, I did not vote for it because I thought it was not fair. I thought the pharmaceutical companies made out like bandits in this deal. I do not think it really was designed for seniors as it should have been.

Now to step back and kind of be forewarned any changes are going to delay implementation and complement it, that I think on its face is obvious. Any changes have to be assimilated into the program and its administration.

But it strikes me that if there is a way to cut through the complexity of this, to get down to something that is just basic that you can understand and explain it to the average person, that is going to help us in setting up computer programs and appointing people to administer them.

So I may not follow your warning about changes. I think honestly a few changes might be for to benefit of the program we need to make it more reasonably understood and easily administered.

Ms. WILENSKY. Solve some problems and create others. And obviously that is your job as members of the Congress to decide.

Ms. DEPARLE. The one I talked about, in particular, the problem of keeping track of beneficiary spending, if you could fill in the doughnut hole, that might help you some there. But the problem is that would cost hundreds of billions of dollars, I suppose, which is why it is there to begin with.

Senator DURBIN. If you are not negotiating with the pharmaceutical companies to keep prices under control, then frankly the costs are going to outstrip the resources of this program is such a short period of time. But again, that gets down to the policy side of it.

But I really do go back to the original premise. We created Medicare in 8 months. We may have modeled it after BlueCross BlueShield. We were up and running and rolling in 8 months after the bill was signed into law.

Now with a 2-year timeframe, people are in a genuine panic in this town as to whether or not this can happen. I think it reflects on the fact that we made this too complicated. It should have been more straightforward.

Ms. DEPARLE. That is part of it. And also, the Administrative Procedure Act and the rulemaking requirements are much more onerous now than they used to be. But I do not think you have any disagreement here that this is very complex.

Senator DURBIN. Ah, for the good old days.

Mr. Chairman, with your permission, I would ask my full opening statement be included in the record.

Senator VOINOVICH. Without objection.

Senator DURBIN. Thank you.

[The prepared opening statement of Senator Durbin follows:]

PREPARED OPENING STATEMENT OF SENATOR DURBIN

The Center for Medicare and Medicaid Services (CMS) has a monumental task ahead. The Balanced Budget Act of 1997 was a complex bill that forced the agency to go in directions it had never gone before, but BBA pales in comparison to this new Medicare bill.

In the next 20 months, CMS will have to not only figure out exactly how this bill is going to work at a practical level, it will also have to set up complex new administrative systems and ensure seniors know how to get their benefits.

Seemingly, the most challenging part, from a management perspective, is the constantly changing environment the bill creates. Prescription drug plans can drop in and out of the program, as can PPOs; drugs can drop on and off formularies; drug prices can rise at unpredictable levels; and seniors can rise above or drop below eligibility levels for low-income benefits and means-testing limits. These are only a few of the fluctuating parts of the bill that will make CMS's job hard and confuse seniors.

Take the drug discount card, which should be the simplest part of the bill. However, even it is complex at the management level and confusing at the senior level. Different drug cards will offer different discounts for people on different drugs at different pharmacies in different locations for different fees. The volume of calls CMS will get from confused citizens will probably rival any previous piece of major social legislation.

While CMS is answering questions from seniors, it will also have to monitor pharmacy benefit managers, pharmacists and Prescription Drug Plans to make sure the savings garnered from drug manufacturers are being passed to the seniors. CMS will have to ensure there is appropriate management of the $600 each low-income senior will receive; ensure people are not being disenrolled; ensure there is pharmacy network access where it is supposed to be, guarantee beneficiary privacy is being protected, and make certain enrollment fees do not exceed $30.

CMS will also need to monitor drug prices on a weekly basis to identify drug discount card programs that are deviating from "expected changes" in drug prices.

These are no small tasks, and my list is not even fully comprehensive. This Committee appreciates the job you have ahead of you and wants to make sure you have the resources to do it. The seniors of America are depending on it.

Senator VOINOVICH. Before we go to Senator Pryor, have you finished your testimony? Would you like a few more minutes?

Ms. DEPARLE. I had a couple of more points to make. May I?

Senator VOINOVICH. Sure, go ahead.

Ms. DEPARLE. I was talking about the difficulties of the computer system, so let me just go on to say that is just one example of a lot of high risk activities that CMS will have to undertake.

And as you pointed out, Mr. Chairman, if these things are not done perfectly all of you will be hearing about it. So it is not as though CMS can just do it quickly. They have to be very careful about how they do this. And they have to do it under the structures of the Administrative Procedure Act.

And my experience was, when I was there, we did a very simple, pretty straightforward rulemaking about modifying the conditions of participation for hospitals and got 50,000 comments. And there have been others that have gotten more comments than that.

And I cannot imagine that a drug bill that is going to involve $500 billion or so changing hands over the next 10 years is going to elicit few comments. I think it is going to be a massive number.

So the rulemaking is going to be very difficult here, too.

In the meantime, CMS has a lot of other challenges. Just finishing up the implementation of the other provisions of a MMA could be a full-time job. Dr. Wilensky talked about the AWP changes to the other Part B drugs. There are all sorts of other administrative changes, changing Medicare Plus Choice into Medicare Advantage. So just finishing up MMA could be a full-time job.

And then, in addition, they have to run all the other day-to-day things that go with managing the Medicare program. And then there is Medicaid and S–CHIP, which all of you care about as well, and which some of you do not think the agency is doing an adequate job with now. So all of that is on their plate.

I made three recommendations to this Subcommittee, the first of which was that you request that CMS provide you with an updated strategic plan, including a human capital plan of the sort that you talked about, Mr. Chairman, detailing what they are going to need to get this job done. And I recommend that you provide them with the resources.

The MMA took a step in the right direction in giving the agency $1 billion but it really did not say what the money was to be used for. And it disappears in September 2005. That really does not make sense. And so in the next budget, the Administration should tell you what it is going to need to really manage this benefit. And the Congress should look seriously at that request and try to help CMS here instead of asking it to do more and more with less and less.

There are also some gaps in their current budget. I mentioned the fact that it is my understanding that the OIG and the DOJ are facing layoffs in their program integrity efforts. It seems to me to be the wrong time to have that happening with Medicare spending getting up to almost $300 billion this year.

Senator VOINOVICH. Where did you say that was, what gaps?

Ms. DEPARLE. First of all, it is my understanding that the funding that the Congress gave to the Department of Justice and the Office of Inspector General under HIPAA, the Health Insurance Portability and Accountability Act, to do Medicare program integrity activities, that is now flat and that those programs are facing layoffs. That is my understanding.

And if that is the case, it seems to me to be the wrong time to be doing that when Medicare spending is supposed to increase to almost $300 billion this year, without a prescription drug benefit. We are introducing a whole new prescription drug benefit that, depending on whose estimates you believe, is going to cost at least $500 billion over the next 10 years. We need to pay attention to the program integrity side of this, as well.

In addition, the agency has been, for years, sort of robbing Peter to pay Paul to come up with its beneficiary education plans. It seems to me that needs to be a more serious plan that they work out with the Congress and where there is a specific appropriation for beneficiary education. And that has not been the case in the past.

Second, I would recommend that you give CMS more flexibility. I talk in my written testimony about personnel flexibility. They need to be able to bring back retirees. They need to be able to hire more high-level staff without FTE restrictions. I suggested to them that they might want to put together a SWAT team of some people with experience in writing regulations and things like that from other agencies.

Those kinds of things are what happened when the original Medicare was implemented back in the 1960's and I think they need to do some of those things now.

Finally, I would agree with Dr. Wilensky that the Congress needs to make sure that it allows CMS time to focus, that if you add new legislative mandates this year or next year on top of requiring the prescription drug benefit to be up and running January 1, 2006 you will probably not be able to get it done. So you need to understand that there are going to be some other things that will probably suffer in the next few months as they focus their time on the drug benefit.

Thank you, Mr. Chairman.

Senator VOINOVICH. Thank you very much. I am really grateful to the two of you for coming here today.

Senator Pryor, you came in late and I do not know what your schedule is, but I would invite you to ask some questions.

Senator PRYOR. I am OK. I want you to go first. I will go second. Thank you.

Senator VOINOVICH. Do you believe that we are going to be able to pull this off?

Ms. WILENSKY. It can happen. It will be hard.

I have thought about whether at some point it would be prudent to have a backup plan in case CMS is a quarter late. What happens if CMS is not really ready to have educational materials mailed out October 1 but could be ready by December 1? Is it possible to have the first year be a three-quarter year?

I would recommend, without having given it sufficient consideration, that that type of planning be put in place because it is easy to imagine the need arising. Controversial regulations are very difficult to deal with.

I had two during my tenure, CLIA and the proposed rule for the RBRVS, the reform payment for physicians. HCFA got 100,000 comments on RBRVS.

I do not know whether there is anything that is that controversial. A lot of comments are part of letter campaigns. But the agency, under the APA, has to respond in writing at the interim final rule with how it has dealt with each of the issues that have been raised. And that is difficult.

There are a lot of reasons that the timeframe is a very tight squeeze. Understanding what would be acceptable to the Congress and the Administration if the agency is a quarter behind schedule for the first year is very important.

Obviously, should the Congress choose to go in a completely different direction in terms of a drug benefit bill, that would stop the clock at that point. But I would assume until such time as that were to happen, the perception is this is the legislation you have, recognition that change really impedes its implementation, and have a backroom plan for what happens if CMS is a quarter late.

I recognize there are a lot of political issues about why that would be difficult to make public.

Senator VOINOVICH. Ms. DeParle.

Ms. DEPARLE. I agree. Yes, I think it can be done. But I would want to be working with the Congress on a contingency plan and I will tell you why.

I think Dr. Wilensky is right that the rulemaking on this will be very difficult. Just the amount of time that it takes to get a rule written, cleared through the Department, cleared through OMB, and then out on the streets and then to allow sufficient time for the public to comment is going to take a number of months.

But that is not even the thing that makes me the most concerned. It is more that this bidding process that has to occur for the prescription drug plans and the Medicare Advantage plans to say how much they are going to charge beneficiaries and what their drug plan is going to look like. All that has to be done by October 2005 so that if a beneficiary in Cleveland is thinking about signing up for this they will know here are the plans that are available to me. Here is how much each one of them would charge me in a premium. Here is how much my subsidy will be if I am a low-income person.

There is a lot of details that will have to be final when they get a piece of paper in the mail in October that says here is what you have. That is my concern, is getting all of those things finalized.

And also, if it is not done well, I am harking back to your concern about beneficiary education. The soft kind of beneficiary education that has been occurring so far that Senator Lautenberg highlighted, that is one thing. But when you get down to sending someone a piece of paper and telling them here is how much the premiums are under the plans you are looking at, you need to allow them some time to figure out, "OK, I take Lipitor. Is that on here? Can I get that?"

And I am just concerned that you want to do this right. That is very important, I think, to you and the Congress and to all of us. If I were at CMS, I would work with the Congress to design a contingency plan, as well.

Senator VOINOVICH. I want to clarify something. I go to meetings and I think I have had 9 or 10 meetings already in Ohio where I

have had listening sessions with senior citizens and get a chance to get some input from them. This is complicated stuff.

It seems to me that if it is going to work they are going to have to have the best information that they can have to make good decisions. We are going to need a whole lot of help. Governor Taft and I are going to go to an OSHIIP training session this month to find answers so that we are more sophisticated in terms of our interface with people. I also am bringing all of my regional representatives in so that they are better educated. But this is going to be a monumental undertaking in Ohio to make sure it gets done.

So the first thing you would do if you were in Dr. McClellan's place is to look at the big picture and determine what the reality is and then maybe come back with some suggestions on how to maybe do it better?

But one fact, and I want to clarify this, is that this is a monumental task. It is not something you can snap your fingers at and have it done. At some of my listening sessions seniors will ask me why they cannot have it now. I try to explain to them that there is a whole lot of work that has to be done before this program can be rolled out. I suspect also that there might be some consideration given to cascading implementation over a longer period of time. This would give the agency some experience with the program rather than just launching the rocket and not knowing if it will get off of the ground and what will happen when it does.

Ms. WILENSKY. Senator Voinovich, it would have been easier if the Congress had chosen to stagger the changes that came in place, for example, of not doing anything to the Part B drug coverage until 2006 and only then start to change Part B coverage. Or having fewer changes with regard to other parts of payments, for it to change to the rurals, changes to oncologist payments, which involve a lot of recalculations with regard to physician payments. I am not suggesting delaying these changes, either politically or at a policy level, would have been necessarily desirable.

It is the fact that these changes, each of which probably could have been accomplished and may well be accomplished during the relevant time period, are happening at the same time as Part D coverages is starting is what makes it so difficult. The Medicaid changes are also huge—neither of us have spoken about Medicaid but next week I am going to speak twice about it, so I have been thinking about what happens to the dual eligibles.

Many changes are required so that beneficiares are regarded as being seniors first and second, in terms of whether they are Medicare or Medicaid participants, plus all of the other Medicaid changes that are going on because of waivers and the children's health insurance program and all of the HIPAA changes. It is astounding how much one agency has going on, change in at least three different areas, only one of which is Medicare Advantage and Part D drugs.

That is the part most peole don't understand. I do not know if it will help you in responding to your seniors, as to why implementing the new benefit is so difficult and takes so long.

Of course, in 1965 we had a very narrow program, basically hospital and physician coverage, modeled to look like something that

was out there, BlueCross and BlueShield. The complexity of all that this agency does now, did not exist then.

Again, I am not willing to say it cannot be done. But it is important to understand how many moving parts there are, not just because the delivery mechanisms are complex but because so much is included in this one bill that impacts a single agency. That is ignoring all of the problems that have been raised about the unusual numbers of people who are retiring.

I had the advantage of thinking about this problem in the early 1990's. We could see what was going to happen over the next decade because of the age structure of the workforce, recognizing it was a significant problem on the horizon, and having the advantage of knowing it would be somebody else's problem.

Senator VOINOVICH. Thank you. Senator Pryor, thank you for coming today.

OPENING STATEMENT OF SENATOR PRYOR

Senator PRYOR. Thank you Mr. Chairman. Thank you.

Let me first ask a question based on my old job as Attorney General of the State of Arkansas. In my 4 years there, we had a number of incidents where scam artists would come to seniors and convince them to purchase fake drug cards. Then these unsuspecting seniors would purchase these cards and would take them down to the local pharmacy, to realize that the cards were worthless.

We also had another occurrence where legitimate companies were aggressively marketing drug cards. But when you actually took the drug cards to the pharmacist, they really did not live up to the senior's expectations. So now the Congress has passed into law and the President has signed a bill that will have a national drug card.

So my question for the two of you is, given potential for fraud and scams, etc., should CMS somehow begin educating the public to beware of bogus drug cards and how to recognize the real drug card? I would just like to get your thoughts on that.

Ms. DEPARLE. Yes. It is my understanding that there has been a spike in the incidents of the type you are describing where there have been perhaps some new shysters who are going door-to-door with what they are offering as cards and asking for payment for them. And I think the agency has put out an alert on that. But it may be that it will require something more aggressive either from CMS or the Justice Department.

Ms. WILENSKY. I have read that exact situation you are describing has indeed been happening. There has been an alert. There is a lot of money at stake here. That usually invites scam and fraud artists to join. It will be very important that while everything else is going forward that some attention is being paid to this issue so that you do not frustrate the seniors and bilk them of their funds and, of course, bilk the taxpayers as well.

Senator PRYOR. One thing, Mr. Chairman, that does concern me about this is a lot of times these scam artists and these folks who are going to rip seniors off and prey on the unsuspecting, a lot of times they will take some sort of event out there that sounds plausible and all of a sudden they come in and offer some sort of service.

We had that after 9/11 where people would come in and try to rip people off and say we are sending money to New York City, and they were not.

Unfortunately, you see these types of scams in many situations. I just see the potential right there so I am glad to hear that CMS is taking steps.

Let me also ask about something else that made a lot of news in the last few weeks and that is where Tom Scully, potentially, told one of his employees not to be candid with Congress. In my view it is extremely important that CMS, your former agency, is candid with Congress because we are the policymakers. We are going to pass this law. And now a lot of us feel like we did not receive accurate information as we were deliberating this.

Let me just ask, from your experience at HCFA, now CMS, are you aware of anything like this happening on your watch when you were there? When you told someone in the agency not to provide information to Congress? Are you aware of anything like that?

Ms. WILENSKY. I am not. I actually had a conversation about this with Guy King, who was the chief actuary for 16 years or so, including the period when I was there and during both President Carter and the Reagan/Bush Administration.

There does seem to be some change. He indicated it would have been very uncommon for the HCFA actuary to have had conversations with the Congress on new legislation unless they involved the Trust Fund. Otherwise that conversation normally would not have occurred.

There is a long history of CBO and HCFA actuaries having different estimates. And my experience has been that once CBO has made an estimate about the cost of new legislation Congress really did not care what administrations said because Congress basically follows its advisers, the CBO, and not the Administration. That is why the CBO was created.

But I am not aware of anybody either being directed or to not come forward with information or threatened if they did.

Ms. DEPARLE. I worked with the CMS actuary, Rick Foster, for 3 years when I was Administrator and it was an honor to work with him. And not only did I not ever instruct him not to give information to Congress or to be candid with Congress, in fact I urged him to speak directly with members of Congress whenever they needed information and not even to tell me what they asked. Because I do think there is a public interest in members of Congress having as complete and accurate information as they can have. Actuaries can be wrong. So can economists. But I think we, as citizens, have an interest in your having as much information as possible when you make your decisions.

Senator PRYOR. Thank you and I agree with you both on that.

Mr. Chairman, if I may, I would just like to ask one or two more questions. And that is a little bit of a follow up on Senator Durbin's question a few moments ago. He quoted an interview by Tom Scully. One of the things Mr. Scully said is that CMS is not going to be a passive payer anymore. CMS is going to be a market organizer.

I am interested if you have any thoughts on Mr. Scully's comment there that CMS's role has changed so much that it will now, under this bill, be a market organizer.

Ms. WILENSKY. Well, CMS follows administered pricing for the most part. That is set in statute. Medicare pays a price for individual physician services or hospital discharges or nursing days that is not negotiable. So to that extent, it has been passive.

But it has not been passive in a lot of other ways in terms of who is allowed to participate or determining quality and appropriateness. This mix of authorizing complicates what the agency can do. Prices are set, whether or not the service is being performed with different quality or even if it was medically appropriate.

I presume what Mr. Scully was referencing to is the bidding process that will go on both for Medicare Advantage and for the Part D private prescription drug plan participation. We will see whether or not there is enough participation to have very much competition.

I am a big supporter of the Federal Employees Health Care Plan which negotiates the prices and benefits that the plans offer.

I think it is a little early to predict a dramatic change for Medicare. The bidding process system is influencing only, at least at this point, a relatively small part of the Medicare program. If the CMS actuary is correct and there is substantial participation in the Medicare Advantage program, which is one of the reasons that there was such a big difference between CMS and CSO, the agency may become involved in price negotiations and become more of a market organizer.

But I would like to remind the Congress that both the actuary and CBO radically overestimated the participation of private plans in the Medicare Plus Choice program, and the actuary was even more bullish than CBO. So I think it is a little early to predict a major change in function for the agency.

The basic choice is either to do administered pricing or to rely on competitive purposes to moderate spending. This bill moves towards a bidding process and is why CBO has said that it would not score additional savings if administered pricing power was granted to CMS regarding Part D drugs.

Senator PRYOR. Do you have any comments on that?

Ms. DEPARLE. No, I am sitting here trying to guess what he means by that. I am not even really sure.

Senator PRYOR. Mr. Chairman, if I might ask one last question. Again, Mr. Scully in this interview said "You are going to find that most of the expertise to pull this off, this new Medicare drug benefit at CMS, lies on the Medicaid side of the agency. I can tell you, having run the place for 3 years, the relationship between the people who run Medicare and the people who run Medicaid is a little like the Serbs and the Croatians. They do not really talk to each other that much."

I am curious about your experience there with the Medicare side versus the Medicaid side and who, in the agency, has the expertise to administer this?

Ms. WILENSKY. The reason Medicaid would be more relevant, although not at the Federal level, is Medicaid covers prescription

drugs. So a lot of the issues that need to be dealt with are dealt with in Medicaid.

But the major role of the Federal Government in Medicaid is mostly oversight. Medicaid is basically a State program that has Federal oversight, very different from Medicare which clearly is a Federal program.

I disagree with the characterization of the people running Medicare and Medicaid. When I went to HCFA, I pulled the people out of Medicare who were working in both Medicare and Medicaid and created a center for Medicaid or Medicaid bureau because I was afraid Medicaid was getting short shrift by having the same people working in both areas, given that Medicare dominates everything that HCFA did. And it was a way to try to give more attention and focus to the people who did work in Medicaid.

But I am not aware, or do not believe, at least when I was there, that there was any friction or difficulties between the group working on these two programs.

Some of the issues in Part D will have to be helped by bringing in people from the private sector who have worked for PBMs. People who have worked for insurance companies that worked on the prescription drug side, could provide some private-sector expertise.

The fact is I do not think either Medicare or Medicaid provides the right expertise.

To the extent that you are using private prescription drug plans, however, it does not require the hands-on expertise that Medicare needs when it is trying to price out DRG 351 or which of all of the 9,000 CPT codes should get included in the RBRVS.

One of the advantages of having the kind of program structure that is in the legislation is Medicare actually is not responsible for individual price negotiation of individual drugs or their presence on a formulary. That is done by the plan. Medicare's major involvement is in determining the bidding process and the definition of geographical areas, and the appeals and the rights processes that are put in place.

So I am not even sure that private prescription drug experience you mentioned is needed.

Ms. DEPARLE. I agree. I would not characterize it that way, either. I did not see friction.

I think every administrator struggles with trying to balance the focus on the two programs. And frankly, I came out of the State of Tennessee where I had worked on Medicaid issues. And I think the agency's focus is, to some extent, reflective of the Administration's focus and the Congress' focus.

President Clinton was very interested in Medicaid so we spent quite a bit of time on it. But the fact is for every one letter I got from a member of Congress about Medicaid, I got 50 about Medicare. And perhaps that is somewhat symptomatic of the time I was there, because I was there during the Balanced Budget Act. And as we have discussed, every provider in the country was upset about getting their Medicare reimbursements cut.

So I found it was difficult to spend as much time on Medicaid as I would have liked. But I did not find the Serbs and Croatians.

What I think he is referring to is that there are two career staff in the Medicaid bureau who had experience with the prescription

drug rebate law, which I know you know about. And they had a lot of the intellectual capital when we began looking at prescription drugs and the pharmaceutical companies and all those sorts of things that CMS has never dealt with before. Those two gentlemen had the experience in dealing with them.

But as Dr. Wilensky says, substantial intellectual capital will have to be built now, building on what is there in Medicaid as well as bringing in some people from the private sector.

A lot of this though is not even going to be intrinsic to prescription drugs. It is just getting rules written, figuring out how to oversee contracts, the hard stuff that you talked about earlier in your statement. And for that, I think, you could bring over some good people from SSA if there are some people there who could be spared, as well as from some of the other agencies who do that kind of thing, and get them on a SWAT team to help the agency.

That is what I would be looking at.

Senator PRYOR. Thank you.

Senator VOINOVICH. I want to thank you very much for being here today. I can assure you that not only your written testimony but the responses that you have made today will be sent over to Mr. McClellan. I think your suggestion that it might be good to have him in here to have an opportunity to spend some time with us is a good one, to ascertain what it is that he thinks we need to do to be of help to him.

I think the issue of workforce flexibilities in order to hire the people that they need to get the job done is one issue. Another, I think is the issue of the budget, a $1 billion deal. But what will CMS need, in terms of additional money, to get the job done once this program is up and running? This is just a one-shot deal.

Looking at some of the other areas in the Department where they have been shortchanged in terms of dollars are also issues that we need to really get at right away.

One of the things I have learned here and Senator Pryor probably joins me in that because he was an attorney general, is Congress in so many instances has really no appreciation for the management challenges of some of these programs.

We get this idea that we pass a law, snap your fingers and it is all done. A lot of my colleagues have never been a mayor. They have never been a governor or an attorney general. And so they just have no idea about how much work it takes to get something done.

It seems to be illogical because if you look at any organization its strength really is in the people that are in that organization. We just do not pay enough attention to that.

So I am really grateful that the two of you have come over here today. Dr. McClellan can learn a great deal from your testimony.

I was thinking about whether we would do that or not, but I would like to invite him in and give him a chance to share with us his observations and maybe discuss some of these issues that you have raised. Are we too ambitious? Are we being asked to do too much at the same time? Are some of the things that Congress asks for in this legislation things that maybe we could delay for a year or 2 years rather than trying to get it all done at one time?

Or is the alternative cascading some of this over a period of time so we get a little more experience with it, so that we can determine whether or not the grand plan is really doing the job that we expect it to do?

Again, thank you very much. The hearing is now adjourned.

[Whereupon, at 11:53 p.m., the hearing was adjourned.]

APPENDIX

TESTIMONY OF
MICHAEL McMULLAN
DEPUTY DIRECTOR, CENTER FOR BENEFICIARY CHOICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ON
IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM
BEFORE THE
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT,
THE FEDERAL WORKFORCE AND
THE DISTRICT OF COLUMBIA

APRIL 8, 2004

Chairman Voinovich, Senator Durbin, distinguished members of the Committee, thank you for inviting me here today to discuss implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), enacted into law on December 8, 2003. The Centers for Medicare & Medicaid Services (CMS) is very proud to have a significant role in implementing this historic legislation, which constitutes the most extensive modifications to the Medicare program since its inception in 1965. CMS is working diligently to meet the numerous and aggressive deadlines outlined in the MMA. CMS' goal is to implement all of the provisions of this legislation in a timely manner and in such a way that the new benefits are as easily understood and accessed by beneficiaries as quickly as possible.

The MMA represents a fundamental change in the Medicare program by offering our beneficiaries more choices in how they receive their care and by establishing a responsive relationship with the providers of that care. This will begin with the Medicare sponsored drug discount card, and will continue as the full prescription drug benefit is implemented in 2006, and represents a lasting change in how CMS and the Medicare program will operate. Whether it is in how we reduce Medicare overpayments or how we improve quality of care, our fundamental goal is to offer our beneficiaries choices of high quality health care, while being more responsive and flexible in how we interact with the health care providers who deliver the services.

CMS STRUCTURE

The CMS accomplishes its mission by working with, and through, others. The Agency employs approximately 4,500 people in locations around the country. However, these employees are only a small portion of a large, complex network of people and groups that make our programs work successfully. Some of the many others CMS works with, and through, include:

- physicians, other health care professionals, providers, and health plans;
- states, territories, and Tribes;
- CMS business partners, who process claims and carry out many of the other administrative functions of CMS programs (e.g., contractors);
- health care groups and associations;
- beneficiary and consumer organizations;
- accrediting bodies;
- other Federal agencies; and
- researchers and others.

These business relationships leverage CMS' resources and are critical to achieving our goals and objectives. For example, since 1965, we have entered into contracts with private companies to administer various functions under the Medicare program. Currently there are 34 companies that hold contracts to process Medicare fee-for-service (FFS) claims. Several of these companies process both Part A and Part B claims: thus 26 serve as fiscal intermediaries and 18 serve as carriers. During FY 2003, we estimate that these claims processing contractors provided claims processing services to about 33 million beneficiaries; worked with approximately 1.1 million health care providers; processed more than 1 billion Medicare claims; paid more than $236 billion for beneficiary services; and handled more than 7.3 million review requests and other kinds of appeals.

The attached chart gives an idea of the scope of how many individuals and organizations are partnered with CMS in carrying out its mission.

MAJOR ELEMENTS OF MMA

CMS' MMA implementation challenges can be categorized into a number of broad categories including a prescription drug discount card and transitional assistance program; the new voluntary Medicare prescription drug benefit; modification of the existing Medicare+Choice program, now renamed Medicare Advantage; and contractor and regulatory reform. The MMA also modified numerous payment systems under Medicare and Medicaid, particularly those affecting rural providers; established new preventive benefits; established a number of demonstration projects; provided for administrative improvements and regulatory process changes; and numerous other provisions. The new law contains substantial and complex tasks for the Agency, the implementation of which requires the concerted effort of thousands of Federal employees and contractors. Given the nature of the work before the Agency and the need for effective, steady leadership, we appreciate the Senate's swift confirmation of Dr. Mark McClellan as the new CMS Administrator.

PAST SUCCESSES

Although new Medicare law creates major changes in the programs administered by CMS, the Agency has dealt with change in the past. Planning and prioritizing for implementation of the Balanced Budget Act of 1997, the Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000, have all been carried out within the past six years. CMS has dealt with the challenges of Y2K and the destruction of our New York contractor's office on September 11, 2001. We have recently implemented a series of quality measures for home health agencies, nursing homes, and hospitals. These last initiatives involved extensive consultation with industry; development of quality measures; systems changes for collection of data; and advertising campaigns to inform beneficiaries. In short, CMS has experience with prioritizing and planning multiple tasks similar to the work that will have to be done with MMA.

EARLY IMPLEMENTATION SUCCESS – THE DRUG CARD

As an example of what we have already done to implement MMA, on December 15, 2003 just one week after the law was signed, CMS published a regulation establishing a new prescription drug discount card program. We solicited applications from organizations interested in sponsoring such programs and on March 25, 2004 announced approved applications. On April 1, 2004 CMS announced the actual drug discount cards that the sponsors will offer. Approved sponsoring organizations have provided CMS with data on the enrollment fees they will charge and on April 29, we expect to post on our website specific pricing data for the drugs amd discounted prices available through these programs. Beneficiaries will be able to sign up for the cards in May and begin realizing the associated discounts on their drug purchases on June 1, 2004. In addition, qualifying low-income beneficiaries will receive a significant additional benefit of $600 annual credit applied toward their drug purchases.

Finally, a major educational campaign, using print and media avenues, has been established to help our beneficiaries understand how to access this new benefit. In particular, we worked with the Social Security Administration to mail a separate letter to Medicare beneficiaries with lower incomes, who are likely to be eligible for the $600 annual credit.

Our consumer website, www.medicare.gov, will house a critical new tool ("Price Compare") for the drug card initiative that will enable users to search for drug discount cards; enter their specific prescription medication needs; and compare the expected discounted prices that each of the cards might offer.

We also organized a drug card conference held on April 7-8, 2004, to educate and train those at the local levels. Congressional staff were encouraged to attend. In addition, we are planning other training days for Congressional staff. Going through these processes will not only result in a viable drug discount card program, but has helped CMS by preparing it for carrying out similar tasks in implementing the drug benefit under Part D.

EARLY IMPLEMENTATION PROGRESS – OTHER PROGRAMS

Establishing the drug discount card program, although a major effort, is not the only work that CMS has accomplished in the past few months when it comes to MMA implementation. We have made substantial progress on many provisions, including completing more than a hundred distinct tasks. The attachment to my testimony details the tasks that CMS has completed to date.

I would like to highlight the progress CMS has made over the last five months. These efforts include:

- updating the physician fee schedule to provide for a positive 1.5 percent increase in payments during 2004 and 2005, as opposed to what would have been a decrease in payments;
- revising payments for drugs currently paid using the average wholesale price, and the accompanying fees for drug administration. These changes in the approach to reimbursement will protect the program from excessive expenditures on drugs while simultaneously properly reimbursing physicians, notably oncologists, for their work in delivering these medications;
- delineating hospital quality reporting requirements for a full market-basket update, which in turn relies on previous work with industry in establishing those quality measures, and previous modifications of IT systems to collect the data;
- making wage index reclassification adjustments to allow qualifying hospitals to receive increased reimbursement;
- increasing payments to rural providers;
- updating payments to Medicare Advantage plans and approving plan enhancements that provide additional benefits or reduced cost-sharing for enrollees;
- drafting, for publication this summer, proposed regulations for Medicare Advantage and the prescription drug benefit;
- steps toward adding a range of preventative services to the Medicare benefits package, including a wellness visit, cardiovascular screening, and diabetes screening;

- progress toward changing our process of contracting with carriers and fiscal intermediaries to incorporate more performance measures and competitive processes;
- setting up demonstrations and pilot projects as required by MMA; and,
- engaging in extensive beneficiary education, and reaching out to our traditional and non-traditional stakeholders, including physicians, hospitals, pharmacists and States, as well as PBMs, employers and third party administrators.

It is obvious from this list of accomplishments that CMS is making substantial progress in meeting the ambitious timelines within the MMA.

IMPLEMENTATION PROCESSES

Effective dates for MMA provisions include several that are retroactive, many that were effective upon enactment and some that go as far out as October 2011. Implementation of these provisions will require publication of numerous proposed and final regulations, systems changes, letters to State Medicaid Directors, educational efforts for providers and beneficiaries, and studies and reports to Congress. CMS will have to hire sufficient employees with appropriate expertise and experience, establish and test major new IT systems, and work out contracting details with outside entities that CMS relies on for implementation of large new benefits. CMS must also work with States, SSA, and other Federal entities, as we implement benefits that will need to be coordinated with their existing programs. Finally, CMS must communicate these changes to beneficiaries in as clear, and effective a fashion as possible so that those who wish to take advantage of the new, voluntary, benefits may do so.

The MMA makes up to $1 billion available to CMS through September 30, 2005 for start-up implementation costs. These funds will be used on activities such as hiring additional personnel, upgrading and adding new information systems, and educating beneficiaries. CMS has already made important funding decisions related to the implementation of the drug card and hiring new employees. CMS continues to develop and implement the budget plan as it moves toward implementation of the remaining provisions.

Human Resources Issues

As noted above, CMS' implementation of the MMA is well under way, but significant work remains. The MMA adds provisions that require new and additional expertise. Specifically, CMS will need to hire individuals with expertise in pharmacy benefits management, clinical personnel such as pharmacists and physicians, individuals experienced with disease management and prevention, and those who understand how employers structure their retiree benefit packages. CMS will need additional IT professionals experienced with the types of payment systems contemplated by the law. Finally, CMS will need to hire individuals experienced with government contracting, as much of the work under MMA, as with most other Medicare programs, will be contracted out. We have begun staffing a number of these new positions.

In addition to new government employees, CMS must contract with a number of outside entities, including pharmacy benefit programs and private health plans, in order to fulfill the mandates of MMA. This work involves establishing parameters for those contracts, issuing a solicitation, examining the resulting bids, and awarding contracts to appropriately qualified organizations. CMS employees overseeing the activities of outside entities also must possess the expertise to ensure that the prescription drug card sponsors and other contractors comply with the medical privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Program Integrity

The work of contractors must then be monitored and supervised to ensure program integrity and effectiveness. The main oversight work of CMS is to see that contractors and providers implement these new programs as established by the Agency and statute. CMS will need to monitor pricing of drugs and benefits provided by drug discount card, drug benefit plans, and Medicare Advantage plans, prior to implementation of MMA as well as afterward. Error rates in payments will need to be established and education made available to providers to help them avoid common pitfalls as they show up. CMS is aware of fraudulent activity involving individuals posing as Medicare officials offering bogus drug discount cards. We have taken

steps to inform beneficiaries of this scheme and have worked with OIG, the FBI and DOJ to prevent fraud in this and other programs administered by CMS. When fraud or abuse occurs, the Agency will address it as appropriate, either through remedial education or punitive measures.

Systems Changes

New and revised payment systems require substantial IT changes within CMS. The Agency will need to be able to process beneficiary eligibility requests, enroll beneficiaries in new benefits, and track utilization of services. In addition, many of the changes made by MMA, particularly benefits being provided on a demonstration basis, are accompanied by a requirement that CMS study the effectiveness of the new programs. These studies involve tracking clinical outcomes and quality measures.

Revised and new IT systems will need to interact with those from other federal agencies, such as the Social Security Administration and the Internal Revenue Service, States, and the private insurers who contract to administer new benefits under MMA, and those offering established Medigap plans.

Beneficiary Education

CMS recognizes that opportunities for beneficiaries to choose new benefits and how those benefits will be delivered may be somewhat confusing. CMS, therefore, has a substantial educational task to help beneficiaries take advantage of these new voluntary programs. To address beneficiaries' educational needs, a major educational campaign has been established to help them understand how to access new benefits under MMA. As you know, the Congress gave us clear direction to educate and inform beneficiaries about important new benefits in the MMA, particularly the drug benefit and the drug discount card. The education campaign uses a variety of means – print materials; community-based outreach; television, print, and radio advertising; the Internet; and, 1-800-MEDICARE – to reach beneficiaries.

We launched a nationwide advertising campaign at the beginning of February to alert beneficiaries to the new benefits that are available under the MMA. Also, at the end of February, CMS began mailing to all beneficiary households a fact sheet that explains these new benefits. In the coming months, we will be particularly focused on getting beneficiaries important information about the drug discount card and transitional assistance program. In early April, a detailed booklet about the drug card was made available at medicare.gov or by calling 1-800-MEDICARE. At the end of April, a shorter publication on the drug discount card will be mailed to every beneficiary household. We anticipate using the website extensively to educate beneficiaries concerning benefits that will be implemented in the future.

The annual publication, "Medicare and You" covers beneficiaries' privacy rights under HIPAA with regard to their interaction with CMS and its contractors. In addition, entities offering the drug discount card and drug benefits are considered health plans for purposes of HIPAA and will be required to provide beneficiaries with a notice of their privacy practices.

In addition, our 1-800-MEDICARE call center is in the process of "ramping up" – training and adding new Customer Service Representatives to answer calls about new benefits. We expect to have about 1,400 representatives in six different call centers in the United States trained and available by the end of this month.

Even with all of these plans and tools, we understood early on that our education efforts could not be successful without solid and dependable community-based outreach. That is why we have also invested in building alliances with other organizations that serve Medicare consumers to help us in disseminating this information.

CONCLUSION

The timelines required under MMA for implementing these important new benefits are ambitious and will require prudent planning and wise use of resources. We at CMS believe that we will be able to meet the ambitious goals laid out in this new statute. I thank you for your invitation to testify this morning and I welcome any questions you may have.

Serving Beneficiaries

CMS works with many others to serve our beneficiaries.

Medicare, Medicaid & SCHIP Beneficiaries	**80 million** *

Hospitals	6,000
HMO's, LTC Facilities & Other	39,000
Physicians & Practitioners	882,000
Labs	173,000
Total Providers	**1,100,000**

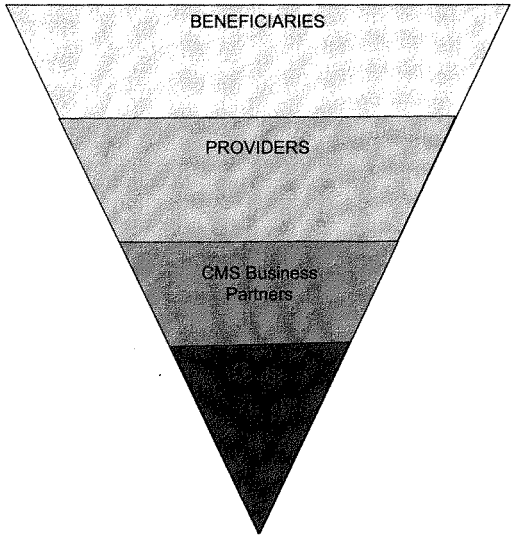
**

State Medicaid / SCHIP Staffing	34,000
State Surveyor Staffing	6,000
Medicare Contractor Staffing	21,000
QIO Staffing	2,500
Total Business Partners	**63,500**

Central Office Personnel	2,925
Regional Office Personnel	1,550
Total CMS Personnel (Apr. 2004)	**4,475**

* Note: The number of beneficiaries was calculated on an average enrollment basis (e.g. person-years of enrollment).

** These counts are based on Medicare data.



Medicare Modernization Act Completed Provisions

Section	Upon Enactment	
211	Immediate improvements – Private Fee-For-Service plans charge higher copays for non-network services	12/08/03
233	Medicare Metropolitan Statistical Area (MSA) - makes the MSA demonstration permanent	12/08/03
401	Equalizing urban and rural standardized payment amounts under the Medicare Inpatient Hospital Prospective Payment System	12/08/03
408	Recognition of nurse practitioners as attending physician with hospice patients	12/08/03
614	Improved payment for certain mammography services Screening mammography services are excluded from the OPPS	12/08/03
622	Limitation of application of functional equivalence standard	12/08/03
624	2-year moratorium on therapy caps; provisions relating to reports	12/08/03
628	Annual update for clinical laboratory fee schedule and laboratory services subject to reasonable charge payment method	12/8/03
941 (a) 941 (b)	Policy changes regarding evaluation and management documentation	12/08/03
921(c)	Medicare Administrator Contractors (access and timely responses)	12/08/03
948	BIPA-related technical amendments	12/08/03
1003	Extension of Institute for Mental Disease (IMD) moratorium	12/08/03

Medicare Modernization Act Completed Provisions

December 2004

921	Provider education and technical assistance	12/09/03
704	Temporary suspension of OASIS requirement	12/11/03
1201	Health Savings Accounts	12/11/03
1860D– 42	Temporary Suspension of OASIS Data on non-Medicare and non-Medicaid beneficiaries	12/11/03
734	Restoration of Medicare Trust Funds	12/15/03
1201	Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemption	12/16/03
1860D	**Medicare Prescription Drug Discount Card and Transitional Assistance Regulation**	12/15/03
105	Additional provisions relating to the Medicare Prescription Drug Discount Card and Transitional Assistance Programs	12/15/03
1860D	Discount Drug Card Solicitation for Drug Card Sponsor	12/19/03
1860D	Prescription Drug Compliance Requirements	12/19/03
1860D-31	**Prescription Drug Territory Assistance Program**	**12/19/03**
628	Payment for clinical diagnostic lab tests – Eliminates payment	12/19/03
103	States transitional prescription drug assistance verification	12/19/03
411	2-Year Extension of Hold Harmless Provisions for Small Rural	12/19/03
411	Hospitals and Sole Community Hospitals Under the OPPS	12/19/03
411	Changes in Transitional Outpatient Payment (TOP)	12/19/03

Medicare Modernization Act Completed Provisions

December 2004 (cont')

412, 601, 602	Medicare Physician Fee Schedule – increase and extension of the annual participation enrollment period	12/19/03
302	Payment for Durable Medical Equipment—Competitive Acquisition	12/24/03
302(c)	Payment for durable medial equipment; competitive acquisition of certain items and services – Transitional Freeze	12/24/03
303	Payment for drugs and biologicals – Revises payment drugs	12/24/03
303	Payment reform for covered outpatient drugs and biologicals	12/24/03
305	Payment for inhalation drugs	12/24/03
601	Physician Fee Schedule – Provider Education	12/24/03
301(a)	Medicare Secondary Payor (MSP) Provisions	12/31/03

January 2004

211	Extending special rule for certain inpatient hospital stays to to rehabilitation hospitals and long term care hospitals	1/07/04
303(a)	Payment for drugs and biologicals – Adjustment to the Physician Fee Schedule	1/07/04
303(b)	Payment reform for covered outpatient drugs and bilogicals	1/07/04
304	Extension of application of payment reform for covered outpatient drugs and other physician services	1/07/04
305	Payment for inhalation drugs – Requires payment for inhalationdrugs furnished during 2004 at 85% of the April 1, 2003 AWP	1/07/04
412	Establishment of Floor on Work Geographic Adjustment	1/07/04

Medicare Modernization Act Completed Provisions

January 2004 (cont')

601	Revision of updates for physicians' services. Sets update for Each 2004 and 2005 at not less than 1.5%	1/07/04
602	Treatment of physicians' services furnished in Alaska	1/07/04
601	Inclusion of Podiatrists, Dentists, and Optometrists under private contracting authority	1/07/04
621(a)(1)	Hospital outpatient department payment reform – Payment of drugs	1/07/04
621(a)(3)	Hospital outpatient department payment reform – Separately payable drug APCs are not eligible for outlier payments	1/07/04
305	Hospital outpatient department payment reform – Separately payable1drug APCs ineligible for outlier payments	1/07/04
621	Hospital outpatient department payment reform –Special payment for Brachytherapy	1/07/04
940(a)	Mediation process for local coverage determinations	1/07/04
503(e)(2)	Recognition of new medical technologies under the inpatient hospital prospective payment system	1/08/04
943	Treatment of hospitals for certain services under MSP	1/07/04
211	Immediate Improvements-- Announce new rates for 2004	1/16/04
211	Immediate Improvements – Plans to submit revised ACR proposals	1/16/04
405(e)	Improvements to Critical Access Hospitals increase payment to 101% of cost	1/16/04
944	EMTALA improvements – Medicare payment for mandated services	1/16/04
944	EMTALA improvements – Establishes a system for prior Review by PROs in the case of termination of participation	1/16/04

Medicare Modernization Act Completed Provisions

January 2004 (cont')

405(e)	Revision of bed limitation for critical access hospitals	1/16/04
103(e)	Medicaid Amendments- Best Price-- Drug Discount	1/21/04
642	Extension of coverage of intravenous immune globulin	1/23/04
642	Intravenous immune globulin – Claims Processing	1/23/04
503(e)(2)	Recognition of new medical technologies	1/28/04
103	Extension of QI-1 Program- Medicaid	1/28/04
236	Payment by PACE providers furnished by non-contract providers	1/28/04
622	Limitation of Application of functional equivalent standard	1/28/04
1860D	Discount Drug Card Applications Received	
302	Pricing file clarifications	1/30/04
303(b)	Payment reform for covered outpatient drugs and biologicals (85% AWP)	1/30/04
236	Payment by PACE providers for Medicare and Medicaid Services	1/31/03

February 2004

1001	Medicaid Disproportionate share hospitals payments	2/04/04
1860D-31	Transitional Assistance available to the Territories	2/04/04
421	1-year increase in home health services in rural areas	2/04/04
626(a)	Update to Consumer Price Index (0% For FY 2005)	2/05/04
626(a)	Changes in payment for services furnished in Ambulatory Surgical Centers for FY 2004	2/05/04

Medicare Modernization Act Completed Provisions

February 2004 (cont')

950	Treatment of certain dental claims regarding excluded services	2/05/04
	Eliminate the requirement for basing payments as Recommended by GAO	2/05/04
911	Establishes Medicare Administrative Contractors (MAC)	2/06/04
911	Increased flexibility in Medicare Administration	2/06/04
911	Expanded identification and workload reporting for CMS Medicare Systems	2/06/04
507	Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals	2/06/04
911	Increased Flexibility in Medicare Administration	2/06/04
626(a)	Payment for Services Furnished in Ambulatory Surgical Centers place of fiscal intermediaries and carriers.	2/06/04
921(c)	Provision of access to and prompt responses from Medicare Administrative Contractors	2/06/04
940	Establishes a mediation process for physicians' trained in Mediation	2/06/04
414	Rate increase for mileage payment for rural and urban ambulance services	2/06/04
414(b)	Rate increase for national and local fee schedule for ambulances	2/06/04
416	Outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas	2/13/04
508 (a-e)	Time appeals process for hospital wage index classification	2/13/04
508(f)	One time appeals process for hospital wage index classification Deeming hospitals reclassified by an act of Congress	2/13/04

Medicare Modernization Act Completed Provisions

February 2004 (cont')

304	Treatment of certain diagnostic test furnished to hospital outpatients in certain areas	2/13/04
405(d)(2)(a)	Physician option to be paid by a CAH or carrier	2/20/04
421, 701	Increased payment to home health agencies in rural areas (5%)	2/20/04
623(b)	Payment for renal dialysis services	2/20/04
106	State Pharmaceutical Transition Assistance Advisory Commission	2/25/04
621(a)	Medicaid definitions for drugs – Payment for sole source drugs	2/27/04
952	Revisions to Reassignment Provisions	2/27/04

March 2004

1002	Inpatient drug prices charged to certain public hospitals excluded	3/02/04
106	State Pharmaceutical Assistance Transition Commission (SPAP), establish and coordinate SPAP and Drug Program	3/05/04
402	Enhanced disproportionate share hospital treatment for rural and urban hospitals with fewer than 100 beds.	3/05/04
502	Raised Indirect Medical Education adjustment	3/05/04
504	Increase in federal rate for hospitals in Puerto Rico	3/05/04
621(b)	Communication of the annual and mid-year updates of the outpatient prospective payment system	3/05/04
507	Moratorium on specialty hospitals	3/19/04
801	Inclusion in Annual Report of Medicare Trustees of information on status of general revenue financing for Medicare Trust Funds.	3/23/04

Implementing the Medicare Prescription Drug Program

Testimony

Presented To

The Subcommittee on Oversight of Government
Management, the Federal Workforce and the District of Columbia

Committee on Government Affairs

United States Senate

By

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April 8, 2004

Mr. Chairman and members of the subcommittee: Thank you for inviting me to appear before you. My name is Gail Wilensky. I am a senior fellow at Project HOPE, an international health education foundation. I am also a former Administrator of the Health Care Financing Administration (1990 to 1992), now called the Centers for Medicare and Medicaid Services or CMS and a former chair of the Medicare Payment Advisory Commission, or MedPAC, from 1997 to 2001. My testimony today reflects my personal views as an economist and health policy analyst and also my experiences as Administrator of HCFA and chair of MedPAC.

The purpose of my testimony today is to review the enormity of the challenges facing CMS as it begins the regulation and implementation phase of the Medicare Prescription Drug Bill, to consider the adequacy of the resources available to CMS for these tasks and to make some observations and suggestions as to how the Congress might be helpful in this process.

The Problem

The Medicare Prescription Drug Bill, known as the Medicare Modernization Act (MMA), represents the largest, most expensive and most complicated set of changes to the Medicare program since its inception. Estimated by the Congressional Budget Office to cost $400 billion over ten years, its main purpose is to establish a new, voluntary drug benefit for Medicare to be delivered by private drug plans or by private health plans and also to establish a new Medicare Advantage program to replace Medicare+Choice. While the primary focus of the new legislation is on providing a new Medicare benefit, and on encouraging the participation of private plans in the Medicare program, the bill also contains many changes to other parts of Medicare. The most

important of these include both major and minor changes to Part B outpatient drug coverage, a variety of changes to Medicare provider payments, and a variety of studies relating to benefit or provider payment changes and other new beneficiary benefits under Medicare.

The Part D drug benefit is scheduled to begin in January 2006. Prior to January 2006, seniors will have access to prescription drug discount cards, and low income seniors will have access to special assistance, to help with their purchase of outpatient drugs. Both the discount cards and the special assistance are set to expire at the end of 2005.

There have been periodic complaints about the timing of the new Part D drug benefit - specifically that it doesn't take effect until 2006. However, these comments are usually made without consideration given to the enormous number of operational decisions that will need to occur and the implementing regulations that will need to be issued prior to November 15, 2005, (the date when current Medicare beneficiaries are scheduled to begin their enrollment for the new benefit). The legislation itself, however, provided some recognition of the enormity of the burden being placed on CMS by providing CMS with an extra $1 billion to support the implementation process and by providing the Social Security Administration with $500 million so that it can support many of the activities associated with determining the income eligibility of seniors for the special low income subsidies in the bill. These monies come from the Hospital Insurance Trust Fund and are available through September of 2005.

The question that remains is whether the support for CMS, and to a far lesser extent the Social Security Administration, is adequate for the additional work that needs to be done and whether

there may be other provisions and/or powers that could be granted to the agency to increase its likelihood of success.

Specific Challenges Associated with the Part D Benefit

Although I am sure that CMS has constructed the equivalence of a large flow chart that lays out all of the decisions that need to be made and regulations that need to issued in order to meet their January 2006 start-time, it may be useful to review the range of decisions that need to occur to better understand the enormity of the burden that has been placed on the agency. These relate first, to the provision of a new benefit using a new delivery system housed in a new center in CMS; second, to a series of changes to the outpatient drugs already covered in Medicare under Part B; and third, to payment adjustments and other modifications to Medicare providers. Finally, CMS continues to have a number of obligations to fulfill from previous legislation as well as its other program responsibilities.

All of this work needs to occur during a period when there has been an unusually high level of turnover in the senior career staff of CMS, along with all of the uncertainties and change associated with an election period. Fortunately the agency will not have to go through the first portion of this activity with interim leadership. The recent confirmation of Dr. Mark McClellan as the new CMS Administrator provides an important source of stability and leadership to CMS, in an agency that would otherwise have been led by acting appointees through much of this early critical period.

CMS (HCFA) has had other significant implementation challenges in its history. The introduction of DRG payments for hospital reimbursement, the resource-based relative value reimbursement system for physicians and most recently, the Balanced Budget Act (BBA) all represent major changes to Medicare and therefore challenges to the agency in terms of implementation. Nancy-Anne DeParle, the Administrator at the time of the BBA, is better able to speak to the challenges presented by the BBA than am I but as complicated as the BBA was, there seems to me to be clear differences between the magnitude of the challenges the agency now faces and the challenges from BBA.

Many of the changes to the BBA were changes to payment systems for existing Medicare providers. The creation of the Medicare+Choice program involved some of the same types of challenges that the agency faces today but the plans participating in M+C were primarily the same plans that had been participating in the previous Medicare risk program. The Provider Sponsored Organization (PSO's) and to a lesser degree the PPO's that were authorized under the BBA would have involved groups who had not previously participated in Medicare, but they never became a significant factor in the program and therefore the problem associated with delivery systems that haven't previously participated in Medicare wasn't present in the BBA. Nonetheless, the challenges to the agency of implementing all of the many changes associated with BBA were formidable and learning from that experience is important.

One of the most significant challenges for CMS under the MMA is that the primary delivery-system - private prescription drug plans that take risk - have not been a part of Medicare's experience and have not been part of private sector experience either. This means that not only

is CMS lacking in staff that has significant experience dealing with the pharmaceutical industry since except for Part B outpatient drug coverage, it hasn't had to be concerned about prescription drugs but more importantly, that many decisions will need to be made about how these new entities should function before they actually exist. These decisions, as well as the relationship between Medicare and these entities, will then have to be formalized in regulation. All of this is doable but it is a costly and time-consuming process.

Presumably these PDPs will come mostly from existing PBM's or from private insurance plans but they will need to be licensed by their respective states before they can begin the process of negotiating with drug manufacturers, establishing formularies and engaging in the other activities that will be involved in becoming a Medicare provider. The complicated nature of the process of establishing actuarial equivalence of drug benefit packages, the bidding process associated with the selection and pricing of PDPs, the premium subsidies and risk corridors around the bids, and the rules establishing the fall-back plans are further examples of the decisions and rule-making that will need to occur before the PDPs will be able to become operational.

Under the MMA, the new drug benefit can be provided either by a prescription drug plan or as part of a comprehensive benefit provided by a private health plan. The legislation defines many changes that will occur as the Medicare Advantage program replaces the Medicare+Choice program, established by the BBA. The first of these was to increase payment rates and to allow plans to change their previous decisions about whether to participate in 2004. Other provisions will be more complicated and controversial and will therefore have a greater impact on the regulatory process. These include decisions defining the number and size of the regions used for

plan participation, the bidding process to take effect in 2006 and the negotiating process to be used by the government around the bidding process.

The new law also contains several provisions to encourage employers to continue providing retiree drug coverage, but these provisions will also add to the series of decisions and rule-making responsibilities that will need to occur before the benefit begins. The most important of these concern the procedures to be used defining the actuarial equivalence language to the Part D benefit and the record-keeping that will need to be maintained by the plans to show that they are in compliance with the equivalence as well as any other requirements imposed in the regulations.

Other Implementation Challenges from the MMA

The other major areas of administrative and implementation challenge in the MMA concern the changes to the existing Part B outpatient drug coverage and associated changes in physician payment that accompanied these changes plus all of the changes in other Medicare provider payments or Medicare beneficiary benefits.

Prior to the passage of the MMA, Medicare provided coverage to a limited number of outpatient drugs that needed to be administered by physicians. These Part B drugs are being continued as a separate program at least temporarily, as the Congress considers their long-term future but their payment will be changed in a number of important ways.

For 2004, Part B drugs will be reimbursed under the same AWP (Average Wholesale Price) methodology that has been used for more than the last 30 years but reimbursed at a lower percentage of AWP. Starting in 2005, most Part B drug reimbursement will be based on Average Sales Price (ASP) rather than AWP. The biggest change in Part B drug reimbursement will occur in 2006, when physicians will choose whether to continue receiving reimbursement for Part B drugs based on ASP or to turn over the purchasing process to a competitive acquisition pricing strategy.

All of these changes in Part B drug reimbursement will pose additional challenges to CMS. In order to have accurate reimbursement, the changes will require accurate reporting of ASP, the Medicaid rebate best price and the average manufacturer price. There is also a peculiar feature in the legislation that has the Office of the Inspector General estimating the "widely available market price (WAMP) which if it differs too much from the otherwise prevailing reimbursement rate, may become an alternative basis for reimbursement. While the WAMP provision does not affect CMS directly, since it's the IG's responsibility, it will lend additional uncertainty to the calculation of the appropriate Part B drug reimbursement in an area.

The administrative and implementation burdens of these changes are substantial, especially when considered in conjunction with all of the other changes associated with the MMA. Establishing the competitive acquisition methodology is likely to pose the most significant challenge to CMS. In order to have this option available to physicians by 2006, the methodology (and associated regulations) will need to be in place by 2005. Since the law requires that there be at least two contractors in each geographic area, a series of decisions will need to be made

concerning the definition of the geographic area, the appropriate quality and access standards that need to be in place and the financial stability and solvency standards that should be imposed on the bidders.

In addition, concern that these changes in reimbursement for Part B drugs might lead oncologists to discontinue providing cancer treats in outpatient settings led the Congress to direct CMS to alter payments to oncologists and other health personnel providing cancer treatments in outpatient settings. The legislation also encourages oncologists to provide additional information to CMS if they believe the new payments do not accurately reflect the costs associated with the provision of chemotherapy and other cancer treatments, a claim long made by oncologists as justifying the overpayment they had been receiving under pre MMA Part B drug reimbursement formulation.

The Congress recognized that maintaining a separate reimbursement strategy for Part B drugs might not be appropriate for the long term. In order to assist Congress in their decision-making process, the legislation directs CMS to submit a report to the Congress in January of 2005 as to whether Part B drugs should be maintained separately from Part D drugs.

Finally, the legislation contains many changes to provider payments for providers not directly involved with the Part D drug benefit or the new Medicare Advantage program
The MMA increased physician payments by 1.5 %, and also directs CMS to make changes to geographic adjustment fact. Neither of these are burdensome changes but the legislation also directs CMS to study ways to make appropriate payments in the future. Because of the current

legislative language, it will be very difficult to formulate alternative strategies that are not enormously expensive. There are also a variety of changes to payments for other Medicare providers that will need to be processed. As is usually the case, there are a large number of studies to be done. Some of these studies are to be done by the General Accounting Office, the IG or MedPAC but many more directly by CMS. The bill also mandates a number of demonstrations that are designed to help the traditional Medicare function more effectively. Finally, the bill contains many of the contractor reforms that were contained in previous year's legislation.

In addition to all of the Medicare-related changes, CMS will need to see that the changes involving Medicaid occur in a timely manner, that the states do not use the distraction of the new legislation to become even more creative in designing strategies that fund Medicaid with only Federal dollars and that the provisions of HIPAA that are still being implemented occur in a timely fashion.

Early Results

Despite the daunting challenges facing the agency, the early results have been promising. The regulations defining the discount drug card were issued shortly after the legislation was signed and the early response by sponsoring organizations has been very promising. CMA has just released the regulation concerning the definition of ASP that will be used by Part B drugs next year.

The confirmation of Dr. McClellan within one calendar quarter after the departure of Tom Scully, the previous CMS administrator, represents the fastest transition in my memory and minimized the amount of disruption that would have otherwise occurred to the agency.

The provision of the additional monies to CMS is both recognition of the enormity of the burden and is allowing for some faster hires than would otherwise occur. The new CMS Administrator would be the best person to determine whether the sum is adequate but given how much the agency's administrative budget has been starved over the years, it may not be.

Concluding Thoughts

Implementing the major provisions of the Medicare Modernization Act will take a Herculean effort by CMS and perhaps some assistance from the Congress as well.

It is very important for the Congress to understand that any changes to the legislation that change or modify the legislation in a significant way either in terms of operational decisions or regulation will make it extremely difficult, if not impossible, for the benefit to start in January of 2006.

It may be useful for the relevant Congressional committees to have occasional briefings on the progress that is being made in implementing the legislation. These should not occur too frequently or will represent one more burden on the agency but if there is a problem, either in the

language of the legislation or the adequacy of the CMS funding, knowing sooner rather than later may improve the likelihood of a successful resolution of the problem.

Temporary hires, IPA's from other parts of government or universities and other flexible hiring strategies may be an important tool for the agency. Hiring individuals who have experience in rule making or in running private sector entities that are similar to those that will be used in delivering the Part D benefit will be difficult. Any impediments that the Congress can remove should be seriously considered, especially if they reflect temporary solutions to temporary problems.

CMS and its predecessor agency HCFA have had a long history of a disconnect between its funding and the responsibilities imposed on the agency by the Congress. The disconnect has been recognized in an open, bipartisan letter published in Health Affairs several years ago, which I supported and signed and reaffirmed by MedPAC, in one of its annual report to Congress during my tenure as chair. Either the Congress needs to provide adequate resources to match the increasing responsibilities it puts on the agency or it should turn to other agencies it is more willing to fund.

The new CMS Administrator will have his own vision of how the agency can best function to meet the needs of the people receiving benefits from the Medicare and Medicaid, the individuals and institutions providing services to these populations and the taxpayer supporting both of these groups. Congress should pay serious attention to what he says needs to be done.

Statement of Nancy-Ann DeParle*

Former Administrator, Health Care Financing Administration (1997-2000)

Before the Senate Governmental Affairs Committee Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia

April 8, 2004

Chairman Voinovich, Senator Durbin, and distinguished Subcommittee Members, thank you for the opportunity to offer my perspective on the management challenges facing the Centers for Medicare and Medicaid Services (CMS) as it prepares to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). I applaud the Subcommittee's leadership in soliciting the views of recent Medicare administrators to provide insight into the challenges we have faced in managing the agency as well as those that await Congress and CMS in implementing the new Medicare prescription drug benefit. Admittedly, Medicare's administrative apparatus is not the most glamorous subject for a Congressional hearing, but understanding its strengths and weaknesses is critical if Congress wants to ensure that Medicare beneficiaries have the prescription drug benefit you envisioned on January 1, 2006.

I served as Administrator of the Health Care Financing Administration (HCFA), the predecessor agency to CMS, from November 1997 until October 2000.[1] Today I will provide my perspective on the significant challenges that CMS faces in fulfilling Congress's vision for the Medicare drug benefit. I begin by describing some recent examples of CMS's effective implementation of major initiatives, from which I draw conclusions about key ingredients for success in an undertaking of this magnitude. Then I outline some of the complexities of the prescription drug legislation and explain why I think it presents a more substantial management challenge for CMS than earlier initiatives. Finally, I offer some recommendations for the Committee to consider as it examines how to help CMS.

Background. CMS is filled with talented, dedicated professionals who work hard to carry out the agency's responsibilities of providing health insurance and other services to more than 74 million Americans. But over the last several years, the agency's workload has increased dramatically, while neither its budget

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[1] References to CMS should be assumed to refer as well to the predecessor agency, HCFA, during the time the author served as Administrator and until the agency's name was changed in 2001.

nor its human capital strategies have kept pace. This has imposed significant challenges on the agency and its staff and creates significant risks for the near term.

I believe that the record shows that when CMS has adequate resources and flexibility, strong support from Congress and the Administration, and leadership and focus from its senior political and career officials, it can tackle almost any challenge. That is, I believe that if you entrust CMS with adequate resources and flexibility, the agency has shown that it will reward your trust. Let me give a few examples that illustrate this point:

- Meeting the Y2K Claims Payment Challenge: CMS staff worked single-mindedly for two years to ensure that the agency's claims payment systems were Y2K ready so that Medicare and Medicaid could continue processing claims from hospitals, physicians, and others without interruption. This work required remediation of old computer systems and, in some cases, deciphering and rewriting millions of lines of computer code that had been written by the Social Security Administration in the 1960's. Recognizing the urgency of this project, Congress appropriated more than $1 billion in additional funding for CMS and its contractors to do this work. Significantly, it also afforded CMS critical flexibility in personnel policies so that we could recruit agency retirees to help and provide retention bonuses to staff we were in danger of losing to more lucrative private sector jobs. Our Chief Information Officer and his deputy were approached numerous times during this project by private sector consulting and information systems companies offering much higher salaries. I am convinced that the personnel flexibility I had--along with their loyalty to the agency--helped me to keep them working on this seemingly relentless project. Just as importantly, the Administrator and the HHS Secretary were united in their commitment to the Y2K remediation project as the agency's number one priority. We were supported wholeheartedly by the agency's union leadership and the leaders of the Congressional committees with oversight over the agency's programs.

- Strengthening Medicare's Fiscal Accountability: At the same time that CMS staff were working to implement the BBA and address Y2K issues, we made major strides in reducing the Medicare payment error rate. In 1997, the Inspector General's first-ever audit of Medicare's books had revealed a fee-for-service claims error rate of 14 percent, which translated into $23 billion in erroneous payments in 1996. Therefore, when I became Administrator, sharpening CMS's focus on fraud, waste and abuse had to be one of my top priorities. We received significant assistance from Congress, which gave the agency and its law enforcement colleagues at the Department of Justice and the HHS Office of Inspector General additional funding through the Medicare Integrity Program created as part of the Health Insurance Portability & Accountability Act of 1996 (HIPAA). By the 1999 audit, we had cut that rate in half, saving Medicare and the taxpayers billions. On top of that, after much

hard work, in 2000 CMS received an unqualified or "clean" opinion from the Inspector General's auditors, signifying that Medicare's accounting records were in order. The agency has continued to make progress in reducing improper payments and strengthening fiscal accountability, thanks in part to Congress' strong support.

- Covering Uninsured Children Through the State Children's Health Insurance Program (S-CHIP): The BBA created S-CHIP to provide a capped entitlement to States for providing health insurance to children whose families cannot afford private insurance but earn too much to qualify for Medicaid. The fact that the law passed was a surprise to almost everyone, and many details were left out of the legislation. CMS staff worked with the States to flesh out the details and get S-CHIP launched in record time, just 3-4 months after passage by Congress. Today, it provides health insurance to some 4.6 million children.

- Designing and Launching the National Medicare Education Program (NMEP): In conjunction with the sweeping changes made by the BBA, CMS designed its first comprehensive beneficiary education campaign. Congress signaled its support for this effort by including it in the BBA and provided seed funding in the form of user fees to be assessed on Medicare+Choice plans. After field testing in 6 States, CMS launched NMEP in 1999. This comprehensive, ambitious, and unprecedented education effort included a beneficiary handbook, 1-800-MEDICARE toll-free line, and www.Medicare.gov internet site. We conducted hundreds of town hall meetings and focus groups with beneficiaries to develop the plan, test it, and gauge what worked and what did not. In 2000, the agency received a rating of 74 on the American Customer Satisfaction Index, a benchmark for customer service quality that includes both the federal government and private industry. This exceeds the national average satisfaction score of 72, and represents one of the highest scores (and most significant improvements in a score) achieved by a federal agency that works directly with the public. CMS staff have continued to refine and strengthen the 1-800-MEDICARE toll-free line, the handbook, and the internet site, and they form the building blocks for the campaign that must now be undertaken to educate beneficiaries about the new Medicare drug benefit.

Medicare Drug Benefit: Execution Risks. I believe there are two significant types of risks facing CMS as it prepares to implement the Medicare drug benefit.

Leadership Risks: First, the agency faces significant leadership risks on both the political or policy and career levels. The departure of the agency's Administrator days after the law was signed by the President left CMS without a confirmed leader for several critical months as it grappled with implementation plans. Several of the agency's key political appointees, including the Deputy

Administrator and the Director of the Center for Medicare Management left either a few months before or at the same time as the Administrator.

CMS needs a strong leader with a clear point of view that can be depended upon by the career staff who develop the regulations, draft the contracts, and execute all the day-to-day decisions to ensure that the prescription drug benefit Congress envisioned will be ready in 2006. Now that the new Administrator has been sworn in and other appointees have been named to fill key Medicare policy vacancies, this vacuum in political leadership should begin to be filled.

But CMS, as an operating division of HHS, is also affected by the stability of the political leadership within the Department. There, too, disruption lies ahead. Secretary Thompson announced more than a year ago that he would be leaving HHS right after the 2004 election, and he confirmed after the MMA's passage that he would not be around when the drug benefit goes live in 2006. Thus, unfortunately, the leadership gap is not completely closed. In implementing the BBA, I relied heavily upon Secretary Shalala's judgment and especially on her support in marshalling the resources of the Department to get things done. For example, it can be extremely difficult to get the attention of the Department or OMB staff who need to review and clear regulations without the Secretary running interference. I am concerned that CMS's leadership today may not get the full benefit of this kind of assistance as they rush to implement the drug benefit.

The "brain drain" in the career leadership at CMS is even more troubling. The past three years have seen an unprecedented--but apparently unnoticed--turnover in the senior career ranks of the agency. In the spring of 2001, CMS had 43 Senior Executive Service (SES) staff holding key leadership positions in the agency. They had the experience, the judgment, and the knowledge to implement complicated legislative mandates: from working with Congressional staff, providers, and beneficiary groups, to crafting regulations, to clearing them through the bureaucracy at HHS and OMB, to working with Medicare's contractors to change the claims payment systems, and everything in between. I listened to them, and I depended on them. Today, more than half of these SES officials have left the agency. Some of the departures were due to predictable attrition, and some of my former colleagues, though relatively young, retired from the government, spurred in part by a buy-out plan put in place by the Bush Administration. Then, too, some senior career staff left CMS to take positions at other government health care agencies, including the General Accounting Office, Congressional Research Service, and the Health Resources and Services Administration within HHS. Whatever the cause, this is an unprecedented level of senior-level career turnover for CMS, and the timing could not be worse.

Administrative Risks: Crafting complex regulations to implement statutes is nothing new for CMS. I alluded to the challenges faced by CMS in

implementing the BBA. As you will recall, the BBA encompassed some 335 provisions that required CMS to design and implement new (or substantially different) payment systems for hospitals, nursing homes, and home health agencies. In addition, it made close to a hundred other major changes to Medicare, many of which required writing or negotiating regulations in compliance with the Administrative Procedure Act and guiding Medicare's 50-plus claims payment contractors through extensive computer system changes. And on top of the myriad changes made to fee-for-service Medicare, the BBA made significant changes to the reimbursement methodology for Medicare managed care, and it created S-CHIP. Unlike the MMA, which gives beneficiaries a new benefit that many of them want, the BBA took away billions of dollars in Medicare payments from providers, which they most assuredly did not want.

But as complex and contentious as the BBA was, I think it pales in comparison with the MMA. With the BBA, except for creating the beneficiary education program and the new MSA, PPO, and PSO plans in the Medicare+Choice program (which never really materialized), the bulk of CMS's work was directed toward implementing new payment systems with a familiar set of providers. We knew the providers and their trade associations well and had worked with them for years. We had an established process for working with the carriers and intermediaries who implemented the changes to the claims payment process. There are always unforeseen challenges when a health care reimbursement system is implemented, and there were plenty with the BBA. But for the most part, CMS knew what to expect.

In contrast, the 176 provisions of the MMA require CMS to design and build a brand new delivery system to deliver a prescription drug benefit to 42 million beneficiaries. This will require CMS to establish relationships with a whole new set of partners that it has not really worked with before in a significant way: pharmacies, pharmacy benefit managers, pharmaceutical companies, and the as-yet-to-be-created prescription drug plans, to name a few. And the agency will have to build substantial intellectual capital in a new area: drug benefits and how to provide and finance them adequately and prudently. Although some progress has been made toward developing this experience in recent years as Congress and the Clinton and Bush Administrations have debated a drug benefit, the fact is that substantial human capital will need to be gained and expertise will have to be built where it does not now exist.

CMS has to build this new delivery system in time for beneficiaries to be able to walk into their corner drugstores and get a prescription filled with a Medicare Rx card on January 1, 2006, only 20 months from today. And in reality, 20 months overstates the amount of time CMS has. After all, the MMA specifies that the initial enrollment period for 42 million beneficiaries must begin no later than November 1, 2005, and that beneficiary education must begin no later than October 1, 2005. Leaving aside the question of whether that leaves

enough time to conduct a meaningful beneficiary education campaign that will leave beneficiaries feeling confident rather than confused, that deadline leaves CMS with less than 18 months to finish the bulk of its work.

I have attached as an appendix to this testimony my grossly oversimplified list of the major activities CMS (and prescription drug plans and States) will have to undertake between now and October 1, 2005. This list is at a fairly high level of abstraction, but considering just a few of the items on it should give you a flavor for how complicated implementation will be.

For example, in order to make sure that the drug benefit's deductibles, cost-sharing, and catastrophic limits work as stipulated in the law, CMS will have to develop a way to keep track of what each Medicare beneficiary spends on drugs. There are certain rules about how to count that spending. Costs are considered incurred, and should be counted, if they go toward the deductible, cost-sharing, or benefits not paid because of the initial coverage limit or "donut hole." But costs are not to be considered incurred, and should not be counted, if they are for drugs that are not covered because of a particular plan's formulary, or if they were paid by an individual or entity other than a family member (with the exception of subsidies paid on behalf of a low-income beneficiary). Keeping track of spending according to these rules will require extensive modifications to the database of claims activity for each beneficiary that CMS maintains called the "Common Working File." And new interfaces will have to be added so that prescription drug plans and MA plans can determine on a real-time basis at the point of sale when a beneficiary has satisfied her deductible, and when her spending qualifies her for the catastrophic protection. Rewriting computer code for the Common Working File is an extremely complex, time-consuming, and risky activity. It can be done, but it is not simple. And if is not done perfectly, millions of beneficiaries and pharmacists will be calling CMS and Congress to complain.

This is just one example of this high-risk nature of an implementation project of this magnitude; there are many more. In my experience, even an activity that seems simple--such as the requirement that the Secretary designate the number and geographic configuration of the regions in which the drug benefit will be offered and plans will compete--never turns out to be so simple. In fact, I have already heard 3 senior members of Congress make comments about this particular provision. Each of them served on the MMA Conference Committee, and each has a different view about how many regions there should be, what they should look like, and what Congress's intention was in directing the Secretary to divide the country into regions. That alone should be enough to tell you how complicated these decisions are.

And of course, CMS does not have the luxury of taking the next year to work out the details of these issues and then announcing what it intends to do next spring. Many of these activities will have to be conducted pursuant to the

Administrative Procedure Act's formal rulemaking requirements, under which an agency must specify in detail its process for implementing a statute in a proposed rule and allow several months for the public to comment and for the agency to respond to each and every comment in writing before finalizing the rule. It will take many months to write, negotiate clearances within HHS and OMB, publish, and respond to the comments about the regulations implementing the MMA. While I was Administrator, even something as straightforward as proposed regulations updating the hospital conditions of participation elicited some 50,000 comments. With $500 billion over the next 10 years at stake, there will be tens of thousands of comments about CMS's plans for the drug benefit. This rulemaking process will be tortuous to say the least.

Other Challenges. Meanwhile, the agency has plenty of other work to do. Implementing the rest of the MMA could be a full-time job by itself. Dozens of fee-for-service payment changes must be implemented, most through rulemaking, to increase payments for hospitals, physicians, and rural providers. Those are relatively non-controversial and in many cases the implementing regulations and systems changes are well underway. But other changes in the MMA reduce payments, and are both complex and controversial. For example, the MMA changed the payment methodology for the Part B drugs Medicare already covers in 2004, 2005, and 2006. The 2004 change is relatively simple (the payment formula is reduced by 10% to "average wholesale price (AWP) - 15%"), but for 2005 and 2006 the reforms introduce first a new basis for payment, and then a new "competitive acquisition program" that will require rulemaking and extensive interactions with physicians, pharmaceutical companies, and other parties. This is just one example of a complex provision in the MMA that must be implemented alongside the new drug benefit. Consider as well that the Medicare+Choice program created by the BBA must be morphed into the Medicare Advantage program, with 2004 revisions to the payment formula that is mandated to revised yet again in 2006. Long-overdue reform of the method CMS uses to contract with private sector entities to pay claims and perform other functions must be implemented in 2005. Dozens of demonstration projects await the RFP process. And contractor payment systems must be reprogrammed to accommodate new preventive benefits.

And no matter how worthy the MMA is of the agency's full and undivided attention, CMS also has many other responsibilities: ensuring that nursing homes and other health care facilities are safe, enforcing the portability guarantees of the Health Insurance Portability & Accountability Act (HIPAA), and working with the States to run the Medicaid and S-CHIP programs. These responsibilities, along with a hundred others, must be attended to as well to meet the health care needs of 74 million Americans who depend on CMS.

Recommendations. I would offer several recommendations to Congress as it considers how to help CMS meet the management challenges of implementing the prescription drug benefit.

- First, request that CMS update its strategic plan, including as a critical component a human capital plan, and provide the agency with additional resources to execute the plan. For several years it has been apparent that CMS's budgetary and human resources have not kept pace with its growing responsibilities. The massive workload of the BBA and its progeny--the Balanced Budget Refinements Act (BBRA) and the Benefits Improvement & Protection Act (BIPA)--stretched the agency's staff and contractor resources way beyond their limits. CMS's funding has not been adequate to meet these responsiblities, much less carry out its other duties effectively. For example, in 1998, the peak year of BBA implementation, CMS had 3942 full-time equivalents (FTEs), compared with 4961 in 1980. I believe the number of full-time FTEs has crept up slightly since 1998, but the point is that CMS is being asked to do more and more with fewer and fewer people and resources.

  The MMA takes a step in the right direction by earmarking $1 billion from the Medicare Trust Fund to be used by CMS in implementing the prescription drug benefit (with another $500 million for the Social Security Administration). However, the $1 billion is available only until September 2005. Thus, at precisely the moment when the real beneficiary education campaign should begin in earnest, CMS's additional resources disappear. This severely hampers the agency's ability to devote these to activities other than ones like the"soft" education campaign HHS launched right after the bill was signed. How can CMS use the $1 billion responsibly to build its infrastructure of people knowledgeable about pharmaceutical benefits management, or for multi-year contracts with private entities to assist with systems changes to track beneficiary drug spending, when it knows that the money disappears in October 2005? While some of the activities CMS will undertake in the next 18 months may be one-time-only investments, many of them will be ongoing, and indeed, will have to be ramped up as spending on the drug benefit increases from 2006-2013, as projected by the actuaries. Therefore, this "cliff" in administrative funding makes no sense.

  The MMA does not specify how the $1 billion is to be spent. It simply says that it represents funding for "start-up administrative costs for Medicare reform." While Congress is sometimes too specific in directing CMS how to spend, for example, research funds, this strikes me as not being specific enough.

  To remedy this, the Administration should submit, and Congress should approve, a CMS budget for FY 2006 that includes a strategic plan outlining what it will take to administer the Medicare drug benefit over the next 5 years and request continued funding from the Medicare Trust Fund. In fact, over time I would recommend that all of CMS's Medicare-related administrative funding (the bulk of the agency's budget) be derived from the Trust Fund. Under the current arrangement, CMS's budget to run the day-to-day

operations of Medicare must compete for limited discretionary appropriations with the National Institutes of Health, the "Leave No Child Behind" program, and other health and education priorities. Congress should also consider giving CMS multi-year appropriations for at least some of its critical administrative activities. The vagaries of the annual budget process are especially difficult for CMS, an agency that depends to a great extent on contracts with private sector entities. CMS needs to have the assurance that the funding will be there from one year to the next for its core Medicare program management functions so that it can enter into multi-year contracts with private sector entities where appropriate.

Congress should be explicit about what it wants CMS to do with this additional funding, as it has been in at least one other case in creating a "performance-based organization" at the student loan agency within the Department of Education. It gave that agency additional funding to meet specific goals and required it to report back on its progress in meeting certain milestones it had developed with Congress. When I left the agency in 2000, we had taken the first steps toward developing a human capital strategic plan, by assessing the skills the agency needed and profiling our current workforce to see where the gaps were. I do not know the current status of this plan, but this Committee should work with the agency to see what progress has been made, and of course, the plan should be a dynamic document that will be updated as changes are made to CMS's responsibilities, such as the addition of a Medicare drug benefit.

In addition, there are other specific gaps in CMS's program management budget that should be addressed. For example, Congress has never provided a specific line item in the CMS appropriation for beneficiary education, although it has repeatedly stipulated--most recently in the MMA--that such activities must occur. Given the importance of educating beneficiaries about the new drug benefit, it is time to deal with this gap explicitly. Further, it is my understanding that the additional funding that Congress earmarked in HIPAA for Medicare program integrity activities at the Department of Justice and the HHS Office of Inspector General has plateaued, and that those agencies now face the prospect of layoffs. That is alarming in view of the fact that the actuaries project that Medicare spending will increase 8.2% this year, to $296.7 billion <u>without the drug benefit</u>, and the fact that CMS will be spending more than $500 billion more in taxpayer dollars over the next ten years on the new drug benefit.

- <u>Second, provide CMS with more flexibility to do its work</u>. CMS has some flexibility in hiring that it should take advantage of, such as interdepartmental personnel appointment or "IPA" authority allowing it to hire detailees from other agencies and even certain outside entities. CMS has used this authority successfully in the past to bring in detailees from the Social Security Administration (SSA) with expertise in running SSA's toll-free customer

service lines; those detailees were enormously helpful in advising us on 1-800-MEDICARE.

CMS needs more of this kind of hiring flexibility. For example, other agencies within HHS, such as the Agency for Healthcare Research & Quality (AHRQ) and the FDA, have special authority to hire clinicians and highly skilled technical and scientific staff at salaries above Federal guidelines, but Congress has never granted CMS this authority. During the intense period when CMS was struggling to ensure that all of its payment systems were prepared for Y2K, Congress gave us the authority to re-hire retirees to come back and help with work that they knew well, while allowing the retirees to retain their pensions. In view of the unprecedented turnover in CMS's top career ranks over the past 3 years, Congress should consider extending this authority to the Administrator again. If our Y2K experience is a guide, I expect there are a number of talented and public-spirited CMS retirees who would be excited about working to make the prescription drug benefit a reality and who could provide critical assistance in writing regulations or specifications for payment systems changes.

For much of the time I was running CMS, we did not have the financial resources to hire new personnel. When we did hire new staff, I did not think we competed very effectively with the private sector--not only because the salaries we offered were lower, but also because the hiring process took so long. I understand that it is still a challenge to recruit, interview, and hire new staff within a reasonable amount of time. Therefore, Congress should give the CMS Administrator the authority to waive certain personnel rules so that he can recruit and appoint highly qualified staff at the SES level without artificial FTE or salary constraints, and hold those staff accountable. As mentioned earlier, there is precedent for this: Congress has granted such authority to the student loan agency within the Department of Education, as well as to the Internal Revenue Service. Beyond the SES, any additional flexibility Congress could give CMS to enable it to hire lower-level career staff with the expertise it needs more quickly and pay them more would help. In addition, given the urgency of the situation, the Secretary should devote more personnel from HHS's centralized human resources operation to helping CMS get its hiring done in a more timely fashion.

Finally, with the addition of a prescription drug benefit, it is clear that CMS is larger and has more complex, high-risk responsibilities than any other operating division at HHS. According to the Administration's FY 2005 Budget submission, CMS will spend an estimated $450 billion on Medicare, Medicaid, and S-CHIP in 2004. This is more than the projected 2004 discretionary spending of all the agencies of the Federal government combined, with the exception of the Department of Defense. The time has come to consider seriously making CMS an independent agency like SSA. As an independent agency, SSA sends its budget request directly to Congress, unfiltered by the

overseers at HHS, OMB, and the rest. SSA's independent agency status also affords it the ability to promulgate regulations without devoting the time and energy to negotiating many layers of clearance at HHS and OMB. Having served on both sides of this equation, I am not convinced that much is gained from the process except slowing it down considerably.

- Third, allow the agency the time to focus on the new prescription drug benefit in the next 18 months, rather than inundating it with new legislative mandates or special pleading. Eighteen months is very little time to accomplish what CMS must accomplish in order to ensure that 42 million Medicare beneficiaries have a prescription drug benefit on January 1, 2006. I believe the agency can do it, but not if Congress changes the law while CMS is trying to write the ground rules based on the MMA, or if Congress and the Administration quibble over every implementation decision the agency makes. If Congress wants CMS to get the job done, CMS must be permitted to prioritize and focus. Congress should understand that the focus needed to get the drug benefit implemented will mean that some other aspects of the agency's work may suffer, and that some less important provisions of the MMA may not be implemented on time.

* * * * * * * * *

Thank you again for focusing on the important steps that must be taken to strengthen CMS's ability to meet the management challenges of implementing the Medicare prescription drug bill. This legislation is as complex as anything the agency has ever faced, and the stakes could not be higher. I believe the agency can meet the challenge if the Administration and the Congress provide it with strong financial resources, flexibility, support, and leadership. Investing in CMS now is critical if we want to ensure that Medicare, Medicaid, and S-CHIP are effectively and compassionately managed in the future.

Appendix

Outline of Major Activities for Implementation of Medicare Prescription Drug Benefit (April 2004-November 2005)

- The Secretary must determine the therapeutic categories for the drug benefit, in consultation with U.S. Pharmacopeia and others. The Secretary should also develop a process for the revision of these categories to reflect changes in therapeutic uses and new drugs, and a process for ensuring that plans notify the Secretary of changes to the formulary.
- The Secretary must establish the regions in which the prescription drug plans (PDPs) and Medicare Advantage (MA) plans will offer the drug benefit.
- The Secretary must establish minimum solvency requirements for PDPs.
- PDPs must be created. In order to participate, a PDP must:
  - either meet the Secretary's minimum solvency standards or be licensed by the State as a risk-bearing entity eligible to offer health insurance in each State where it intends to offer a prescription drug plan to Medicare beneficiaries;
  - negotiate with pharmaceutical companies to obtain pharmaceuticals in each therapeutic class;
  - determine whether to use a formulary, and if so, set up a pharmaceutical and therapeutic committee to develop and review the formulary as well as an independent review and appeals process;
  - set up drug-utilization management programs, quality assurance measures, medication therapy management programs, and a program to control fraud, waste and abuse;
  - prepare to issue prescription drug cards to beneficiaries that meet standards developed by the Secretary;
  - develop information systems that can interact with Medicare's information systems to track beneficiary utilization and progress toward meeting deductible and catastrophic spending limits and set up systems to provide monthly explanations of benefits to beneficiaries;
  - submit bids to the Secretary for each region in which they intend to offer a prescription drug plan specifying the premiums they propose to charge and other information; and
  - disclose to the Secretary the aggregate negotiated price concessions received from drug manufacturers, along with information sufficient to determine the impact of those price concessions on beneficiary premiums.
- The Secretary must conduct a bidding process for PDPs and MA plans in each region, review the bids, determine if the law's requirement have been met, including requirements relating to beneficiary protections, and approve plans for each region.
- The Secretary must establish the amounts of Federal premium subsidies to be paid to plans, which will be determined based on a formula that depends

on plan bids and national average bids, and develop reinsurance and risk corridors.

- The Secretary must assure that beneficiaries in each region will have a choice of at least two plans offering a prescription drug benefit, one of which is a PDP. Two PDPs are required if no MA plan is available. If the minimum number of plans does not materialize, the Secretary may approve limited risk contracts or, failing that, the Secretary is to establish a separate process for approving "fallback" plans that would be paid on a cost basis for providing the drug benefit.
- The Secretary must determine Part D premiums to be paid by beneficiaries, which can vary by plan but not within a plan.
- The Secretary must review retiree plans to determine if they qualify for subsidies and determine how to provide employer subsidies for retirees.
- The Secretary must develop a system to provide subsidies for low-income beneficiaries work with the States to ensure that dual eligibles get access to the Medicare drug benefit. The Secretary will also need to develop a system to ensure that States maintain their level of spending on behalf of dual eligibles according to the schedule in the MMA.
- States must set up systems to help dual eligibles get enrolled in the Medicare drug benefit, including new asset tests.
- The Secretary must develop payment systems to pay subsidies to PDPs (and existing systems that pay monthly premiums to Medicare Advantage plans must be updated).
- The Secretary must revamp existing information systems that keep track of beneficiary deductibles and claims in order to track each beneficiary's costs for prescription drugs that are eligible to count toward meeting the catastrophic limit, and ensure that PDPs and MA plans can interact with these systems.
- The Secretary must design and conduct activities to educate beneficiaries, including comparative information about benefits and formularies under each plan, monthly beneficiary premiums, and cost-sharing. The education campaign is to be coordinated with similar activities for the MA program and must begin by no later than October 1, 2005.
- The Secretary must implement a system to collect Part D premiums from beneficiaries, working with the Social Security Administration.
- The Secretary must design and implement a system to allow enrollment by existing and new beneficiaries in Part D, the prescription drug benefit, beginning November 1, 2005.

SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS HEARING ENTITLED: "DOES CMS HAVE THE RIGHT PRESCRIPTION? IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM" APRIL 8, 2004

Senator Voinovich:

Question 1:

How else does CMS foresee providing beneficiaries with access to useful and accurate information? Please describe in detail CMS's education and outreach plan regarding the new drug discount card. Please include specific steps CMS will take to address the needs of more vulnerable populations.

Answer:

CMS Response: CMS has launched a national effort to educate Medicare beneficiaries on the Medicare-approved drug discount cards and other ways to access more affordable prescription drugs. The effort utilizes the communication channels that people with Medicare and those acting on their behalf may have ready access to. The channels include www.medicare.gov, 1-800-MEDICARE help line, one-on-one counseling through State Health Insurance Assistance Programs, advertising, publications (including informational brochures mailed directly to people with Medicare), and other channels.

The following are summaries of the major initiatives currently underway to reach and educate beneficiaries about the Medicare-approved drug discount cards:

1-800-MEDICARE (1-800-633-4227) Helpline
The 1-800 Medicare Help line provides services to Medicare beneficiaries 24 hours a day, seven days a week in English, Spanish, and TDD. All calls are routed through the 1-800 MEDICARE Interactive Voice Response Unit (IVR). The IVR provides frequently asked questions, the ability to order publications, along with other opportunities for beneficiaries to get their questions answered without talking to a Customer Service Representative (CSR). Beneficiaries who do not get their question answered in the IVR or who wish to speak to a live person are transferred to a CSR.

To aid the CSRs in answering questions, the 1-800 MEDICARE CSRs use a desktop application called the Next Generation Desktop (NGD). To ensure accurate and consistent answers are provided to all beneficiaries, the CSRs are required to use an extensive set of scripted answers in English and Spanish that are contained in the NGD. CSRs also access interactive databases providing information including choices of health plans, participating physicians and Medicare-approved drug cards.

Specifically for the Drug Card we are taking additional steps to address the needs of the more vulnerable populations.

1) We are increasing the capabilities to handle an anticipated 5.5 million additional calls for FY 04 due to the Prescription Drug Discount Card legislation. To accomplish this we have added two additional call centers (bringing the total to 6) and tripled the total number of CSRs on staff. We have fully trained all of the CSRs to handle not only the normal 1-800 MEDICARE inquiries but also the Prescription Drug Discount Card inquiries.

2) CSRs launch www.medicare.gov to provide information about getting help with their prescription drug costs. CSRs are currently using the Prescription Drug and Other Assistance tool to access the drug price comparison database. CSRs will be able to provide callers, either orally or by mail, with zip code specific information regarding Medicare approved drug discount cards in their area and the potential cost savings they may receive.

3) The IVR has been updated to include Frequently Asked Questions (FAQs) related to the Prescription Drug Cards and the ability to order the CMS Prescription Drug Publication.

4) The extensive set of scripts contained in the NGD have been updated to include answers to prescription drug questions. The scripts developed are consistent with the information being published by CMS in venues such as the Prescription Drug publication and the www.medicare.gov web site.

Advertising

CMS is releasing a new round of public information advertising as part of the existing 1-800-MEDICARE education campaign. The new advertisements are designed to raise awareness about the new discount cards as well as the assistance available for people with Medicare to choose the card that is right for them.

A new 30-second television ad, which began airing the week of April 25, emphasizes the $600 credit available to millions of low-income beneficiaries through these Medicare-approved prescription drug discount cards and certain Medicare Advantage programs. Beneficiaries are then advised to call Medicare through the toll-free help line 1-800-MEDICARE, "the official source of Medicare information". This ad will run through June 14th. A second television ad that will begin airing on May 10 focuses on helping people with Medicare choose a card that is best for them by steering them to the website or 1-800-MEDICARE.

The two television ads are being aired on national network and cable programs that are heavily viewed by the age group of most people with Medicare. Also, the campaign includes print and Internet advertising.

Advertising educating Spanish-speaking, low-income beneficiaries on the $600 credit available on the Medicare-approved drug discount card was also developed. This campaign, entitled, "Farmaceutico," consists of television, radio, print and Internet banner ads. This campaign was launched throughout the continental United States on April 26 and will

continue through June 20. A second advertisement strategy, targeted to Puerto Rico, is in development and will launch on May 10 and continue through June 25. This advertising consists of radio and print to introduce and explain the transitional assistance plan for people residing in Puerto Rico.

Publications

CMS has issued a variety of printed materials to inform and educate people with Medicare about the drug discount cards. These publications were tested with a variety of beneficiaries to ensure that they are understandable especially to those with lower education levels. These publications include the "Guide to Choosing a Medicare-Approved Drug Discount Card." This booklet explains the program, including eligibility and enrollment information, and provides step-by-step guidance for comparing discount cards. This publication is available in English, Spanish (will be printed by the end of May), Braille, and English audio. A shorter overview of this document was mailed to every Medicare beneficiary household starting April 20th. A tip sheet was also developed to help people with Medicare and their caregivers use the price comparison website and enroll in a discount card. These materials are available at www.medicare.gov or through 1-800-MEDICARE.

CMS is also in the process of updating and consumer testing "Medicare & You 2005," the handbook that is mailed to current Medicare beneficiary households each October and monthly to new enrollees to include information about the drug discount cards. A beneficiary poster is also being developed that will be placed in physician offices, health centers, and other appropriate locations to further assist people with Medicare in understanding the drug discount cards.

National Partnerships

CMS currently partners with more than 140 organizations and groups on education and outreach efforts. These partnerships enable a potential reach of approximately 250 million beneficiaries, caregivers and other interested parties. Information is provided to partners through various information channels – a partners Web page on www.cms.hhs.gov, periodic meetings/forums, listserves and publications.

CMS has taken steps to expand the partnership base to provide stronger entrée into community and faith-based service organizations, health information providers, and aging outreach centers – groups who work with those Medicare beneficiaries most in need of affordable prescription drugs. Efforts include establishing new partnerships with organizations serving Medicare beneficiaries and caregivers, including those reaching lower-income groups; increasing partner understanding of the Medicare-approved drug card program and how it works; and working with partners to develop effective ways to reach those eligible for the $600 credit.

State Health Insurance Assistance Program (SHIP)

SHIPs provide one-on-one counseling in thousands of locations familiar and accessible to beneficiaries. The SHIPs handle complex health insurance problems that require in-depth knowledge of local programs and services to provide a more comprehensive solution to a beneficiary's individual circumstances. While the main channels of the outreach and

education plan (1-800 MEDICARE, www.medicare.gov, publications, etc.) provide information to most beneficiaries, the SHIPs are available to beneficiaries who prefer and need in-person assistance.

Regional Education About Choices in Health (REACH)
CMS' ten Regional Offices (ROs) implement the REACH program that cultivates community-based partnerships with organizations that use existing outlets to conduct education activities for populations with barriers caused by low-income and differences in language, literacy, location and/or culture. Training, population-specific materials and outreach support are planned for those partnership activities. The partnership networks that serve as trusted information intermediaries for low-income and hard to reach beneficiaries include community-based organizations such as faith-based organizations, minority health providers, senior centers, community centers, and coalitions that promote the welfare and health care access of vulnerable populations. Many REACH partners serve beneficiaries with information and assistance familiar, community settings.

National Training Program
A national training program has been developed to educate and train CMS staff, partners, and information intermediaries who are responsible for educating beneficiaries about their health care choices, benefits, rights and protections. This training program includes a module on the Medicare-approved drug discount card and additional modules are being developed to address the other provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Medicare-approved drug discount card module has been provided to all ten of the CMS ROs where they are being used to train partners and people with Medicare on the drug card. The training module is available on the CMS web site. The module will be part of a comprehensive training package that is presented at the training workshops held by each CMS RO during July and August of 2004.

Medicare-Approved Discount Drug Card Training Module
A Web-Based Training module on the Medicare-approved drug discount card is available on the CMS website. Additional modules addressing additional provisions of the MMA will be developed and posted on the CMS website.

Prescription Drug and Other Assistance Programs (PDAP) Training CD-ROM and Video
A computer-based training program on CD-ROM and a video on how to use the PDAP database have been developed and distributed to partners throughout the country. Approximately 6300 CD's and videos have been sent to partners including SHIPs, advocacy groups, CMS ROs, area agencies on aging, libraries, community-based organizations, senior centers, state insurance departments, etc.

Question 2:

Within 4 months, CMS was able to roll out a brand new discount drug card, which will have an immediate impact on our nation's seniors. We all know this is a temp program until CMS can offer a full prescription drug benefit. To do this, CMS has had to forge new partnerships w/ health benefit providers. How will this experience better position CMS as

they begin to implement the full drug benefit -- a benefit providers and CMS alike have no experience administering?

Answer:

CMS Response: CMS expects to gain significant drug benefit administration experience from the implementation of the Medicare-approved discount drug card program. Mostly the drug card program will give CMS the opportunity to learn firsthand how pharmacy benefit managers and health plans, many of which are approved card sponsors, conduct their business. This includes how these entities contract with pharmaceutical manufacturers and pharmacies as well as how they develop their pricing structures. The drug card will allow CMS to become more familiar with how drug benefits are marketed and what the most appropriate messages and means of communication are for the Medicare population. In turn, the card sponsors will learn how to interact with CMS as a business partner, and how to address the unique needs of the Medicare population. In addition, we have been able to benefit from, and build upon, the previous work and/or public comment on such features as the development of formulary categories and classes, the Price Compare website, and standardized industry formats for data reporting. Although CMS and providers have had no direct experience with administering a stand-alone drug benefit, we have already been able to learn a great deal about best practices in pharmacy benefit management from M+C (MA) organizations and other benefit managers of integrated health benefits. All of these experiences will be directly applicable to the tasks that CMS and the prescription drug plans will have to take on with the implementation of the Part D program.

Question 3:

CMS relies heavily upon partnerships with its contractors to process payments to Medicare providers. What is CMS doing to be proactive with their partners to educate providers on the numerous changes included in MMA in order to avoid errors?

Answer:

CMS Response: CMS has an existing infrastructure that supports the development and dissemination of information to enrolled fee-for-service providers. This infrastructure consists of staff at CMS Central and Regional Office staff and the fiscal intermediaries and carriers. The MMA has numerous changes that must be communicated with physicians and providers to avoid errors in billing. Our activities include:

Open Door Forums (ODF)

CMS has hosted a number of ODFs on specific MMA provisions. ODFs are hosted by senior CMS staff, are open to the public, and have on hand, policy staff to answer questions and address concerns. ODFs were established to give Medicare providers direct access to key policy staff on a regular and ongoing basis. Thus far this fiscal year, over 20,000 partners have participated in the ODF process.

Contractor Instructions/associated Medlearn Matters…Information for Medicare Providers

MMA provisions are typically implemented through instructions to our claims processing contractors. To date, we have issued 34 MMA-related instructions. CMS has also issued associated educational articles, branded as *Medlearn Matters,* for 35 provisions. Both of these numbers are increasing on a weekly basis. These are educational articles written in easy-to-understand language that usually accompany the release of new or revised Medicare program changes. MMA articles are clearly identified in a separate table on the *Medlearn Matters* Web page. These national articles ensure that a consistent message is delivered to all Medicare providers. We recently established a *Medlearn Matters listserv* that is available to the public and provides notice of new articles on a flow basis. The articles are also posted on the *Medlearn* Web page, the CMS site for provider education, at http://www.cms.hhs.gov/medlearn/matters.

Contractor Outreach

Medicare contractors are key to reaching individual providers for whom they process claims. Contractors are required to publish Medlearn Matters articles in their regularly scheduled provider newsletters, post notices of new articles on their web sites and listserves and utilize CMS educational products in their outreach activities.

Regional Office (RO) Outreach

CMS has 10 ROs that have staff dedicated to reaching regional and local provider organizations. The ROs utilize CMS materials to educate physicians and providers on changes to the Medicare program. The ROs develop an annual outreach plan and have focused on changes under the MMA in 2004.

Provider Partnerships

CMS has established partnerships with national associations representing all provider types. The purpose of these partnerships is to 1) invite feedback on our educational products and efforts and 2) utilize their reach to their respective membership as a way to get Medicare information into the hands of providers. We provide our partners up-to-the minute information on regulations, new instructions and educational articles, as well as other changes relevant to the provider type.

Exhibit Program

CMS hosts informational booths at national and local provider association meetings. This outreach effort offers a very unique opportunity for the agency to have direct contact with providers, distribute relevant MMA and other education materials. This fiscal year, CMS will participate in 90 national and regional conferences throughout the country.

Provider-specific Web Pages

CMS has developed a number of provider-specific web pages on http://www.cms.hhs.gov/providers, to convey relevant Medicare information to a provider community. Two CMS Press Releases have announced the web pages. All pages have a prominently displayed link to *Medlearn Matters* articles; and CMS utilizes the "highlights" section of each provider web page to notify affected providers of changes resulting from the

MMA. Direct links to pertinent regulations, CMS contractor instructions, and specific *Medlearn Matters articles* are frequently highlighted to draw attention to changes.

Provider Listserves
CMS has developed a network of provider listserves (electronic mailing lists) that allow providers to sign up to receive immediate notice of MMA regulations, program changes in billing procedures, Medlearn Matters articles and other important news. Since MMA was passed, we have substantially increased the number of notices sent out on our listserves. The link to CMS provider listserves can be found at http://www.cms.hhs.gov/mailinglists/.

Medicare-Approved Drug Card and Transitional Assistance Program
CMS has conducted a special outreach campaign for the drug card program. We recognized the importance of making sure fee-for-service providers were aware of the new program and knew where to refer their Medicare patients should questions arise. Our campaign includes articles, brochures, journal ads and posters for physician and other provider offices. We have established a website for providers with information relative to the drug card at http://www.cms.hhs.gov/medlearn/drugcard.asp

Question 4:

What lessons has CMS learned from implementing payment and other program reforms that will help the agency collect information about the drug program after it has been implemented, evaluate its operation, and decide whether adjustments are necessary.

Answer:

CMS Response: Our previous experience in implementing payment reforms, such as the development of the health status risk adjustment model, has taught us that it is imperative to collect the utilization data from the private plans, even though we are not paying the claims, so that we have the data we need to evaluate the level of services provided to our beneficiaries. We are working on a comprehensive data strategy that will serve the requirements not only for accurate payment of risk-adjusted subsidies, reinsurance and risk sharing, but also for oversight of quality indicators such as medication interactions and prescribing patterns, and program auditing.

Question 5:

Starting in 1990, the General Accounting Office has identified Medicare on its High-Risk list. The list was last updated in January 2003. Then GAO identified improper payments, inadequate monitoring of managed care plans, financial management processes, information technology, and contracting practices as weaknesses. What is your plan of action for addressing the problems that have Medicare on the GAO High-Risk list?

Answer:

CMS Response: In December 2003 CMS prepared a detailed status report summarizing the issues and presenting the status of our activities and planned actions regarding those areas GAO identified as weaknesses. On December 9, 2003, CMS met with GAO to review and discuss this material. A copy of that document is attached. CMS continues to implement the planned actions presented in that report.

The GAO Findings & Related OMB Deliverables Major Management Challenges and Program Risks at HHS

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Pay Appropriately for Medicare Services

SUMMARY OF ISSUE: The CMS has mixed success refining payment methods due in part to insufficient data on providers' costs and beneficiaries' use of services. Specific examples: Skilled Nursing Facilities, Home Health Services, and Physician Services.

I. ***Medicare Part A: Inpatient PPS Hospital Rates***

Under Section 1886 (d) of the Social Security Act (the Act), a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively-set rates was established effective with hospital discharges beginning on or after October 1, 1983. There are currently more than 4000 hospitals that receive payment under the inpatient Prospective Payment System (IPPS). Under this system, Medicare payment for hospital inpatient operating costs is made at a predetermined, specific rate for each hospital discharge.

Under the IPPS, payment for inpatient hospital services is based on a rate per discharge that varies depending upon:

a. The nature of the services provided.
b. The national labor standardized amount, adjusted for geographical hospital wage differences.
c. The national non-labor standardized amount.
d. Certain other adjustments such as disproportionate share (DSH), indirect medical education (IME) payments, high cost outlier payments, and payments for new technology, if applicable.

The following formula summarizes this payment calculation:

PPS Payment = [(labor-related standardized rate * hospital wage index) + nonlabor-related standardized rate] * Diagnosis Related Group (DRG) Relative Weighting Factor] + adjustments (DSH/IME)

Note: Hospitals in Alaska and Hawaii receive a cost of living adjustment on the non-labor related rate.

II. *Operating Policies And Procedures*

DRG Reclassification--Cases are classified into DRGs for payment under the IPPS based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status. Hospitals report the diagnosis and procedure information using specific codes. The codes used by the hospitals are found in the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) manual. Fiscal intermediaries enter the information into their claims systems and subject it to a series of edits within the Medicare Code Editor (MCE), which are designed to identify cases that require further review before classification into a DRG can be accomplished.

After passing the MCE edits and any further adjustment of the claims, cases are classified by the GROUPER software program into the appropriate DRG. The GROUPER program is used both to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review File (MedPar). The data in this file is used to evaluate possible DRG classification changes and to recalibrate the DRG weights.

- **Paying Appropriately for Medicare Services Requires Frequent and Carefully Targeted Refinements.** The GAO report (page 7) indicates that, "A major challenge in administering payment methods—either through fee schedules or bundled payments—involves adjusting the predetermined amounts to better account for differences in patients' needs and providers' local markets to ensure that the program is paying appropriately and adequately."

CMS Activity: Recalibration of DRG Relative Weights—CMS ensures appropriate and adequate payment by recalibrating the DRG relative weights. For FY 2004, the DRG relative weights were recalibrated using the FY 2002 MedPar File data, which was the most recent discharge data available. The 2002 data is based on all PPS hospital discharges and short-term acute care hospitals in waiver states, after passing through the MCE and common working file (CWF). The FY 2002 MedPar file includes data for approximately 11.3 million Medicare discharges.

To arrive at the FY 2004 recalibrated DRG relative weights, Center for Medicare Management (CMM) regrouped all the claims using the DRG classification revisions discussed above. Then charges were standardized to eliminate geographical differences. The average standardized charge per DRG was computed by summing the standardized charges for all cases in the DRG and dividing by the number of cases in that DRG. Statistical outliers were eliminated, and the average charge for each DRG was then recomputed and divided by the national average standardized charge per case to determine the relative weight. The relative weights developed according to this methodology result in an average case weight that is different from the average case weight before recalibration. Therefore, the new weights are normalized by an adjustment factor, so that the average case weight after recalibration is equal to the average case weight

before recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under PPS.

- The GAO report (page 7) indicates that, "CMS has had mixed success in making refinements to payment methods. The agency's difficulties stem, in part, from insufficient data on providers' costs and beneficiaries' use of services."

CMS Activity: CMS has access to a large amount of cost data collected annually from the Hospital Cost Report Information System (HCRIS). The cost data is found on Worksheet D-1 Part II of the Medicare cost report. In addition, CMS tracks utilization of beneficiary services through the MedPAR. As mentioned above, the records for all Medicare hospital inpatient discharges are maintained in the MedPar, and based on utilization trends, the data in this file is used to evaluate possible DRG classification changes and to recalibrate the DRG weights.

Wage Index Update: The hospital wage index is updated annually by CMM based upon data collected from the Medicare cost reports submitted by hospitals. The Medicare cost report data is found on Worksheet S-3 under Part II of the report. This data is submitted electronically by hospitals to their respective fiscal intermediaries (FI). The FI performs an intensive review of the wage data using edits and desk reviews to identify irregular data in accordance with CMM guidelines.

Once the FI has completed its review of the data, it transmits the data to CMS through the Health Care Provider Cost Report Information System (HCRIS). CMS performs an intensive review of the wage data, mostly through the use of edits designed to identify irregular data. If any needed data revisions are identified by CMS the data file is sent back to the FI for correction.

CMM then uses the data to compute the wage index[1]. The wage index reflects total adjusted salaries and hours for each hospital. Adjusted salaries include net hospital salaries, certain contract labor costs, wage-related costs, and home office salaries and fringe benefits reported by the hospital.

Prior to computation of the wage index, CMS makes the data file containing the wage data used to compute the wage index values in the final rule available to hospital associations and the public for review in order to identify any potential errors made by CMS or the FI in the entry of the final wage data.

If a hospital identifies incorrect wage data, due to an error by CMS or the FI in the entry or tabulation of the final wage data, it should prepare a letter outlining why it believes that an error exists, include supporting information and submit the letter to both CMS and it s FI requesting the correction. The FI will review the request and supporting documentation and contact CMS to discuss its findings. Corrections are then made based on accepted requests from hospitals.

CMS then computes the final wage index and publishes it in the Federal Register as a final rule. The updated wage index values are then entered into the PRICER program s MSAX file, maintained by CMM, for use in pricing the respective fiscal year s claims.

[1] The step-by-step computation of the wage index can be found in the Final Rule, 68 FR 45398: August 1, 2003.

CMM Validation Review: CMM updates the PRICER program to reflect the changes to the PPS rates as published annually in the final rule. In addition, PRICER is updated for any subsequent changes during the year. Once PRICER has been updated, CMM performs two validation reviews to determine if the updates have been made and the program is operating properly. The first review is performed at CMS Headquarters by CMM personnel. CMM personnel input "test billing" data into the system (usually the data is specific to pricing criteria that has changed from last year) and the system generates test file reports which are reviewed to ensure that the program correctly adjusted pricing for the updated factors. After the initial review the PRICER program is released to the Standard System Maintainers (SSM) via Connect: DIRECT, an electronic bulletin board, and CMM prepares for the second validation review. The second validation review is performed on site at the Florida Fiscal Intermediary (FI), the largest SSM, which processes 90 percent of PPS claims. The review, both a systems and claims check, consists of selecting a number of claims (claims are chosen that would reflect changes published in the FR) and manually recalculating the amount of reimbursement. Comparisons are then made between the manually calculated amount and the reimbursement calculated by the system to ensure that (1) the SSM's mainframe system is interpreting the program correctly and (2) the pricing updates are being correctly reflected in the reimbursements for claims. If any errors are identified in the review, the problem is researched and any needed corrections to the program are made on site by the CMM staff. Note: A CMM programmer accompanies the staff that performs the review at the FI. Testing is performed again to ensure that any changes made by the programmer have been accepted by the system. The documentation generated during the review process for the recalculation testing is brought back to Central Office. However, changes made to the standard system to correct errors are not documented.

CMS Actions with Respect to Reforming Payments for Skilled Nursing Facilities

Skilled Nursing Facility payment actions relevant to the following GAO report:

Nursing Homes: Aggregate Medicare Payments Are Adequate Despite Bankruptcies. GAO/T-HEHS-00-192. Washington, D.C.: September 5, 2000.

The CMS is actively pursuing efforts to enhance the database that will serve as the basis for making decisions regarding possible refinements in the case-mix classification system.

Background

The SNF prospective payment system (PPS) was implemented in July 1998, using a 44-group case-mix classification system based on the Resource Utilization Groups, version III (RUG-III). Section 101(a) of the Balanced Budget Refinement Act of 1999 (BBRA) established a temporary adjustment to the payment rates for certain specified payment (RUG-III) groups, effective April 1, 2000. Under the BBRA legislation, this temporary rate increase (which results in approximately $1 billion in revenue per year for the SNF industry) remains in effect until CMS implements case-mix refinements in the SNF PPS. In addition, section 311(e) of the Benefits Improvement and Protection Act of 2000 (BIPA) has directed us to conduct a long-term study of case-mix adjustment in SNFs that will examine comprehensive changes to the system as well as potential alternatives, and it also requires us to issue a report with any appropriate recommendations to the Congress by January 1, 2005.

Current Status

In July 2001, CMS awarded a contract to the Urban Institute to commence research in connection with developing case-mix refinements. As we noted in the preamble to the SNF PPS proposed rule for FY 2004 (68 FR 26762, May 16, 2003), the research being conducted by the Urban Institute has already revealed several promising avenues for making more comprehensive changes to the current case-mix classification system, such as incorporating comorbidities and complications into the classification strategy. However, these and other approaches will require additional research and analysis before they can be considered for potential implementation. We plan to include the results of the research in which we are currently engaged in the report to the Congress that section 311(e) of the BIPA requires us to submit by January 1, 2005.

CMS Actions with Respect to Reforming Payments for Home Health Services

Home Health Agency payment actions relevant to the following GAO reports:

Medicare Home Health: Prospective Payment System Will Need Refinement as Data Become Available, GAO-HEHS-00-9. Washington, D.C.: April 7, 2000.

Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending, GAO-HEHS-00-176. Washington, D.C.: Sept. 8, 2000.

The CMS does not agree with the recommendation to include a statutorily required risk sharing provision for home health PPS. Risk sharing was one of many features of early research on PPS that were used to entice voluntary participation in the demonstration. The CMS continues to believe that risk sharing is administratively incompatible with, and is conceptually contrary to the principles of a prospective payment system. Providers would not know that they could rely upon the government's payments until after the fact.

The GAO proposal would potentially require Medicare to provide additional payments to an HHA at the end of the year if the HHA's cost were higher than its total payments capped at a certain percentage. Or, in the alternative, GAO would require Medicare to recoup payments already made to the HHA if the HHA's cost were lower than its total PPS payments capped at a certain percentage. One of the beneficial features of PPS is that all payments occur in a predictable and timely manner. A cost-based risk sharing provision would reinstate retrospective reimbursement.

As a practical matter, the data needed to implement the GAO's suggestion is not readily available for end-of-the-year adjustments. Agency-specific cost report data is required to determine cost margins, and the earliest clean cost reports are settled, without Fiscal Intermediary fieldwork or audit work, 18 months after the end of an HHA's cost reporting period is the earliest point Medicare would be able to compare an HHA's allowable costs with its total PPS payments.

Finally, the industry has raised issues with regulatory burden associated with cost reporting requirements. A risk-sharing provision based on cost reports data would perpetuate the use of cost reports in their current form and hinder attempts to reduce cost reporting burden. It would also require continued audit and review functions to a greater degree than a PPS system.

We are aggressively monitoring the ongoing implementation of the Home Health PPS and developing refinements under contract with Abt and Associates to better align costs, resource use, and payment.

Calibrating Payments for Medical Products

SUMMARY OF ISSUE: Medicare's payment approaches are tied to historical charges and lack the flexibility to keep pace with market changes. As a result, Medicare payments often exceed market prices.

CMS Actions with Respect to Reforming Payments for Medical Equipment and Supplies

Durable Medical Equipment payment actions relevant to the following GAO report:

Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs, GAO-02-833T Washington, D.C.: June 12, 2002.

As GAO indicates, an interim final rule on use of the inherent reasonableness (IR) authority for adjusting payments for medical products paid under Part B was published on December 13, 2002. This rule was mandated by the Balanced Budget Refinement Act of 1999 and outlines the process for making IR adjustments, including an overview of the steps that must be taken to ensure that valid and reliable data is used in making IR determinations.

Many of these steps are based on GAO recommendations from their 2000 report on IR and require extensive data collection efforts by CMS.

The CMS is currently working with a contractor to develop the written guidelines that detail the process to be used by CMS and its contractors to ensure the use of valid and reliable data. Once this contract is completed we can begin gathering data for use in making IR adjustments for items that we determine have grossly excessive or deficient payment amounts.

The CMS also continues its evaluation of its DME competitive bidding demonstration and expects to complete a report in the near future.

CMS Actions with Respect to Reforming Medicare Part B Drug Payments

Drug payment actions relevant to the following GAO reports:

Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs, GAO-02-833T. Washington, D.C.: June 12, 2002.

Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO-01-1118. Washington, D.C.: September 21, 2001.

On August 20, 2003, CMS published a proposed rule to revise the current payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis, as required by section 429(b) of BIPA and section 1842(o) of the Social Security Act. Types of drugs that would be affected by this proposed regulation, include drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, oral anti-cancer drugs, immunosuppressive drugs, and drugs furnished by dialysis facilities that are not included in the end-stage renal disease (ESRD) composite rate payment.

In the proposed rule, we solicited public input on four options.

Summary of Options

Option 1. ***Comparability provision: CMS contractors' private business payments applied locally***

We would issue additional guidance to our contractors on the application of the "comparability" provision in the statute (Sec 1842(b)(3)(B)) to drug payments. This provision requires carriers to limit the Medicare Part B payment for a "charge" based service to the amount the carrier would pay for a comparable service furnished under comparable circumstances in its private side business.

Option 2. ***Average AWP discount: general reduction for all drugs***

For all drugs, we would lock-in the AWPs as of April 1, 2003 and pay a uniform average AWP discount off of these amounts. We would seek comment on the appropriate average AWP discount in the range of 10 to 20 percent.

Option 3. ***Market monitoring: specific market-based reductions for high expenditure drugs based on GAO/OIG studies and a general reduction for the remaining drugs***

Market-based targeted reductions: For high expenditure drugs, we would use the market analyses performed by GAO and OIG to reduce the locked-in AWP by a drug specific percentage. For example, the average market price for Procrit is approximately 87% of current AWP based on the OIG and GAO studies.

General reduction: For low expenditure drugs, we would pay a percentage of the locked-in AWP as in option 2. We would seek comment on the appropriate discount in the range of 10 to 20 percent.

Option 4. *Competitive Acquisition Program and Average Sales Prices:* establishment of a competitive acquisition program coupled with a requirement that manufacturers submit Average Sales Prices (ASP) to CMS

Under this option, we would establish competitive acquisition areas and entities would bid to supply drugs to physicians in one or more of these areas. A physician could choose annually to acquire drugs from one of these entities and the entity would be responsible for billing Medicare. Alternatively, a physician could choose to purchase drugs and bill Medicare. If a physician elected to purchase drugs, we would pay the physician the ASP for the drug. Manufacturers would be required to furnish us with the ASP for each of their drugs quarterly.

Limited Efforts to Obtain Data-Driven Feedback to Assess Payment Policies

SUMMARY OF ISSUE: The CMS needs to use current and reliable data to make payment policy decisions; for example, outpatient drugs. The VA has access to detailed information on market prices that would assist Medicare in setting appropriate, efficient payment amounts for covered drugs.

CMS Actions with Respect to Obtaining Data-Driven Feedback to Assess Payment Policies

The CMS currently has in place a data-driven analytical plan to evaluate the impact of newly implemented CMS payment systems. For example, the Chronic Care Policy Group (CCPG) currently works with the RAND Corporation, MedPAC, ORDI, OACCT, and others in the health and scientific community in obtaining data-driven feedback to study margins and impact analysis regarding the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS). In working with these entities CCPG can evaluate the IRF PPS to ensure CMS is providing adequate payments to IRFs, while also ensuring the quality of care to Medicare beneficiaries is not compromised.

Our data-driven analysis includes, but is not limited to, evaluating: utilization and payment levels, provider characteristics, beneficiary characteristics, quality indicators, and operational implementation.

Ensuring Proper Payments Under the Medicare Physician Fee Schedule Payment Methodology

How is the payment amount calculated for a 2004 Medicare physician fee schedule service?

2004 Payment Amount = ((WRVU)x(WGPCI) + (PERVU)x(PEGPCI) + (MPRVU)x(MPGPCI)) x (2003 CF * 2004 Update)

2003 CF = 2003 Conversion Factor
2004 Update = MEI x (Penalty/Bonus due to comparison against expenditures) x (minor adjustment required by statute)

Note: Changes in the payment amount for an individual service are required, by law, to be done in a budget neutral manner.

What are the data sources and how are the data reviewed?

Data	Description	Data Review Activities
Work Relative Value Units (WRVUs)	The amount of physician work relative to other services associated with a given fee schedule service.	WRVUs for new and modified services : Value Update Committee (RUC), a colla specialties. CMS physicians and analyst five years, all WRVUs are subject to pul modified as necessary to ensure they refl
Practice Expense Relative Value Units (PERVUs)	The amount of practice expenses associated with a fee schedule service (clinical staff, nonclinical staff, rent, supplies, equipment, etc.)	Changes to PERVUs are continually rec Advisory Committee (PEAC), a collabo specialties. PERVUs for new services a PERVUs are subject to public comment.
Supply/Equipment Prices	The prices associated with supplies and equipment in the practice expenses.	CMS maintains current pricing and equi research by a contractor. These amount being finalized.
Supplemental Practice Expense Survey Data	Part of the formula in determining PERVUs is the practice expense per hour (PE/hr) for any given physician specialty.	PE/hr amounts are based on an AMA su process for physician specialties to re-su with the Lewin Group to work with spec surveys to ensure statistical validity and
Malpractice RVUs (MPRVUs)	MPRVUs account for the relative costs of physician malpractice insurance within each payable Medicare service.	MPRVUs are verified every 5 years by c premium data collection from State DOI made as necessary.
Medicare Economic Index (MEI)	The MEI measures inflation in physician costs.	CMS' Office of the Actuary conducts th sources used in calculating the MEI.
Geographic Practice Cost Indices (GPCIs)	There is a GPCI factor for each type of RVU. GPCIs account for relative cost differences in 89 geographic regions in the country.	GPCIs are reviewed and modified as nec gathering and analysis by our contractor Census, Housing and Urban Developme

What physician fee schedule management issues and risks has GAO identified and how has CMS responded?

- ***Major Management Challenges and Program Risks Department of Health and Human Services* (January 2003, GAO-03-101).** GAO indicated that CMS needs the capacity to generate data regarding access to ensure that payment policies that impose fiscal discipline are not compromising access. They also indicated that other activities, such as communication with providers, might also need attention.

    - CMS has many activities underway to monitor beneficiary access. These include: (1) initiated a targeted beneficiary survey on access issues in 11 geographic areas; (2) trend analysis of the Consumer Assessment of Health Plans data (fee-for-service version); and (3) developed a claims based monitoring system.

    - Regarding carrier communication issues, CMS has worked closely with the GAO on their studies in this area. On the most recent survey of carrier phone center operations currently underway, CMS staff provided technical assistance on the questions used and are helping evaluate carrier responses. CMS is looking forward to the results of this project.

- **Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees GAO-02-44IT, February 14, 2002).** GAO provided analysis and suggestions on the SGR system.

    - The SGR system is required by law. Congress is currently examining their options in this area and CMS stands ready to make any changes that could result from Congressional activity.

- **Medicare Physician Payment: Need to Refine Practice Expense Values During Transition and Long Term GAO-99-30, February 1999,).** GAO recommended: Use sensitivity analysis to identify issues with the methodology that have the greatest effect on the new practice expense RVUs, conduct additional data collection and analysis, and develop a plan for updating the practice expenses.

    - The practice expenses for 5,358 physician fee schedule services have been refined since 1999 through the collaborative process between CMS and AMA's Practice Expense Advisory Committee. This represents 87% of fee schedule dollars.

    - In the December 31, 2002 final physician fee regulation CMS addressed comments on our practice expense methodology. We describe how services without physician work are not necessarily biased by our methodology and why modifying the way indirect practice expenses are allocated may not improve payment amounts.

- **NOTE: CMS participated in a GAO entrance conference on 10/23/03 regarding GPCI methods and calculations.**

- CMS is looking forward to working with GAO on this issue and is looking forward to the results of GAO's work. It is possible that Congress will enact changes to the GPCI methodology.

Better Contractor Information to Oversee Improper Payments

***SUMMARY OF ISSUE*:** Oversight has improved in the last few years and several GAO recommendations have been adopted. CERT will provide much needed measure of contractor performance.

CMS Response

The CMS continues to make great progress in calculating national paid claims error rates and estimates of improper claims payment through the Comprehensive Error Rate Testing (CERT) program. We expect to release the 2003 national claims error rate by the end of November. CERT will produce not only the national paid claims error rate, but also contractor, provider type, and service specific paid claims error rates for all claim types except PPS hospitals. CMS' ability to have this level of depth to the error rates will permit us to more effectively target out actions toward error reduction, but to also manage and oversee contractor performance over time. We are currently validating the calculations of our CERT contractor, and reaching cross-component agreements on a CMS error rate reduction plan, to help lower the paid claims error rate. In addition, the Medicare contractors are also developing error rate reduction plans. These plans will address what caused the errors, what contractors are currently doing to fix the problems that caused errors, and contractor recommendations regarding what CMS can do to help lower the error rate.

Balancing Provider Burden Guarding Program Payments

SUMMARY OF ISSUE: Physicians often do not receive complete, accurate, clear, or timely guidance on Medicare billing and payment policies. The CMS acknowledges a need to improve communications with physicians and has undertaken initiatives to improve communications, but has not taken action on GAO's specific recommendations.

CMS Response

The CMS plans to provide a variety of venues for disseminating information to, establishing in-person contact with, and obtaining direct feedback from the physician community. These venues serve as effective outreach, education and development channels for CMS to enhance communication and promote a culture of responsiveness with physicians. Through activities that involve direct interaction with physicians, such as the Open Door Forums and PPAC meetings, CMS is able to quickly respond to issues that might impede their delivery of quality healthcare to our nation's seniors. Other activities, such as the Physician-specific web page, the Medicare Learning Network, the Internet-Based Transaction Pilot and deployment of the Next Generation Desktop (NGD) will make information more readily accessible to the physician community. These efforts help facilitate the effective exchange of information among the physician community. All the planned activities represent CMS' vigorous efforts, on its own accord as well as through its contractors, to communicate with physicians in a thorough, timely and relevant manner through many mediums. These efforts are and will continue to help physicians better understand and conduct Medicare business with CMS and, in turn, will help CMS foster a positive, well-informed business relationship with physicians. All such communication venues essentially amount to an approach that reflect the Agency's efforts to promote a culture of responsiveness with the physician community and it is this multi-faceted effort which remains a key initiative of the Secretary and CMS Administrator. **See detailed plan, attached.**

Major Milestones Include:

Exhibit Program: The Exhibit Program is an effective outreach channel for CMS to enhance communication and promote a culture of responsiveness with physicians. The Program has been extremely well received by the physician community. The Exhibit Program facilitates and ensures the exchange of information between providers and assists CMS in fostering a positive, well-informed business relationship. In coordination with the Regional Offices, PCG/CMM establishes a formal CMS presence at national provider association meetings and conferences throughout the country. Through the Program, we directly distribute information that is crucial to the delivery of medical care to our beneficiaries. CMS also gathers questions and/or concerns at these Exhibits and bring these issues to the Agency to be addressed by an area specialist. This program aids in the clarification of CMS policies and administrative procedures for our association partners and individual providers. This is an ongoing activity that is conducted throughout all quarters of the fiscal year.

Q3/FY03

American Medical Association – 6/19/03

Q4/FY03

Associations of American Indian Physicians – 8/1/03
American Academy of Family Physicians – 8/1/03
National Medical Association – 8/2/03

Q1/FY04

American College of ER Physicians – – 10/15/03

The Medicare Learning Network (MLN): The MLN is the brand name given to education and outreach products and services developed specifically for Medicare providers. It includes information developed in various forms of media, including print materials, videos, and web-based training courses. MLN is supported by the Medlearn web site (cms.hhs.gov/medlearn), which was established to give health care providers one stop shopping for their Medicare educational needs. The web site provides direct links to the physician-specific web pages, access to our web-based training courses, news of upcoming training events, and ordering information for our current educational products.

Q4/FY03

Registration/Product Ordering: This system went on-line in April, 2003, and gives physicians a user-friendly way to register for web-based training (WBT) courses and upcoming educational events. For those courses and events that carry continuing education credits, the system will track which courses the physician (as well as his or her staff that may also be participating in the event or taking the on-line course) has taken and the number of continuing education credits that have been given. The system also provides an easy way to order, free of charge, those educational products available through MLN. These products currently include videotapes on HIPAA and flu billing, as well as brochures on diabetes self-management and power wheelchairs.

Q1/FY04

HIPAA Billing Web-based Training: This is a new WBT module that is currently under development to address the needs of the physician community for using the new electronic billing form required under HIPAA, beginning October 16, 2003.

Q3/FY03

Presentation at National Customer Service Conference for Physicians (June 03): This presentation was done in conjunction with Dr. Ken Simon, who is a Chief Medical Advisor at CMS. The purpose was to give a physician audience information on the resources available through CMS for Medicare education and to explain some of the ways that they can participate in various Medicare rulemaking processes.

Q4/FY03

Consistency contract: This is a contract that will have the contractor develop national articles on various coverage and billing topics that our Medicare contractors will use in their bulletins. This will give physicians and other providers a more consistent national message.

Q2/FY04

Evaluation and Management (E & M) Coding FAQ Product: Educational products address FAQs pertaining to E & M coding. The type of product that will be created will be an FAQ brochure. This has not yet been created because the Qs & As have not been cleared internally. This will hopefully be accomplished by Q2/ FY04. Money for the creation of this product has been allotted in our FY04 budget. The cost will be minimal to create the brochure. The brochure will be placed on the Medlearn website and will be available for downloading by physicians and other interested providers. Hard copies will not be distributed.

Q1/FY04/Q2/FY04

MSP updated materials: Update current educational materials/products to make more user-friendly. Funds and staffing resources have been made available for development of these materials, both in our FY03 and FY04 budgets. We are presently working on four 'Fact Sheets' and are targeting to have them completed in **Q1/FY04.** We plan to expand into the next phase of our MSP 'update' information during **Q2/FY04**; i.e., development of national articles for contractor bulletins as well as a PowerPoint presentation (the audience would be providers, clinical and front office staff). The fact sheets will be available for downloading by physicians and other interested providers via our Medlearn Website. Hard copies will not be distributed.

Q1/FY04

Medicare Billers Guide: Helps physicians' staffs understand Medicare properly and bill correctly the first time. Funding has already been allocated for the Medicare Billers Guide. In Q1/FY04, the brochure will be placed on the Medlearn website and will be available for downloading by Part B providers, including physicians and their respective billing agencies. A limited hard copy distribution will be available as well upon request.

Q3/FY03

ABN Brochure: educational materials to fully explain purpose of ABN (e.g., when it should be used, etc.)

Q4/FY03

HIPAA 101 Satellite Broadcast in July 03': A national broadcast on the basics of HIPAA

Q3/FY03

Physician-specific web page: The physician audience page on the CMS web site, www.cms.hhs.gov/physicians, was developed in concert with the physician community. The information provided assists individual physicians in obtaining specific 'specialty' information more quickly as well as general Medicare information of interest to physicians. Medicare program resources for physicians available from this site include information on the physician fee schedule, participation, enrollment, coverage and payment policies, billing, regulations, education, and much more.

The Physician-specific web page was developed in third quarter of FY03 and continuous changes/improvements are made on an ongoing basis. The web page serves as a useful existing resource for physician community.

Q1/FY04

Links on Physician-specific web page to Medicare Manuals: The physician web page currently has several links to the Medicare manuals as they exist in their present form. However, on October 1, 2003, the Agency is implementing an "Internet-only manual system" and as such, these links on the physician web-page will be consolidated into one new link so the physician community will be able access program information in a much more efficient manner. The establishment of the new link will occur as expeditiously as possible after October 1, 2003.

Q3/FY03

Physician-specific web page tool: The physician-specific web page includes a tool which provides the capability to search pricing amounts, payment policy indicators, RVUs, and GPCIs by a single procedure code, a range of codes, and a list of procedure codes, under the Medicare physician fee schedule. It also allows physicians to search a specific carrier, or a specific carrier locality. The website is www.cms.hhs.gov/physicians/mpfsapp/default.asp.

The Physician-specific web page tool was developed in third quarter of FY03 and updates are made on continuous basis. The tool serves as a useful existing resource for physician community.

Q4/FY03

Posting of National Correct Coding Initiative edits on Physician-specific Web Page: In September 03', CMS will be posting National Correct Coding Initiative edits on the web page. In general, these edits address incompatible procedures and diagnosis codes.

Q4/FY03/Q1
FY04 – 1st pilot
Q3/FY04 – 2nd pilot

Contractor Toll-free lines Integrated Voice Response (IVR) pilot: Implements new technology to increase customer service to physicians. This pilot is exploring the feasibility of a cost saving voice recognition IVR pilot study with two contractors. This will enable CMS to begin development of voice recognition applications to improve the delivering of eligibility and claims status information to legitimate users, which includes the physician community.

Background

The CMS has funded two Medicare carriers to pilot natural language speech recognition on their IVRs. The first of these pilots should be operational early in **Q1 FY04** and the second should be in place no later than **Q3 FY04**. We expect these IVR pilots to improve the quality of answers provided to physicians seeking eligibility or claims information in two ways:

1. This IVR pilot includes speech recognition features that will allow physician callers to speak information in response to questions. Speech will replace the cumbersome entry of alphanumeric information necessary to communicate with earlier IVR applications. Thus, if a physician is seeking eligibility information and is asked to confirm his right to the information by entering the patient's name and HIC#, this process will be easier and less error prone with speech a recognition application.

2. Second, the speech recognition IVR will confirm physician disclosure information and retrieve the answers to physicians' eligibility and claims questions direct from CMS' computer systems. This means that the information will be correct and consistent every time without human intervention.

Another potential benefit of these pilots is that the voice recognition will allow the call center to require more questions to be answered via the IVR, thereby freeing up the CSRs to handle other, more complex questions. Call centers will be able to better focus their CSR training on these complex issues. Continued deployment of the Next Generation Desktop will also facilitate the CSR's ability to access information in a standardized way across all call centers.

Attachment of Detailed Plan

CMM 5a.doc

Attachment (CMM 5c.doc)

Follow-up Review of CMS Response (dated 2/25/02) to February 2002 GAO Report Entitled "MEDICARE – Communications with Physicians Can Be Improved"

Below is a point-by-point response -- in the way of a historical summary & current status with timeframe being from February 2002 to the present -- to all the action-type items mentioned the CMS Response dated 2/25/02 to above-mentioned Report. The Agency Response itself can be found on pp. 30-35 of Report. Please note the clarification points listed below with respect to this document:

1 In reviewing the CMS Response (dated 2/25/02 and on pp. 30-35 of Report), there are numerous areas/sections within the Response that indicate we have either done something, are in process of taking some action, or will be doing something in future - such language exists either within a bullet item, excerpt from a given paragraph or a response to a specific GAO recommendation;

For ease of review/reference:

2. We have extracted from the CMS Response, all such areas/sections and the extracted information is in italics within this document;

3 The grey-shaded heading prior to each item indicates which division(s) in PCG is responsible for a given item;

4. A page number where the item exists in the Report itself is also indicated; and

5 For the most part, we are providing the information (historical summary & current status with timeframe being from February 2002 to the present) in bullet format.

We provide Medicate contractors with in-person instruction and a standardized training manual for them to use in educating physicians, providers, and suppliers on new CMS policy initiatives (e.g., new prospective payment systems). These programs provide consistency and help ensure that our contractors speak with one voice on national issues.

Historical Summary/Current Status (February 2002 to Present)

We continue to recognize that **consistency** is key to successful provider communications. As such, we have in place the following:

- **Trainer (TTT) Education Campaigns:** To ensure that consistent educational information is shared with Medicare providers, CMS' central office has an outside contractor that develops uniform training materials that are used to conduct sessions with Medicare contractors prior to those contractors doing local training of providers. These sessions, namely 'Train-the-Trainer (TTT)' education campaigns for Medicare contactors, typically include a series of conference calls, power point presentations, training guides and other useful training materials. To further ensure consistency of message, ROs also participate in such training sessions.
- **Consistency Contract**: We are continuously developing national educational materials for Medicare contractors and ROs to use in their provider bulletins and other educational campaigns to promote consistency of CMS messages. We recently awarded a contract to significantly increase the number of national articles and other educational materials that are shared with Medicare contractors and ROs. That is, a consistency contract is in place whereby national educational materials are being developed and made available to Medicare contractors and ROs to ensure consistent educational information is provided to Medicare

providers, thereby helping to ensure that a consistent message is delivered on a national basis.

- **Medicare Learning Network (MLN):** There is an overall increased effort to develop educational products to be used on national basis. Specifically, we developed the Medicare Learning Network (MLN), which is a brand name given to education and outreach products and services developed specifically for Medicare providers. It includes information developed in various forms of media, including print materials, videos and web-based training courses. MLN is supported by the Medlearn web site (cms.hhs.gov/medlearn), which has been established to give health care providers one stop shopping for their Medicare educational needs. The web site provides direct links to the physician-specific web pages, access to our web-based training courses, news of upcoming training events and ordering information for our current educational products.
- **Improvement Effort for National Dissemination of Materials:** We have improved our national dissemination methods so that a consistent message reaches a broader yet more targeted audience. Specifically, we have (a) expanded use of the Internet as a provider communication tool by developing a number of provider-specific web pages on the Medicare website at cms.hhs.gov; (b) launched an initiative, namely a provider partnership network with pertinent national associations to open up an ongoing dialogue regarding their educational needs; (c) set up electronic listservs for purposes of communicating important messages quickly to our provider groups; and (d) implemented the expansive Open Door Forums (ODFs) initiative in an effort to be more responsive to the concerns of provider and beneficiary groups.

Via our Satellite Learning Channel, which we launched in November 2001, we provide Medicate contractors with the latest information on contemporary topics of interest. We recently completed the installation of a network of satellite dishes at all contractor call centers to improve or training efforts with contractor customer service representatives.

Historical Summary/Current Status (February 2002 to Present)

As of October 2003, the Satellite Learning Channel's network of satellite dishes includes all contractor call centers as well as 57 Indian Health Service (IHS) facilities. The list below outlines broadcasts that have been aired since February 2002, planned broadcasts for remainder of 2003 and scheduled broadcasts for 2004.

- 2/02 – HIPAA: Introduction to the Administrative Simplification Regulation
- 3/02- Home Health Prospective Payment System
- 4/02 – Ambulance Fee Schedule
- 4/02 – Understanding the Correct Coding Initiative
- 6/02 – HIPAA: Implementing the Administrative Simplification Regulations
- 11/02 – CMS: A Guide for Physicians, Suppliers and Providers
- 1/03 – Kick-off of the CMS Indian Country Satellite Network
- 4/03 – Update on Rapid Testing for HIV
- 5/03 – Clinical Strategies for Insulin Therapy
- 6/03 – Clinical Presentation and Laboratory Diagnosis on Agents of Bioterrorism

- 6/03 – Adult Immunization Update
- 7/03 – HIPAA 101 (basics of HIPAA)
- 7/03 – Holding Up Both Ends of the Sky: Juvenile Justice Partner
- 9/03 – Terrorism: Dealing with Risks and Consequences
- 9/03 – HIV: The Impact on Women
- 10/03 – Sexually Transmitted Diseases & the HIV Connection
- 10/03 – Vaccinate before you Graduate
- 10/03 -- Flu Billing Made Easier
- 10/03 -- Sexually Transmitted Diseases & The HIV Connection
- 11/03 -- Satellite Broadcast Medicare Resident and New Physician Guide
- 11/03 -- Long Term Care
- 11/03 -- HIV Prevention in Care Settings
- 12/03 -- Long Term Care
- 12/03 -- Cardiac Markers Presenter Allan Jaffee
- 12/04 -- Diabetes: Research on Diabetes Prevention
- 2/04 -- Understanding the GPNET Online
- 3/04 -- Medicare Part B and RPMS TPB- Billing Errors and How to Solve Them
- 4/04 -- How Tribal Communities Can Benefit from Medicare
- 5/04 -- Satellite Broadcast Medicare Resident and New Physician Guide
- 6/04 -- A Guide to Physicians and Suppliers
- 7/04 -- Medicare Resident and New Physician Guide Satellite RE-Broadcast
- 8/04 -- Prevention
- TBD/04 -- RPMS Patient Registration Version 7.0 – Highlights

We now have a program for monitoring the training sessions conducted by our contractors so that we can obtain feedback from providers and work collaboratively to find new ways of communicating with them.

Historical Summary/Current Status (February 2002 to Present)

- When we issued our manual instructions regarding contractor provider communications in January 2003, we included a requirement that contractors must include an evaluation tool at the end of every educational program.
- When CMS performs a CPE, these evaluations are reviewed to ensure that they were provided during the sessions and that the contractors used the information as they developed future programs.

"We are in the process of re-evaluating Medicate contractor bulletins and other communications with providers, and have taken steps to standardize and make more consistent the information contained in contractor bulletins by developing national information articles on significant Medicate policies."

Historical Summary/Current Status (February 2002 to Present)

To help ensure consistency in communications:

- **Consistency Contract**: We are continuously developing national educational materials for Medicare contractors and ROs to use in their provider bulletins and other educational campaigns to promote consistency of CMS messages. We recently awarded a contract to

significantly increase the number of national articles and other educational materials that are shared with Medicare contractors and ROs. That is, a consistency contract is in place whereby national educational materials are being developed and made available to Medicare contractors and ROs to ensure consistent educational information is provided to Medicare providers, thereby helping to ensure that a consistent message is delivered on a national basis.

- New communication products have been and are continuing to be developed regarding changes in, and newly implemented, Medicare policies and regulations. A range of communication products are continually being developed that are subsequently used by carriers and intermediaries in their bulletins, websites, and any other provider education/training vehicles available. Specifically:
  - We are developing and producing plain language materials (e.g., brochures, pamphlets, and other media used to disseminate information to providers.
  - To date, we have successfully developed brochures on the topics listed below as well as three "plain language" fact sheets regarding the Long Term Care Hospital Prospective Payment System.
    - Advanced Beneficiary Notice (ABN)
    - Diabetes Awareness
    - Glaucoma Screening
    - Power Wheelchairs

"Over the past year, CMS has made it a practice to make available a list of Web-Based, frequently asked questions (FAQs) for major Medicare program initiatives, which are publicly available to all providers over the Internet."

Historical Summary/Current Status (February 2002 to Present)

Improvement Effort for National Dissemination of Materials: We have improved our national dissemination methods so that a consistent message reaches a broader yet more targeted audience. Part of this effort includes the expanded use of the Internet as a provider communication tool by developing a number of provider-specific web pages on the Medicare website at cms.hhs.gov. Each of these pages contains a direct link to pertinent FAQs.

- With regard to provider-specific web pages, eight new provider web pages have been developed for ambulance, long-term care hospitals, Medicare drugs, telehealth, hospitals, National Correct Coding edits, Durable Medical Equipment and Practice Administration. Seven web pages have been revised to improve content and navigability (physician, hospital inpatient, hospital outpatient, MedLearn, Home health, end stage renal disease and ambulatory surgical centers. Additionally:
  - Three web pages (skilled nursing facility, hospice, and federally qualified health centers) will be updated by November 15, 2003.
  - A new web page for Rural health will be posted by November 15, 2003.
  - A web page for EMTALA will be developed by the end of CY 2003.
  - We plan to explore with our internal and external partners the need for additional provider/supplier specific web pages.

The FAQs are maintained in the Right Now database web tool on the CMS website. We now have expiration dates on the FAQs to keep them timely and provide for continual review by FAQ owners. In November 2002, revisions and deletions were made to over 100 of the physician and PPS FAQs on the database. Also:

- Beginning in October 2002, with the development of our new provider audience pages and the revision of existing ones, we link to FAQs specific to that audience for easy reference and accessibility.
- In the revised template for the CMS Internet page cms.hhs.gov, FAQs continue to be linked from a menu bar right under the CMS heading for quick reference when accessing the home page.
- We plan to improve the FAQ categories for easier selection and to increase the use of FAQs by our subject matter experts.
- "We have established electronic listservs on priority initiatives that have enabled us to keep thousands of subscribers informed about the latest Medicare changes. We expect to continue these practices for future significant initiatives, as well as investigate the feasibility of developing a new system to capture, compile, and index FAQs."

Historical Summary/Current Status (February 2002 to Present)

Improvement Effort for National Dissemination of Materials: We have improved our national dissemination methods so that a consistent message reaches a broader yet more targeted audience. Part of this effort includes (a) launching an initiative, namely a provider partnership e-mail distribution list which will build a provider partnership network with pertinent national associations to open up an ongoing dialogue regarding their educational needs; (b) setting up of electronic listservs for purposes of communicating important messages quickly to our provider groups; and (c) improving the categorization and accessibility of FAQs.

The provider partnership network builds a provider partnership network with pertinent national associations. The goal of the partnership is to make associations (and thus its members) aware of the various educational materials and services that are available from CMS, get feedback as to the information and educational needs of specific provider types, and have the associations assist us in disseminating provider communications via use of e-mail distributions. Also:

- We are developing a Provider Partnership Directory database to assist us in forwarding relevant CMS provider information to these partners on an on-going basis.
- We have been contacting additional associations to expand our contact base and to schedule individual, in-person meetings.
- We are continuing to populate our Provider Partnership Directory database to identify additional contacts.
- Since October, 2002, we have developed three new listservs: physicians, ambulatory surgical centers, and ESRD, in addition to the provider listservs that already exist: CMHC, home health, inpatient rehabilitation facility PPS, and OPPS.
- We use our listservs to communicate important messages quickly to our provider groups. Examples of messages sent include notice of the posting of proposed regulations,

announcement of the satellite broadcast on "Building Caregiver Coalitions, notice of the press release on the Medicare Electronic Transactions Contingency Plan.

- Also, our FAQs are currently maintained in a web tool called RightNow. We are looking to make enhancements to this tool to improve the categorization of the FAQs for easier accessibility.

An Open Door Forum (ODF) ListServ has been set up so all providers have the opportunity to join this ListServ to receive notification of upcoming ODFs. CMS currently maintains a list of 9,500 and growing ODF listservs.

- "We provide a variety of resources, such as Reference Guides, FAQs and Computer-Based Training courses, online at the Medicare Learning Network homepage, www.hcfa.gov/MedLearn.htm. Medlearn provides timely, accurate, and relevant information about Medicate coverage and payment policies, and serves as an efficient, convenient provider education tool."

Historical Summary/Current Status (February 2002 to Present)

Medicare Learning Network (MLN): There is an overall increased effort to develop educational products to be used on national basis. Specifically, we developed the Medicare Learning Network (MLN), which is a brand name given to education and outreach products and services developed specifically for Medicare providers. It includes information developed in various forms of media, including print materials, videos and web-based training courses. MLN is supported by the Medlearn web site (cms.hhs.gov/medlearn), which has been established to give health care providers one stop shopping for their Medicare educational needs. The web site provides direct links to the physician-specific web pages, access to our web-based training courses, news of upcoming training events and ordering information for our current educational products.

Some of our current MLN activities include the following:

- **Registration/Product Ordering:** This system went on-line in April 2003, and gives physicians a user-friendly way to register for web-based training (WBT) courses and upcoming educational events. For those courses and events that carry continuing education credits, the system will track which courses the physician has taken and the number of continuing education credits that have been awarded. The system also provides an easy way to order, free of charge, those educational products available through MLN. These products currently include videotapes on HIPAA and flu billing, as well as brochures on diabetes self-management and power wheelchairs.
- **HIPAA Billing web-based training**: This is a new WBT module that is currently under development to address the needs of the physician community for using the new electronic billing form required under HIPAA, beginning October 16, 2003.
- **Presentation at National Customer Service Conference for Physicians (6/03):** This presentation was done in conjunction with Dr. Ken Simon, Chief Medical Advisor at CMS. The purpose was to give a physician audience information on the resources

available through CMS for Medicare education and to explain some of the ways that they can participate in various Medicare rulemaking processes.

- "We recently established a National Physician and Provider Organization Exhibit Program designed to disseminate information from CMS to physicians and providers at various professional conferences held throughout the country."

Historical Summary/Current Status (February 2002 to Present)

The Exhibit Program is an effective outreach channel for CMS to enhance communication and promote a culture of responsiveness with the provider community. The Exhibit Program facilitates and ensures the exchange of information between providers and assists CMS in fostering a positive, well-informed business relationship. This is an ongoing activity that is conducted throughout all quarters of the fiscal year. Listed below are exhibits conducted between February 2002 and November 2003:

	2002
• HIPAA Conference	Feb. 11-13,02
• American Dietetic Association	Feb. 12-14
• American Medical Group Association	Feb. 20-23
• American Association for Home Care	Feb. 20-22
• Federation of American Hospitals	Mar. 3-6
• American Pharmaceutical Association	Mar. 15-19
• American Academy of Hospice & Palliative Medicine	Mar. 21-23
• National Hispanic Medical Association	Mar. 22-23
• Renal Physicians Association	Mar. 23-24
• American Health Lawyers Association	April 3-5
• American Society of Internal Medicine	April 11-14
• National Kidney Foundation	April 17-21
• Visiting Nurses Association	April 24-26
• National Rural Health Association	May14-17
• American Psychiatric Association	May18-23
• American Society of Colon & Rectal Surgery	June 4-8
• American Physical Therapy Association	June 5-8
• American Nurses Association	June 29-July2
• National Association of Hispanic Nurses	July 17-19
• Association of American Indian Physicians	August 1-6
• National Medical Association	August 4-6
• National Hospice & Palliative Care Org.	Sept. 10-12
• Congress of Neurological Surgeons	Sept. 21-26
• LifeSpan	Sept. 22-24
• American Academy of Otolaryngology	Sept. 22-25
• National Renal Administration Association	Oct. 9-12
	2003
• American Health Lawyers	Jan. 23-24
• American Society of Aging	Mar. 13-16
• Federation of American Hospitals	Mar. 18-21
• American Medical Student Association	Mar. 19-22
• National Hispanic Medical Association	Mar. 21-23
• Renal Physicians Association	Mar. 22-24
• American Pharmaceutical Association	Mar. 28-Ap1
• American College of Cardiology	Mar. 30-Ap2

• American Health Lawyers	April 2-4
• American Academy of Audiology	April 3-5
• American College of Physicians	April 3-5
• National Association of Psychiatric Health Systems	April 6-8
• National Hospice & Palliative Care Org	April 10-12
• American Geriatrics	May 14-18
• American Psychiatric Association	May 17-22
• American Academy of Physician Assistants	May 22-27
• American Diabetes Association	June 13-17
• American Medical Association	June 14-19
• American Academy of Nurse Practitioners	June 28-Jul3
• Association of American Indian Physicians	Aug. 1-6
• National Medical Association	Aug. 2-4
• American Academy of Family Physicians	Oct. 2-5
• American Psychiatric Association	Oct. 30-Nov2
• Southern Medical Association	Nov. 6-8
• American Public Health Association	Nov. 15-19

DPRE staff are in process of developing the 2004 Exhibit schedule, incorporating local, regional and national associations to further disseminate information from CMS to physicians and providers. Listed below is a tentative 2004 exhibit schedule, pending budget and other approvals:

	2004
• American Academy of Hospice & Palliative Care	Jan. 22-25
• National Council for Prescription Drug Program	Feb. 28-Mar3
• American College of Cardiology	Mar. 7-10
• Renal Physicians Association	Mar. 20-22
• American Pharmaceutical Association	Mar. 26-30
• American College of Physicians	April 22-24
• National Rural Health Association	May 26-29
• American Diabetes Association	June 4-8
• American Medical Association	June 12-16
• American Nurses Association	June 25-30
• National Medical Association	July 31-Aug5

"Eleven Open Door Forums were established in August 2001 for virtually every physician and provider type that participates in the Medicate program. Regularly held listening sessions are being conducted throughout the country to allow us to hear directly from physicians and health care providers about what it's like to live and work every day under the rules we develop."

Historical Summary/Current Status (February 2002 to Present)

- The Open Door Forums (ODFs) are monthly and bi-monthly calls to the physicians and providers.
- The monthly ODF calls include:
  - ⇔ Physician
  - ⇔ Hospital & Quality Initiative
  - ⇔ Home Health, Hospice, DME

- ⇔ Rural Health
- ⇔ Skilled Nursing Facilities/Long Term Care

- The bi-monthly calls include:
  - ⇔ Nurses & Allied Health Professionals
  - ⇔ Pharmaceutical, Pharmacy, & Device Manufactures
  - ⇔ Disability
  - ⇔ Diversity
  - ⇔ End-Stage Renal Disease & Clinical Laboratories
  - ⇔ Health Plans
- Since the start of the ODF, there have been 3 new forums. These forums include:
  - ⇔ New Freedom Initiative (monthly)
  - ⇔ Ambulance (bi-monthly)
  - ⇔ Low-Income Health Access (bi-monthly)
- To allow for additional CMS communication with physicians, provider types and stakeholders regarding special topics such as new policy regulations, press releases, etc., Special forums were established. These Special forums were held as special issues arose for needed discussion.
- Listed below are all of the forums since January of 2002. Important findings are as follows:
  - ⇔ There has been a 415 percent increase in participation in the forums.
  - ⇔ There has been a 145 percent increase in the number of forums.
  - ⇔ There has been a 750 percent increase in the number of special forums.
  - ⇔ There are over 9,000 participants registered to the Open Door Forum ListServs.

FY 2002 Open Door Forums

Note: This Forum information begins in January 2002. The Participant information begins in May of 2002

Forum	**Total Forums**	**Total Participants**	
		Face-to-Face	**Online**
Disability	5	28	42
Diversity	2	5	14
End-Stage Renal Disease (ESRD)	3	145	188
Health Plan	6	54	259
Home Health, Hospice, DME	9	79	359
Hospital	8	91	979
Pharmaceutical, Pharmacy, & Device Manufactures	5	35	76
Nurses & Allied Health	5	31	90
Physician	9	36	546
Rural Health	8	43	484
Skilled Nursing Facility/Long Term Care	9	77	439
Totals	69	624	3476
Total Open Door Forum Participants	**4100**		

FY2002 Special Open Door Forums

Forum	Total Forums	Total Participants	
		Face-to-Face	Online
Low-Income Health Access	1	80	110
Group Billing Therapy	1	70	772
Totals	2	150	882
Total Special Open Door Forum Participants:	1032		
Total Open Door Forum and Special Open Door Forum Participants:	**5132**		
Total Open Door Forums and Special Open Door Forums:	**71**		

FY 2003 Open Door Forums

Forum	Total Forums	Total Participants	
		Face-to-Face	Online
Ambulance	2	0	340
Disability	5	5	81
Diversity	4	56	123
End-Stage Renal Disease (ESRD)	5	183	560
Health Plan	5	64	276
Home Health, Hospice, DME	10	95	1938
Hospital	12	144	3082
Low-Income Health Access	4	128	332
New Freedom Initiative	5	39	754
Pharmaceutical, Pharmacy, & Device Manufactures	6	46	368
Nurses & Allied Health	7	68	181
Physician	12	642	2418
Rural Health	11	168	1017
Skilled Nursing Facility/Long Term Care	12	176	1793
Totals	100	1814	13263
Total Open Door Forum Participants	**15077**		

FY2003 Special Open Door Forums

Forum	Total Forums	Total Participants	
		Face-to-Face	Online
DME	1	10	58
Special OPPS:			
Hospital	1	26	614
Pharmacy	1	46	307
Physician	1	15	255
Manufactures	1	21	246
Press Conference	1	0	21

Special Hospice	1	6	197
Special Home Health Quality Initiative	1	46	700
PACE	1	20	101
Special Forum on Grijalva Case	1	1	251
Hospital	1	20	329
Special Hospital	1	3	195
Special Therapy Cap	1	15	916
Special DME	1	18	140
Special HIPAA	1	54	1613
Special Forum on Wheelchairs	1	60	228
Special Critical Access Hospitals	1	23	411
Special Hospice	1	100	208
Totals	18	484	6790
Total Special Open Door Forum Participants:	**7274**		
Total Open Door Forum and Special Open Door Forum Participants:	**22351**		

- "Strengthening of the operational support of the Practicing Physician Advisory Council, which plays a key role as a Federal Advisory Committee Act-compliant advisor body, is assisting CMS in identifying issues challenging practicing physicians."

Historical Summary/Current Status (February 2002 to Present)

Consistent with statutory requirements, PPAC meetings have been held quarterly since February 2002, and new administrative procedures have been adopted to improve the effectiveness of the meetings, as follows:

- Satisfaction surveys are now being conducted on a yearly basis through GSA to ascertain Council member feedback on the effectiveness of the Council. CMS has benchmarked another advisory council (RHAC) to identify processes or practice improvement ideas to increase the efficiency and effectiveness of the Practicing Physicians Advisory Council (PPAC).
- CMS implemented new operating procedures in which CMS components respond to all recommendations by the next scheduled meeting (when feasible) with a response of adopt, adopt with change or not adopt. If the recommendations are not responded to at the next meeting, the item remains on the status and update list as old business until a response is given.
- Policy and operational staff are present at all PPAC meetings, which allows them the opportunity to hear directly from PPAC regarding issues that affect practicing physicians.
- Recent changes have been implemented regarding meeting agendas being set for items that are in the proposed, or open for comment phases in which PPAC could provide CMS with useful information on issues affecting practicing physicians. CMS also queries the PPAC members and conducts regular conference calls with the Chair of the Council to obtain agenda items that the members feel are relevant issues to be discussed at meetings.
- Meeting procedures have been revised to an "old business" and "new business" format which assists the Council Chairman to have a more smooth flow of agenda items,

meeting flow and recommendations. The meeting reporter is available to reiterate any statements needed in real time, which also supports smooth operating procedures.

- Council members receive all materials for their meetings via e-mail well enough in advance to review and prepare for meetings.
- CMS is being proactive with new Council members in terms of bringing them to meetings before being sworn in for purposes of observing the dynamics of meetings. They also receive a binder that contains FACA information, PPAC Reports spanning 1 year, reimbursement information, useful phone numbers, Council member list and agency organizational grids.

"This year we are establishing plans for a customer satisfaction survey and focus group program in order to advance our initiative for obtaining physician/provider/ supplier input to their customer service needs."

Historical Summary/Current Status (February 2002 to Present)

- A Medicare Contractor Provider Satisfaction Survey instrument will be used to assess providers' satisfaction with professional interactions and overall perception with our Medicare contractors.
- The survey will address diverse Medicare business functions at the individual contractor level [e.g., provider communication (formerly provider education and training), claims processing, provider inquiries, appeals, provider enrollment, medical review and provider reimbursement].
- Formative studies were conducted with providers from diverse provider types and geographical areas and survey questions were developed.
- Validation testing was performed in six (6) regional offices with different provider types and the survey and its scoring mechanism were tested and explored for efficacy and applicability.
- The survey was submitted to the Office of Management and Budget; and it was published in the Federal Register on 10/3/03 and we anticipate approval by mid March 2004.

Completed Projects

Q1&Q2/03	Formative Studies with physicians, providers, and suppliers
Q2/03	Development of 1st draft survey
Q3/03	Development of 2nd draft survey
Q4/03	- Validation Testing with physicians, providers, and suppliers
	- Development of 3rd draft survey
	- Development of survey instrument and methodology for administration
	- Preparation of packet and submission to Office of Management & Budget (OMB)
	- Published on Federal Register

Projected Projects*

Q2/04	- Obtain OMB clearance
	- Selection of pilot sample commences
Q3/04	- Pilot Launch; information to local, state, and national associations/organizations
	- Sample selection completed
	- Survey field period begins/pre-notification letters
	- Letter with URL, ID, and password numbers for survey participation are -sent
	- Follow-up postcard or telephone calls are originated
Q4/04	- Survey field period ends
	- Submission of draft report of results
	- Submission of final report

- Preparation and submission of OMB packet for full administration of -survey (after completion and analysis of pilot survey results)

*The preceding FY 04 dates are estimates, and should only be understood as anticipated completion dates.

We agree with GAO about the importance of accurate and consistent answers to provider inquiries and this past year we implemented a new program of performance standards, including more effective oversight and evaluation. We have quality call monitoring procedures, contractor guidelines, and performance standards in place to ensure that contractors know what is expected and so that we can be satisfied that the contractors are meeting/exceeding our expectations. We also want to know about the issue and misunderstandings that most affect provider satisfaction with our call centers so that we can provide our customer service representatives with the information and guidance to make a difference. We are exploring various feedback mechanisms and contractor profiling to obtain this information.

Historical Summary/Current Status (February 2002 to Present)

Quality Call Monitoring (QCM):

- **Summer 2001:** Formed a workgroup of contractor and CMS RO and CO staff to review and revise the Quality Call Monitoring (QCM) process. The scorecard and chart was split into three distinct sections -- Adherence to the Privacy Act, Customer Skills Assessment and Knowledge Skills Assessment. Separate categories and scores provides a clearer indication of a CSR's performance relative to an individual skill and allows for an immediate and focused coaching session. The new tools were tested throughout Fall 2001 and rolled out to the call centers in February 2002.
- **Summer 2002:** Created a QCM Manual that explains the QCM process in detail.
- **Fall 2002:** Began working with SAIC to develop a web-based database where the call centers would enter the data collected through the QCM process. Having every call center's data available on the web allows CMS near real-time access to monitor and take action with centers that may be experiencing problems related to the accuracy of information provided.
- **Fall 2003:** Formed a workgroup of contractor and CMS staff to revise the QCM chart. The chart was updated to address issues that arise in the call center related to reviewer subjectivity. The new chart was effective October 2003. The group also updated the QCM database Users Manual.

Additionally:

- **Summer 2003** - The ROs began to conduct remote monitoring of the provider call centers. As they identified problems through this monitoring, they worked with the call center to address the problem.
    - ⇔ Status: This monitoring will continue at least through March 2004. In November 2003, CO staff will also do some remote monitoring.

- **Summer/Fall 2003** – Working to make the provider supplier service plans (PSPs) and the companion quarterly update reports more useable for the ROs and for CO to use to identify training needs for providers and customer service representatives.
    - ⇔ Status: A database is almost complete. Also working to establish a standardized format for PSPs as well as a standardized method to report the most frequent inquiries received. This information will allow CMS to better identify areas that are appropriate for national training materials for providers and customer service representatives, national FAQs, and areas where responses can be automated.
- Current Status: In FY04, we plan to use a provider satisfaction survey to help identify areas for improvement. This survey implementation is dependent upon OMB clearance.

"Because our physician and provider education, outreach, and customer service activities are relatively new, we do not yet have outcome measures to demonstrate that what we are doing is effective. While we are implementing tools to measure the impact of our interventions (e.g., a Quality Call Monitoring Scorecard and Customer Service Representative standards), we will not be able to objectively measure the effect of those interventions until we are farther down the road. We believe, however, that we are doing the right things and are optimistic that these activities will improve our communication with physicians and other providers and suppliers."

Historical Summary/Current Status (February 2002 to Present)

- In FY 03, PCG convened a technical evaluation panel to develop outcome measures for provider communication and customer service activities. The final product was delivered in October 2003.
- We plan to use many of the TEP measures as part of the FY04 incentive pilot. The metrics are still under negotiation with the contractors. The incentive pilot will allow CMS to determine whether the measures are useful in the real world to demonstrate the effectiveness of provider communication activities.
- In March 2003, we solicited proposals from contractors for our e-bulletin initiative. This initiative allows contractors to stop issuing paper bulletins and replace them with electronic methods of information dissemination. Most of them began in the third quarter of FY03. At present, there are 27 contractors who are participating in this initiative, representing 39 different contracts (FI, carrier, DMERC). We will evaluate the success of this initiative in November/December 2003 and determine whether or not to expand it further.

"We appreciate GAO's recognizing that our resources are limited. Many of the observations and suggestions contained throughout the report represent initiatives CMS would gladly undertake if it had the resources to do so. We are doing a lot with the resources we have and will continue to seek additional resources. In the meantime, we continue to examine ways to use our existing resources in creative ways, such as making greater the use of the Internet, other e-commerce tools, and other media, as a way of improving the ways in which we share information with, and receive information from, physicians and other providers and suppliers."

Historical Summary/Current Status (February 2002 to Present)

So as to maximize the use of technology-based educational initiatives, we have been

targeting information content to different types of providers, including non-physician providers and suppliers of care. The following web-based training (WBTs) courses (can be classified as 'other media') are now available on the Medlearn web site and are illustrative of this initiative:

- World of Medicare
- Front Office Management
- Medicare Home Health Benefit
- Diagnosis Coding: Using the ICD-9-CM
- Adult Immunization
- Medicare Secondary Payer

- **FY 2003:** Provided funding for Contractor Toll Free lines Integrated Voice Response (IVR) pilots (can be considered as 'other media') at Empire and Trailblazer. These pilots will utilize automated speech recognition IVR technology to improve customer service, increase the use of their IVRs and offer automated beneficiary eligibility information and other services for providers.
- Current Status: Empire IVR will begin operation in November, 2003; and Trailblazer IVR will begin operation in second quarter of FY04

We have made significant progress towards our goal of consolidating links to all relevant material on individual provider-specific audience web pages (can be classified as 'use of internet'). The following web pages have been either created or revised since September 2002:

- Physician Regulatory Issues Team page – revised and updated 9/18/02
- Ambulance - created 10/15/02
- Long Term Care Hospital - created 11/25/02
- Drug Web Page – created 1/23/03
- Physicians Information Resource Page – extensive revision 3/21/03
- Telehealth - created 3/21/03
- Hospital Inpatient – revised 4/10/03
- Hospital Outpatient - revised 4/10/03
- Critical Access Hospital - created 4/10/03
- Hospital (Inpatient Rehabilitation Facilities) – revised 4/10/03
- Hospital Home page – created 4/10/03
- Home Health – revised 5/30/03
- Durable Medical Equipment page – created 8/20/03
- National Correct Coding Edits page - created 9/2/03
- Ambulatory Surgical Centers page – created 9/5/03
- Medicare Home page – revised 9/12/03
- End stage renal disease page – revised 9/30/03

We will soon be posting a new Rural Health page and revising two existing pages, namely Skilled Nursing Facility and Hospice.

Also, in August 2003, we started a six-month Internet Based Transaction Pilot with WPS to test the feasibility of providing eligibility and claims status data to providers over the Internet. Implementation of this pilot required extensive work with OIS and WPS to address internet security issues.

NOTE: The 'e-bulletin initiative' and 'listservs', which qualify as 'use of internet' are addressed elsewhere in this document. Similarly, our 'provider partnership e-mail distribution list' which can be considered an 'e-commerce tool' is also discussed in detail elsewhere in this document.

GAO Recommendation

Assume responsibility for the publication of a national bulletin, for providers, in addition to issuing a quarterly compendium of regulations. Carriers would be responsible for preparing supplements to CMS' national bulletin regarding local medical policy issues."

CMS Response

The CMS is very interested in making the information that is furnished to physicians, providers and suppliers as useful, clear, and understandable as possible. To this end, CMS has taken steps to "nationalize" information contained in contractor bulletins and newsletters sent to physicians, providers, and suppliers. Often, CMS has developed national information articles on significant Medicare policies, programs, or issues. These articles are carefully written to be lucid and comprehensible and to effectively communicate with the target audience. These national articles are distributed to all Medicate contractors who are instructed to publish them in their next provider bulletins.

Historical Summary/Current Status (February 2002 to Present)

To help ensure consistency in communications:

- **Consistency Contract**: We are continuously developing national educational materials for Medicare contractors and ROs to use in their provider bulletins and other educational campaigns to promote consistency of CMS messages. We recently awarded a contract to significantly increase the number of national articles and other educational materials that are shared with Medicare contractors and ROs. That is, a consistency contract is in place whereby national educational materials are being developed and made available to Medicare contractors and ROs to ensure consistent educational information is provided to Medicare providers, thereby helping to ensure that a consistent message is delivered on a national basis.
- **Medicare Learning Network (MLN):** There is an overall increased effort to develop educational products to be used on national basis. Specifically, we developed the Medicare Learning Network (MLN) which is a brand name given to education and outreach products and services developed specifically for Medicare providers. It includes information developed in various forms of media, including print materials, videos and web-based training courses. MLN is supported by the Medlearn web site (cms.hhs.gov/medlearn), which has been established to give health care providers one stop shopping for their Medicare educational needs. The web site provides direct links to the physician-specific web pages, access to our web-based training courses, news of upcoming training events and ordering information for our current educational products.

"Additionally, for fiscal year (FY) 2002, CMS is planning a National Provider Bulletin Project. The project will be used to determine the practicality of establishing a national source for the information and material included in provider bulletins while also allowing for the communication of local contractor concerns. The effort will also evaluate the publication and distribution process for the bulletin."

Historical Summary/Current Status (February 2002 to Present)

The ROs have historically each publicly done their own newsletter but in FY03, they've undertaken the planning of a national newsletter. In light of RO efforts to publish a national newsletter, CMS central office will focus its attention to overall consistency of education materials, as described below:

- **Trainer (TTT) Education Campaigns:** To ensure that consistent educational information is shared with Medicare providers, CMS' central office has an outside contractor that develops uniform training materials that are used to conduct sessions with Medicare contractors prior to those contractors doing local training of providers. These sessions, namely 'Train-the-Trainer (TTT)' education campaigns for Medicare contactors, typically include a series of conference calls, power point presentations, training guides and other useful training materials. To further ensure consistency of message, ROs also participate in such training sessions.

- **Consistency Contract**: We are continuously developing national educational materials for Medicare contractors and ROs to use in their provider bulletins and other educational campaigns to promote consistency of CMS messages. We recently awarded a contract to significantly increase the number of national articles and other educational materials that are shared with Medicare contractors and ROs. That is, a consistency contract is in place whereby national educational materials are being developed and made available to Medicare contractors and ROs to ensure consistent educational information is provided to Medicare providers, thereby helping to ensure that a consistent message is delivered on a national basis.
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- **Improvement Effort for National Dissemination of Materials:** We have improved our national dissemination methods so that a consistent message reaches a broader yet more targeted audience. Specifically, we have (a) expanded use of the Internet as a provider communication tool by developing a number of provider-specific web pages on the Medicare website at cms.hhs.gov; (b) launched an initiative, namely a provider partnership network with pertinent national associations to open up an ongoing dialogue regarding their educational needs; (c) set up electronic listservs for purposes of communicating important messages quickly to our provider groups; and (d) implemented the expansive Open Door Forums (ODFs) initiative in an effort to be more responsive to the concerns of provider and beneficiary groups.

  - In March 2003, we solicited proposals from contractors for our e-bulletin initiative. This initiative allows contractors to stop issuing paper bulletins and replace that activity with electronic methods of information dissemination. Most of them began in the third quarter of FY03.
  - There are 27 contractors participating representing 39 different contracts (FI, carrier and DMERC). We will evaluate the success of this initiative in November/December 2003 to determine whether to expand it further. The methods of dissemination used by the contractors range from increased promotion of their Websites to CD-ROMs issued on a periodic basis.

GAO Recommendation

Establish new performance standards for carrier call centers that emphasize providing complete and accurate answers to physician inquiries. Carriers' monitoring of their carrier call center

operations should also be expanded to assure that these performance standards and policies are followed.

CMS Response

As previously stated, we agree with the need to focus on improving the quality of our provider customer service. Last year, our Medicate contractors received 24 million telephone calls from physicians and providers, and it is imperative that the contractors provide timely, correct, and consistent answers. We have several initiatives underway to address this need:

Historical Summary/Current Status (February 2002 to Present)

- **Summer 2001:** Formed a workgroup of contractor and CMS RO and CO staff to review/revise the Quality Call Monitoring (QCM) process. The scorecard and chart was split into three distinct sections -- Adherence to the Privacy Act, Customer Skills Assessment and Knowledge Skills Assessment. Separate categories and scores provide a clearer indication of a CSR's performance relative to an individual skill and allows for an immediate and focused coaching session. The new tools were tested throughout Fall 2001 and rolled out to the call centers in February 2002.
- **Spring of 2002:** With the help of call center industry experts, we created five training videos on various topics of interest for the call centers. One video focused on how to calibrate within the call center. Local calibration ensures increased objectivity among the reviewers in a call center. This allows management to more easily determine areas where CSRs may need increased training.
- **Fall 2002:** Began working with SAIC to develop a web-based database where the call centers would enter the data collected through the QCM process. Having every call center's data available on the web allows CMS near real-time access to monitor and take action with centers that may be experiencing problems related to the accuracy of information provided.
- **Summer 2003:** Where technology allowed, CMS ROs began remotely monitoring provider call centers to assess the accuracy and completeness of the information provided. The reviews are based on a common scorecard designed by CMS.
- **Fall 2003:** All call centers are required to provide remote access to their call centers. This will allow the ROs to remotely monitor all provider call centers.
- Current Status: Began working with SAIC to survey the current remote monitoring practices among government and private organizations. The results of this study will form a baseline of best practices and will be used to design a strategy for remotely monitoring CMS' Medicare provider call center services.

Contractor Performance Evaluation (CPE) Reviews. *We have performance standards, quality call monitoring procedures, and contractor guidelines in place to ensure that contractors know what is expected and so that we can be satisfied that the contractors are reaching our expectations. For the FY 2001 period and for the first time, Medicare contractors' physician and provider telephone customer service operations were reviewed against these standards and procedures separate from our review of their beneficiary customer service. During these weeklong CPE reviews, we identify areas that need improvement and "best practices" that can*

be shared among our other Medicare physician and provider call centers. As a result of the reviews, performance improvement plans will be instituted when needed, and CMS staff in our Regional Offices will continue to monitor the specific contractor throughout the year. Separate from the CPE reviews, the Medicate Contractor Consortium Management Officers, responsible for each contractor, perform regular reviews throughout the year, including a check on the contractors' provider customer service.

Historical Summary/Current Status (February 2002 to Present)

- **Fall 2002:** Developed a revised CPE protocol that focuses heavily on validating the QCM findings reported to CSAMS. This includes listening and scoring calls to verify the accuracy of the reviewer's score.
- **Fall 2002:** Added instructions on the development of working papers to the CPE protocol. Well-organized working papers substantiate the findings of the review team and provides a wealth of information about the contractor's operation to those who did not participate in the review.
- **Fall 2003:** Developing a desk review protocol that will be used by the ROs to formally review all contractors that were not part of a National Review each fiscal year.
- Conducted the following eight CPE provider inquiry reviews since fiscal year 2002:
    - Cigna DMERC--2002
    - Administar DMERC--2002
    - Health Now DMERC--2002
    - Palmetto DMERC--2002
    - BCBS of Montana--2002
    - UGS--2002
    - BCBS of Arkansas--2003
    - BCBS of Georgia--2003
    - Administar DMERC—2003

Desktop Initiative *We have begun a modernization program that gives the Medicare contractor customer service representatives, who handle physician/provider inquiries, state-of-the-art desktop tools to enable improved responsiveness in handling telephone inquiries and combine this technology upgrade with the development of standardized resource materials and training for those customer service staff.*

Historical Summary/Current Status (February 2002 to Present)

- We have begun to deploy the Next Generation Desktop (NGD) at Medicare contractor sites. Release 1 is specifically for DMERCs. Release 2 adds Part B functionality and contains some amendments to correct identified issues.
- The long-range goal of the NGD is to allow customer service representatives to answer written, telephone, and walk-in inquiries from both providers and beneficiaries in a user friendly and efficient manner, availing themselves of quick access to timely claims processing information.
- AdminiStar Federal is the contractor developing the NGD.
- Deployment has been completed for telephone inquiries at AdminaStar Federal for their DMERC, Part B and Part A workloads.
- Deployment has been completed at the HealthNow DMERC.
- Deployments in the upcoming months (October 2003 onward) include:
  -Trailblazer
  -Palmetto
  -HGSA
  -Anthem East
  -UGS
  -First Coast

Quality Call Monitoring (QCM) Procedures. *We have recently formed Central Office/Regional Officer/contractor workgroups to review the contractor performance standards, QCM scorecard, QCM criteria chart, and the monthly telephone data reporting processes, and make changes to tailor them to the needs of physicians, providers and suppliers. The QCM workgroup made significant changes in the wording of monitoring criteria and in the weighting of segments of the scorecard to increase its relevance for monitoring provider calls. The scorecard was tested throughout October and early November 2001, and was implemented on a national level beginning December 2001. There are two separate overall scores for the QCM. The first addresses "soft skills" (common to all customer service operations), and the second addresses "accuracy/completeness." This allows for more directed coaching sessions and service improvement.*

Historical Summary/Current Status (February 2002 to Present)

- **Summer 2001:** Formed a workgroup of contractor and CMS RO and CO staff to review and revise the Quality Call Monitoring (QCM) process. The scorecard and chart was split into three distinct sections -- Adherence to the Privacy Act, Customer Skills Assessment and Knowledge Skills Assessment. Separate categories and scores provides a clearer indication of a CSR's performance relative to an individual skill and allows for an immediate and focused coaching session. The new tools were tested throughout Fall 2001 and rolled out to the call centers in February 2002.
- **Summer 2002:** Created a QCM Manual that explains the QCM process in detail.
- **Fall 2002:** Began working with SAIC to develop a web-based database where the call centers would enter the data collected through the QCM process. Having every call center's data available on the web allows CMS near real-time access to monitor and take action with centers that may be experiencing problems related to the accuracy of information provided.
- **Fall 2003:** Formed a workgroup of contractor and CMS staff to revise the QCM chart. The chart was updated to address issues that arise in the call center related to reviewer subjectivity. The new chart was effective October 2003. The group also updated the QCM database Users Manual.

Creating Call Center Profiles. *In FY 2001, we visited eight of our largest Medicare contractors to collect information on their operations, their use of technology, their performance data, their most frequently asked provider questions, and their training needs. We subsequently collected similar information from all of the remaining Medicare call centers via an online profile. The profiles have been analyzed to identify additional training needs and other improvements we can make at our contractors. These improvements will be implemented through a Customer Service Training Plan (see below).*

Historical Summary/Current Status (February 2002 to Present)

- These FY01/FY02 Profiles were baseline information on provider call centers.
- The profiles have not been updated.
- **Monthly:** We collect and analyze performance data via CSAMS (see below).
- **Monthly:** We collect and analyze traffic data via MCI Customer Service Center (see below).
- Current Status: In the first quarter of FY04, SAIC is surveying all provider call centers to update the profiles in regards to the centers' use of technology; and a workgroup is designing a contractor profile database with information relevant to both call centers and provider outreach activities.

Creating a Customer Service Training Plan. *Based upon the call center profiles we have gathered, we have drafted a Customer Service Training Plan to address the training needs of our Medicare customer service representatives. This training plan will bring uniformity to the contractor training, and improve the accuracy and consistency of the information that representatives give to physicians and providers across the country. Our first training effort will focus on the Correct Coding Initiative. Customer service representatives will be trained on the language and concepts of coding issues so that they can properly direct physicians and providers to the best sources of information or make sure that the appropriate technical expert responds to the caller in a timely fashion. We plan to off this and other training via a satellite network.*

Historical Summary/Current Status (February 2002 to Present)

- **February 2001:** Customer Service Training Plan and Recommendations completed, based on call centers' stated training needs.
- **April 2002:** Correct Coding Initiative (CCI) Reference Guide for CSRs forwarded to all provider call centers and later placed on MedLearn website.
- **April 23, 2002 and May 14, 2002:** National training on CCI concepts for CSRs was aired via the CMS Satellite Learning Channel.
- **June 2002:** Along with the CCI training, CMM issued a PM with specific guidance to CSRs on the handling of CCI and coding questions not within the scope of their responsibility.
- **August 2002:** HIPAA Reference Guide for CSRs was forwarded to all provider call centers and later placed on MedLearn website. The guide offers specific information on how to apply for a HIPAA waiver and was used to train the National HIPAA Hotline CSRs as well.
- **May 2003:** Guidelines for releasing personal health information (PHI) to providers were added to the Disclosure Desk Reference for Call Centers, effective July 2003.
- Current Status: An interactive, web-based training module is now being developed for CSRs based on the above guidelines for releasing PHI to providers. The module is scheduled for completion by early 2004; and development and deployment of the Next Generation Desktop (NGD) throughout the system is continuing, including working to increase the functionality for provider CSRs.

Holding Telephone Customer Service Conferences. *In March 2001, we held our first National Telephone Customer Service Conference for Medicare contractor call center managers and our Central and Regional Office staff. The conference emphasized our goal of improved customer service and served as a forum for exchanging ideas on best practices. Our next conference is scheduled for July 2002.*

Historical Summary/Current Status (February 2002 to Present)

- **FY02:** The July 2002 National Telephone Customer Service Conference was being planned as a part of CMS' National Customer Service Conference, previously held biannually by the Center for Beneficiary Choices and the CMS Regions. That conference

would include provider telephone customer service and provider outreach segments. The conference was cancelled for FY02.

- **Summer 2002:** Planning resumed for a National Customer Service Conference, including provider telephone customer service and provider outreach.
- **June 2003:** Conference was held in Scottsdale, Arizona.
- Current Status: Our next National Customer Service Conference is scheduled for Summer 2005. However, a provider education conference is currently scheduled for CO, RO, and contractor staff for June 2004.

Conducting Monthly Call Center Meetings. *We currently hold monthly conference calls with contractor call center managers and CMS Central and Regional Office staff to identify problems, give contractors additional information, and resolve issues.*

Historical Summary/Current Status (February 2002 to Present)

- **2000:** At the beginning of CMM's responsibility for Medicare provider call centers, the first conference calls with CMS central office and regions and Medicare provider call center managers were held on an ad hoc basis and discussion focused on the issues of toll free line installation.
- **January - May, 2001**: Calls were held on a regular monthly basis through the first 6 months of 2001.
- **July 2000**: CMM joined with CBC to hold joint monthly calls with the Medicare call centers (most of which share locations and upper management) and to call the group the Call Center Users' Group (CCUG).
- Current Status: CCUG calls continue to be held the third Wednesday of each month.

Analyzing Baseline Performance Data. *Medicare call center managers were required to report data from October 1999 through May 2001 (and monthly thereafter), on a variety of performance measures. We are analyzing these data to determine contractors' relative performance and the impact of the installation of toll-free lines on contractor workload and performance.*

Historical Summary/Current Status (February 2002 to Present)

- **April 2001:** Issued PM directing Medicare call center contractors in the collection of baseline (FY00 and first two quarters of FY01) data based upon the Customer Service Administrative Management System (CSAMS) measures that CBC developed for collecting beneficiary call center data.
- **June 2001:** Analysis of baseline data began to answer questions about the performance range of contractors and inform standard setting activities.
- **August 2001:** Joint CMM/CBC workgroup did an extensive review and assessment of performance measures and reduced the required reporting by half in order to focus on those most important ones.
- **November 2001**: Issued PM directing Medicare provider call center contractors to report their performance data into CSAMS beginning in January 2002.

- **January 2002:** CSAMS reporting by provider call centers began, and call centers submitted their December, 2001 data.
- Current Status: A monthly report giving the call attempts, call completions, and percent of calls complete for each line of business (Part A, Part B, DMERC) is prepared for senior management. The data comes from MCI Customer Service Center data. MCI reports also give us contractor-by-contractor traffic information so that we can identify and work with those who appear to be having problems handling their call volume. CSAMS performance data are also analyzed to further diagnose problems.

Monitoring of Medicare+Choice Plans

SUMMARY OF ISSUE: The MCO health plans misreport financial data or do not have reliable accounting records to support their estimates. This affects the benefits provided to enrollees, the amounts enrollees must pay in cost sharing, or the amounts the MCO contributes to an escrow account used to maintain benefit or cost-sharing levels in the future. The GAO recommends that CMS calculate errors; develop a mechanism to address audit findings; and communicate corrective actions to MCOs. The CMS disagreed it lacked a formal audit resolution process but did develop an action plan that GAO will monitor.

Eliminating ACR Audit Findings

Background

Section 1857 (d)(1) of the Social Security Act requires the Secretary to provide for the annual audit of financial records (including data related to Medicare utilization, costs, and computation of the adjusted community rate) of at least one-third of the organizations offering Medicare + Choice plans. The Secretary, or any person or organization designated by the Secretary, can audit or inspect any books and records of Medicare + Choice organizations (M+CO) that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

The HHS OIG and contracted auditors conducted the first reviews during contract year 2000, using agreed-upon procedures. Since contract year 2001, contracted auditors have been engaged to provide an opinion by conducting a review of whether management's assertions can be relied upon. The assertion must be signed by the Chief Financial and Executive Officers of the organization submitting the Adjusted Community Rate Proposal (ACR). The required assertion is:

> "I hereby certify that I have examined the accompanying Adjusted Community Rate proposal and attached worksheets for the contract period identified in Part IA, line 7. To the best of my knowledge and belief, this proposal contains true and correct statements prepared from the books and records of the contracting organization in accordance with applicable instructions, except as noted. In addition, I certify that this proposal agrees with the Plan Benefit Package form submitted for the same contract period.
>
> If "yes" appears on line 17, Part IA, the plan contact person named on line 8, Part IB, is authorized to submit selected changes (as listed in CMS's ACR instructions) to this ACR."

The types of opinions that the contracted auditors can issue are:

- An unqualified opinion – which indicates that the M+CO's management assertion can be relied upon. The ACR may not be 100% accurate, but findings, if any, were either infrequent and/or immaterial.

- A qualified opinion – which indicates that the M+CO's management assertion may be relied upon only to the extent limited by audit findings. There are non-frequent material findings or frequent immaterial findings.

- An adverse opinion – which indicates that the M+CO's management assertion cannot be relied upon. Findings were either very material and/or very frequent.

M+C organizations were selected for audit in such a way that all of the current contractors have been audited at least once. All of the currently contracting M+COs have been provided with CMS feedback as to the type of corrective action that should have been taken with regard to the audit findings for previous years.

With regard to reviews for contract year 2003 and beyond, the Health Plan Benefits Group (HPBG) is moving to a system where necessary corrective action is specifically requested at the time HPBG provides a report to an M+CO. HPBG monitors the M+CO until its corrective action plan (CAP) is effectively implemented. The types of corrective action that will be requested will primarily be of two types. One will be improvement in the manner in which the M+CO prepares its ACR. The second of these two types will be refunds to beneficiaries in those cases where the review findings indicate that beneficiaries have been overcharged for the services they have received. There is no opportunity for CMS to compensate an organization for review findings that are financially disfavorable to an M+CO.

If an M+CO is unresponsive to a request for corrective action, HPBG will consider the organization for an enforcement action under its Standard Operating Procedures for M+C Enforcement and the Termination of Medicare Contracts. Enforcement actions could include; (1) civil money penalties in amounts ranging from $10,000 to $100,000 (not to exceed), depending on the violation; (2) suspension of enrollment of Medicare beneficiaries, (3) suspension of payment; and (4) suspension of all marketing activities.

Responsibilities of Division of Finance and Benefits Analysts

There are six analysts within the Division of Finance and Benefits (DFB) who are assigned to liaison with the contracted auditors with regard to specific M+COs. These auditors participate in their assigned M+COs' entrance and exit conferences and receive the draft and final audit reports pertaining to their assigned M+CO's.

These analysts are responsible for providing CMS feedback to the contracted auditors on the draft reports and preparing letters transmitting final audit reports and setting forth specific corrective actions the M+COs must take with regard to the reports. The letters are prepared for the signature of the Director of the DFB.

Feedback to Auditors on Draft Audit Reports

Within seven days of receipt of the draft audit report, the assigned analyst must schedule a meeting with the Product Consistency Team (PCT) and provide a copy of the draft report to all members of the PCT (all four analysts) as well as the Assigned Actuary and DHPA's Financial

Analyst. All members of the PCT should carefully review the report and identify any findings with regard to which there are questions or concerns. However, the assigned analyst will lead the PCT meeting and obtain a consensus as to what questions and concerns should be relayed to the contracted auditor. The assigned analysts should relay those questions and concerns to the contracted auditor as soon as the PCT meeting is held.

Transmission of Final Audit Reports

After the final report is received, the assigned analyst must prepare the necessary correspondence for signature by the division director. A meeting of the PCT should be scheduled to review all draft correspondence. A consensus of the members of the PCT as to whether the correspondence is properly prepared should be reached before it is submitted to the division director for signature. The kind of correspondence that will be necessary will depend on the auditor opinion.

- If the review opinion is **unqualified** and there **is not** a need for the organization to improve the manner in which it prepares its ACR, the letter should transmit the report and inform the M+CO that no corrective action is required.

- If the review opinion is **unqualified** and there **is** a need for the organization to improve the manner in which it prepares its ACR, the letter should transmit the report and identify the specific ways in which the M+CO needs to improve the manner in which it prepares its ACR. The letter should require that the M+CO submit its corrective Action Plan (CAP) within 45 days. There are no material findings when an unqualified opinion is issued, so it is unlikely the corrective actions required will include refunds to beneficiaries.

  Upon its receipt, the corrective action plan must be reviewed. If the CAP is acceptable, a letter informing the M+CO how CMS will be monitoring its achievement of its CAP should be prepared.

  If the CAP is unacceptable but not egregiously so, a letter explaining the ways in which it is unacceptable and requesting that the CAP be resubmitted within 30 days should be prepared. Upon its receipt, review the resubmitted CAP and determine whether it is acceptable. If the CAP is acceptable, prepare a letter informing the M+CO how CMS will be monitoring its implementation of its CAP.

  If the resubmitted CAP is not acceptable, refer the M+CO to the Division of Health Plan Accountability (DHPA) for consideration of enforcement action (see below).

  If a CAP accepted by DFB is not successfully implemented, refer the M+CO to DHPA for consideration of enforcement action (see below).

- If the review opinion is **qualified,** a letter should be prepared transmitting the final report and identifying the corrective actions that the M+CO needs to take. The required actions will most likely include improvements to the manner in which the M+CO prepares it ACR and refunds to beneficiaries. The letter should require that the M+CO submit its CAP within 45

days. Note that there is no way that CMS can compensate an organization for review findings that are financially disfavorable to the M+CO.

Upon its receipt, review the corrective action plan. If the CAP is acceptable, prepare a letter informing the M+CO how CMS will be monitoring its achievement of its corrective action plan.

If the CAP is unacceptable but not egregiously so, prepare a letter explaining the ways in which it is unacceptable and give the M+CO a deadline for resubmitting the CAP. Upon its receipt, review the resubmitted CAP and determine whether it is acceptable. If the resubmitted CAP is acceptable, prepare a letter informing the M+CO how CMS will be monitoring its achievement of its CAP.

If the resubmitted CAP is not acceptable, refer the M+CO to the Division of Health Plan Accountability (DHPA) for consideration of enforcement action (see below).

If the CAP is egregiously unacceptable, refer the M+CO to the DHPA for consideration of enforcement action (see below).

If a CAP accepted by DFB is not successfully implemented, refer the M+CO to DHPA for consideration of enforcement action (see below).

- If the review opinion is **adverse,** immediately refer the M+CO to the DHPA for consideration of enforcement action (see below).

Referrals to DHPA for Consideration of Enforcement Action

In those instances where DFB cannot negotiate an acceptable CAP, where the M+CO does not effectively implement the CAP, or the review opinion is adverse, the M+CO should be referred to the DHPA for consideration of enforcement action. DHPA has Standard Operating Procedures for M+C Enforcement and the Termination of Medicare Contracts. The SOP's contain a Case Referral Form, which should be used for the referral. A copy of the referral form is attached for easy reference.

A meeting of the PCT should be scheduled to review the referral. A consensus of the members of the PCT as to whether the referral should be submitted to DHPA should be reached.

DHPA Case Referral Form

** *Complete this form to describe issues to be considered jointly by the Division of Health Plan Accountability and the Division of Finance and Benefits. .*

Plan Name: _____

Medicare Contract Number: _____

Date: _____

DFB Assigned Analyst _____
(Preparer)

CO Plan Manager _____

RO Plan Manager _____

NARRATIVE SUMMARY OF PROBLEM:
State whether the M+CO is being referred because DFB has not been able to negotiate an acceptable CAP, the M+CO has not effectively implemented an accepted CAP, or the review opinion is adverse. If DFB has not been able to effectively negotiate a CAP, provide a brief summary of DFB's attempts to do so. If the M+CO has not effectively implemented an accepted CAP, provide a brief summary of its attempts to do so and the additional action that is needed. If the review opinion is adverse, summarize the corrective action that is needed.

LIST OF DOCUMENTATION AVAILABLE TO SUPPORT CLAIM:
Prepare and include a complete set of documentation, including the draft report, final report and all correspondence between DFB and the M+CO concerning the final report.

RECOMMENDED NEXT STEPS:
Based on the summary of findings and other preliminary analyses, state your recommendation for quickly resolving the identified potential problem. Options include taking regulatory enforcement actions, including sanctions, civil monetary penalties, non-renewal of contract, and termination. Other options include suspension of contract, applications to expand service areas, or temporary suspension of marketing activities. State whether additional reviews may be necessary to obtain other information.

E-mail and provide a hard copy of the form to the HPBG and DHPA Directors.

Corrective Action Plan: "Medicare+Choice Audits: Lack of Audit Follow-up Limits Usefulness" (GAO-02-33)

GAO Recommendation

To improve the utility of the audit reports and usefulness of their findings, the CMS Administrator should communicate to each Managed Care Organizations (MCO) specific corrective actions needed for future ACRP submissions.

CMS Response

Communications between CMS and the M+C Organizations regarding the ACR audit/reviews for contract years 2000 and 2001, started with the Division of Finance and Benefits (DFB) mailing a notification letter outlining all findings (along with a copy of the report) to the M+C Organizations. The letter highlighted the findings that the organizations disagreed with and requested formal comments as to why they felt the findings were incorrect. The responses were due no later than 45 days from the date of the notification letter. These letters were/are to serve as CMS's official acknowledgement that errors were found in the ACR submissions by the contractors.

If the findings were non-egregious, the M+CO would be notified of CMS' expectation for the plan to address and improve the process concerning the non-egregious findings.

If the findings were egregious the DFB may send the M+CO written notification indicating the need for a corrective action plan (CAP). The CAP will be developed by the M+CO and contain a discussion of procedures that the M+CO plans to implement to prevent the same types of errors from recurring. M+COs will be required to submit a CAP within 30 days of receiving the CAP request. The CAP request letter will direct that CAPs be submitted to the appropriated DFB Analyst. The DFB analyst will review each initial CAP submission to determine if the M+CO adequately addressed each finding. The DFB analyst will also consolidate all comments and respond to the M+CO within 60 days from the receipt of the CAP, either approving the CAP or requesting a revised CAP for any finding that was not adequately addressed.

For contract year 2002 and beyond, the ACR will be audited by professional CPA's and Actuaries. Agreed upon procedures were applied to contract year's 1999 and 2000. For contract year 2002 and beyond; M+CO's receiving either a qualified opinion or adverse opinion from the CMS hired CPA's and Actuaries may be notified for the need of a corrective action plan (CAP). If the M+CO received an unqualified opinion, the organization will be notified of CMS' expectation for the plan to address and improve the processes concerning the findings stated in the unqualified opinion report. If the organization chooses to not address findings stated in the unqualified report, CMS may consider the need for a CAP.

Each CAP will be required to include a discussion of each finding with specific action steps to be taken. The CAP shall include the names, official titles, and telephone numbers of personnel responsible for implementation. Target dates shall be listed for the successful completion of each

action to be taken. CMS shall impose a due date for the submission of the CAP on an individual basis depending on the number and severity of findings.

If the organization chooses to not adhere to the aforementioned corrective action plans, and repetitive egregious findings occur, CMS may impose intermediate sanctions. The types of intermediate sanctions and civil monetary penalties available to CMS are described under Section 422.750 of the Code of Federal Regulations (CFR). The sanctions taken against a Medicare + Choice organization consistently failing to follow ACR guidelines and instructions can include: (1) civil money penalties ranging from $10,000 to $100,000 depending upon the violation, (can impose $10,000 a week, per deficiency), after the organization is notified by CMS (2) suspension of enrollment of Medicare beneficiaries, (3) suspension of payment to the Medicare + Choice organization for Medicare beneficiaries who enroll, and (4) the requirement that the Medicare + Choice organization suspend all marketing activities to Medicare beneficiaries for the Medicare + Choice plan subject to the intermediate sanctions. Section 422.756 of the CFR further states that the sanction shall remain in effect until CMS notifies the Medicare + Choice organization that CMS is satisfied that the basis for imposing the sanctions has been corrected and is not likely to recur.

Section 2 and process flow diagrams 0.0.0 and 1.0.0 of the Standard Operating Procedures for Imposing Civil Money Penalties on M+C Organizations, developed by the Division of Program Accountability & Payment, provides an outline for the Intermediate Sanction Process. As stated, standard operating procedures for imposing civil money penalties on M+C organizations has been established by the Division of Program Accountability & Payment.

CMS Action Steps and Target Dates

Action Steps	Target Date
The CMS sends the M+CO a Notification letter highlighting the report findings.	(M+CO response within 45 days)
CMS issues a CAP request to the M+CO.	(M+CO response within 30 days)
The CMS response to M+CO regarding the approval or disapproval of CAP.	(M+CO response within 60 days)
The CMS sends letter to the OIG notifying them of CMS' intention to impose sanctions.	(within 30 days) after M+CO CAP resolution)
The CMS notifies the M+CO of intent to impose intermediate sanctions the same time as with the OIG. The OGC must concur prior to the issuance must concur prior to the issuance of sanctions.	(15 days) for the M+CO to agree for the M+CO to agree to sanctions or request reconsideration).
(The OIG may choose to impose a civil monetary penalty). The CMS may choose to suspend or marketing & enrollment of Medicare beneficiaries).	
(The CMS may choose to suspend payment to the M+CO).	

The Office of General Council (OGC) must be notified as well as the OIG when CMS/DFB/OACT proposes CMPs. If the OIG concurs with CMS' decision to impose CMPs, then CMS will decide whether to send a "pre-demand" letter to the M+CO. This is an administrative procedure that allows the parties to negotiate possible settlement without making a formal "demand."

When imposing a CMP, CMS through the OIG, notifies the Department of Justice (DOJ) of its intent to impose a CMP. CMS refers the CMP case to the DOJ for review and determination as to whether separate civil or criminal action is warranted against the particular M+CO. The DOJ has 10 days in which to make the determination to send a demand letter.

When a CMP is imposed on an M+CO, the M+CO may appeal CMS' determination to impose a CMP.

Appeals Process

Per Standard Operating Procedures for Imposing Civil Money Penalties on M+C Organizations, developed by the Division of Program Accountability & Payment, "the M+C organization may appeal CMS' determination to impose a CMP in accordance with provisions described in 42 Parts 1003 and 1005. This process is comprised of three distinct phases: the administrative law judge hearings stage; the appeal to the Departmental Appeals Board stage; and the judicial review stage. Any CMP appeal case that proceeds to these stages will be primarily administered by the HHS/Office of General Counsel. While CMS/HPBG staff will be responsible for following the progress of any such proceedings, the responsible CMS analysts will not be overseeing the day-to-day activities involved in the appeal process. As such, these processes are not described here but rather have been added as three separate appendices to this SOP." See Appendices A, B and C of the Standard Operating Procedures for Imposing Civil Money Penalties on M+C Organizations, for description of the three distinct appeal phases.

GAO Recommendation 2

To improve the utility of the audit reports and usefulness of their findings, the CMS (CMS) Administrator should fully implement plans to calculate the net effect by plan and potential impact of Adjusted Community Rate Proposal (ACRP) audit findings and adjustments.

CMS Response

For contract year 2002 and beyond (contract year 2002 ACR's are currently being audited by CMS' contracted CPA's and Actuaries) an actuarial and audit opinion will be provided to CMS by certified CPA's and Actuaries. The actuarial and audit "findings" require quantification to evaluate the net effect by plan and potential impact on the Adjusted Community Rate Proposal, as well as determine the appropriate opinion: unqualified, qualified, or adverse. The offering of an audit and actuarial opinion amplifies the need to quantify results.

CMS Action Steps and Target Dates

Action Steps	Target Date
Entrance Conference	First day of field work
Field work communication	Field work time frame
Exit Conference	Last day of field work
Review and Draft of Final Report Containing Audit and Actuarial Opinion	30 days after exit conference

The CPA's and actuaries, as well as the M+CO, are aware of the need to continuously communicate with CMS during the ACR audit.

GAO Recommendation 3

To improve the utility of the audit reports and usefulness of their findings, the CMS Administrator should develop and implement a follow-up mechanism to address the audit findings in a timely manner.

CMS Response

Within 30 days after CMS accepts the Final ACR Audit Report, the Division of Finance and Benefits (DFB) mails a notification letter outlining all findings (along with a copy of the report) to the M+C Organizations. The letter highlights the findings that the organizations disagree with and requests formal comments as to why the M+CO feels findings are incorrect. The M+CO responses are due no later than 45 days from the date of the notification letter. These letters serve as CMS's official acknowledgement that errors were found in the ACR submissions by the contractors.

Furthermore, an agree/disagree matrix is included in the Final Audit Report. The matrix lists each audit "finding" and designates whether the M+CO agrees or disagrees with the "finding". The M+CO is provided the agree/disagree as preparation for the exit conference. The exit conference provides the opportunity for the M+CO, CMS and the CPA's and Actuaries to discuss all issues. Note: the professional CPA's and Actuaries performing the audits are under CMS' directive to communicate all issues to the M+CO as they occur.

CMS Action Steps and Target Dates

Action Steps	*Target Date*
Exit Conference	Last day of field work
M+CO answers agree/disagree matrix	Included in Final Audit Report
M+CO receives notification letter	30 days after CMS accepts Final Audit Report
M+CO responds to notification letter	45 days after date of Notification Letter

In a January 23, 2003 email, GAO requested a CMS response to each of the items shown below:

GAO Request # 1

Reiterate to the M+C organization the importance of following CMS' instructions in preparing the ACRP's. Emphasis should be placed on the issues noted in our individual reviews (e.g., use of actual base year costs).

CMS Response

The CMS sends each organization a Notification of Findings Letter with a copy of its Audit Report. This cover letter to the MCO clearly states that CMS expects the findings will be corrected in future ACR filings. The letter states "It is the intent of CMS to ensure that future ACR submissions should be corrected for those items noted as audit findings and/or reportable conditions in order to be in full compliance with CMS's ACR instructions. Failure to correct items noted in the audit report may warrant the imposition of intermediate sanctions and/or result in CMS's consideration of other adverse actions including termination of the Medicare contract in accordance with 42 C.F.R. 422.306(a)(2)."

Additionally, CMS emphasizes the importance of following CMS' instructions by conducting an annual lessons learned conference with ACR auditors to discuss results of the contracted audit year. The audit program specifically requires the auditor to document observed instances where the MCO did not follow the ACR instructions, even if the instance is not material. These lessons learned issues relating to the ACR instructions are noted for the annual lessons learned conference provided by CMS for participating M+COs as well as the annual ACRP training seminar conducted for participating M+COs. CMS conducts an annual lesson learned conference and an ACRP seminar in Baltimore with MCO personnel to discuss the ACR instructions and recent audit findings and observations. The seminar also highlights the Plan Benefit Package (PBP) and the electronic submission of both the ACR and PBP. Another opportunity for CMS to emphasize the need for the organizations to follow the ACR instructions is the Annual Call Letter. The Call Letter is presented to the industry and addresses changes to the ACRP and important ACRP items, which may include ACR instruction issues. Finally, electronic Desk Reviews are performed by CMS for each ACR submission. The Desk Review involves two to three reviews of the ACR package to ensure it was submitted in accordance with the ACR instructions. The M+COs are informed of their mistakes and must correct the mistakes before the ACR can be successfully submitted to CMS.

GAO Request # 2

Work with the M+C organizations to have them develop corrective actions to address the deficiencies noted in their audits to ensure that future ACRP submissions are correct.

CMS Response

CMS agrees with this request and is in the process of developing corrective action procedures for the M+COs. CMS has combined the expertise of participating M+CO staff, ACRP audit contractors, as well as CMS staff, to develop a plan for addressing audit findings. This plan acknowledges the development and monitoring of a corrective action plan (CAP) for egregious as well as repetitive non-egregious findings and addresses CMS' option of sanctions for not adhering to a CAP.

In addition to CMS developing corrective action procedures, CMS provides training to the industry twice a year to discuss the ACRP process. CMS conducts a seminar to discuss the ACRP submission and Instructions as well as a lessons learned conference to discuss recent audit issues.

GAO Request # 3

As part of the CMS biennial monitoring protocol reviews, ensure that M+C organizations have accounting systems and procedures in place that would facilitate proper preparation of their ACRPs.

CMS Response

At this time it is not CMS' intention to incorporate a review of an organization's accounting system, for the purpose of ACRP preparation, into the monitoring protocol. We believe such a requirement would impose a significant burden on the M+C and may severely restrict a M+C's ability to chose and operate an accounting system sufficient for its own needs. CMS believes that current regulations, instructions and audit procedures are sufficient to ensure that ACRPs are prepared in an accurate manner. For example, current regulations stipulate that an M+C have personnel and systems sufficient for the organization to organize, plan, control and evaluate financial activities. These systems are reviewed at the time of the initial application. Further, CMS annually releases instructions on the proper reporting and submittal of the ACRPs. Each year CMS reviews these submittals for compliance. In addition, at least every three years, and more frequently if determined necessary, CMS audits the ACRP submissions to ensure the submittals are supported by the M+Cs accounting and other financial records. In instances where findings are disclosed CMS notifies the M+C of discrepancies, as outlined in the CMS response to the GAO finding #1 of this document.

In an October 16, 2002 email, GAO requested a CMS response to each of the items shown below:

GAO Request #1

"To provide information on actions CMS has taken to fully implement plans to calculate the net effect by plan and the potential impact of ACRP audit findings and adjustments, have CMS' plans been fully implemented? If not, what is the status? Provide a copy of CMS' plans, to include plans to calculate the net effect by ACRP and the potential impact of the ACRP audit findings and adjustments. Provide a summary of the computations of the net effect for each ACRP and at least a few of the detailed computations that support the summaries."

CMS Response

The CMS contracted with a consulting firm to review reports judged to have egregious findings. The objective was to analyze documentation supporting findings reported to CMS for the 2000 ACR submission season and to verify the auditors' estimates of overcharges to MCO Medicare enrollees. The reviewed reports were prepared and issued by the Office of Inspector General (OIG) and PricewaterhouseCoopers (PWC).

The OIG reports showed overcharges to Medicare enrollees totaling $84 million. A summation of the undercharges totaled $87 million with a net effect of $3 million in undercharges to the enrollees. The review of the PWC reports found overcharges of $475,230 to the Medicare enrollees.

The consulting firm's findings were as follows:

- OIG documented its findings thoroughly, which allowed the contractor to analyze them fully.
- OIG used questionable methodology for calculating enrollee overcharges.
- PWC did not document its findings well enough to include them in the review. (Note: At a later date, PWC was able to produce documentation for their adjustments to the audited ACRs.)

The consulting firm concluded that: "CMS would take a relatively high risk of levying inappropriate sanctions on MCOs and of failing to apply sanctions if it relied on its auditors' estimates for the MCO plans in the study". Their report stated further that the OIG could not recalculate certain questionable ACR values, thus causing the consulting firms estimates subject to uncertainties that would require input from MCOs to resolve.

The CMS believes the consultant's report clearly shows the need for a deliberate and careful policy toward determining whether sanctions should be applied based upon the auditors work papers. To meet this goal, CMS is requiring the auditors to submit copies of their work papers with the reports for the 2003 ACR audit period. This step will permit CMS analysts to immediately review the reports along with the work papers and make a judgment rather than rely solely on the contents of the auditors' reports. As for the 2000 audit period, CMS is still

evaluating the content of the consultant's report and the quantification process used by the auditors for their findings.

GAO Request #2

"To provide information on the actions that CMS has taken to develop and implement a follow-up mechanism to address the audit findings in a timely manner, please provide CMS' plans for the follow-up mechanism. Also, please provide information for each year showing that audit findings were followed up in a timely manner."

CMS Response

The findings reported in each of the 2000 and 2001 contractor reviews were entered in CMS' Health Plan Management System (HPMS). This information tracking system contains the name of the audited MCO, reported findings, and the accounting firm performing the review (See Attachment A). It also contains the date CMS informs the MCO of the audit results and requests the MCO to either concur or non-concur with each of the findings (Note: a copy of the audit report is also sent to the MCO). This correspondence is known as the Notification of Findings Letter and requires the MCO to respond to CMS within 45 days from the date of the letter (See Attachment B). A CMS analyst will follow up with the MCO if no reply is received within the established timeframe. HPMS is currently tracking findings for 130 audited MCOs from the 2000 and 2001 ACR audit periods.

While some of the findings were clerical in nature, others were considered more serious (e.g. entries on the ACR worksheets lacked supporting documentation). CMS knew it had to demonstrate to the MCOs the importance of following ACR instructions when preparing the ACR worksheets. To meet this goal, CMS drafted an **Action Plan for Eliminating Findings** (See Attachment C) for its staff to follow. This document is currently being reviewed internally to determine its effectiveness in obtaining ACR worksheets prepared in accordance with the ACR instructions. However, its main objective is to put the MCO on notice that continued errors will not be tolerated. For example, MCOs with reported egregious findings will be required to submit a Corrective Action Plan (CAP) within 30 days of receiving a CAP request from CMS (Note: this request would be a part of the Final Determination Letter). The CAP must contain a discussion of procedures the MCO plans to implement to prevent the same types of errors from recurring during subsequent review periods. CMS shall review the CAP to ascertain if it adequately addresses each of the findings, and shall respond to the MCO within 60 days from receipt of the CAP. An MCO with repetitive non-egregious findings shall also be required to submit a CAP to CMS for review. The progress of all CAPs shall be monitored by HPMS.

Contractor reviews are currently being performed at 40 MCO sites for the 2002 ACR audit period. For the first time, contractors shall be required to provide both examination and actuarial opinions on MCO management's assertion that the ACR worksheets were prepared in accordance with ACR instructions. Reported findings shall again be entered in HPMS for tracking purposes. With the completion of this review period, HPMS shall contain findings for three years of audit activity. CMS will use this information to select MCOs for review for the

fourth year of audit activity. MCOs with egregious findings, or recurring non-egregious findings, will comprise this list.

GAO Request #3

"To provide information on whether CMS communicated to each MCO specific corrective actions needed for future ACRP submissions, provide copies of sample communications along with a summary listing of the MCOs and the communication they received. If CMS communicated the corrective actions needed, what actions did CMS take to ensure that the corrective actions were implemented?"

CMS Response

After CMS reviews each of the MCO's responses to the findings contained within the Notification of Findings Letter, it will issue a Final Determination Letter (See Attachment D) to the MCO presenting its final decision on the need for a CAP and whether intermediate sanctions shall be imposed.

To date, CMS has not requested a CAP from a managed care organization. However, CMS is moving toward that goal. Within the last several months, CMS staff has reviewed contractor work papers (2000 and 2001 audit periods) for several MCOs to substantiate findings contained within the contractors' reports and ascertain if the findings were adequately supported. Once this process is completed, the necessity for CMS to request a CAP should be clarified. CMS has a responsibility to verify that all findings are adequately supported and explained by the auditors before any thought is given to requesting a CAP. CMS believes there should not be a "rush to judgement" in situations in which the MCOs were more ignorant of the instructions than deliberately entering fictitious information on the ACR worksheets. If a MCO continues to repeat the same errors on its yearly ACR worksheets, CMS could sanction a managed care organization as outlined within the **Action Plan for Eliminating Findings.**

The CMS realizes it must continue to educate the MCOs on the importance of following ACR instructions when preparing their ACR worksheets. CMS analysts continue to respond to questions posed by the MCOs concerning reported findings, and assist MCO staff in understanding the ACR instructions. On December 5, 2002, CMS will invite representatives from the managed care community to attend a one-day conference to discuss the recently completed 2003 ACR submission period. CMS will discuss the most prevalent errors found during the desk review process and make recommendations to eliminate those errors from future submissions. CMS will also request comments from the MCOs to improve the ACR preparation process.

The CMS is also seeking to improve the audit process. On March 4, 2003, CMS will hold a conference with MCO representatives who were recently audited. The purpose of the conference will be to discuss the results of the 2002 audit period and to solicit comments from the MCOs on how the review process can be improved. Feed-back received from this meeting will be used at a March 11, 2003 conference with CMS's contractors so they are aware of the concerns raised by

the MCOs. This is the starting point for making changes to the examination program used by the contractors when performing their reviews.

GAO Response #4

Please provide any other information that you believe may be pertinent to our follow-up work.

The CMS shares with the GAO the importance of following up on errors disclosed during audit process. HPMS has been used to track the MCOs comments on reported findings. However, we believe it is just as important to make sure that the findings reported by our contractors are verifiable and supportable in their work papers. CMS has completed its review of work papers from several contractors for findings we considered egregious, and are taking steps to evaluate the need for requesting CAPs. We agree that CAPs, and ultimately sanctions, are necessary to ensure that the MCOs understand the importance of preparing the ACR worksheets in accordance with ACR instructions. Preventing overcharges to Medicare enrollees is essential to the well being of the individual as well as the program.

The CMS believes it has an adequate process in place to follow up with the reported findings and to prevent the errors from recurring. We still believe that education plays a role on the front end of this process. Every year CMS conducts an ACRP conference at central headquarters with the managed care community to go over the ACR worksheets and instructions. MCO staff is encouraged to raise issues and questions on the preparation of the ACR worksheets. As mentioned earlier, lessons learned conferences are held throughout the year to raise the knowledge levels of MCO staff preparing the worksheets and contractor staff reviewing them.

As for sanctioning MCOs, CMS believes that the consultants report concerning over and undercharges points out that CMS must move carefully before proceeding with an action that could needlessly put the MCO in a defensive posture.

Financial Management

SUMMARY OF ISSUE: The CMS and contractors have weaknesses, but CMS has made some progress in addressing them. The CMS needs to take further steps to better analyze contractor financial data and develop financial systems (a single integrated financial accounting system for financial activities), processes and controls that routines generate reliable, useful, and timely information for decisions makers.

The CMS's oversight has improved in the last few years and several GAO recommendations have been adopted. The CERT will provide much needed measure of contractor performance.

Medicare Financial Management: Further Improvements Needed to Establish Adequate Financial Control and Accountability, AIMD-00-66

GAO Recommendation 1

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to, in developing procedures, coordinate with the central and regional office staff responsible for contractor oversight to ensure that resources are applied appropriately for timely follow-up with contractors on implementation of corrective actions to address financial statement audit findings.

CMS Response

The CMS issued in May 2001, written standard policies and procedures for CMS central office and regional offices to follow in processing corrective action plans (CAPs) resulting from Chief Financial Officer (CFO) audits, Statement on Auditing Standards (SAS)-70 reviews, as well as other financial management audits and reviews performed by consulting/certified public accounting firms, the Office of Inspector General, and the General Accounting Office. These procedures will ensure that all CAPs are received, reviewed, and adequately implemented to resolve all audit findings timely. This was completed May 2001.

GAO Recommendation 2

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to improve oversight of contractor financial activities by working with the central and regional office staff responsible for annual contractor performance evaluations to: (1) refine and expand procedures for review of contractor financial activities; (2) provide staff with the necessary skills to evaluate contractor financial activities; and (3) identify specific contractors and financial activities to be reviewed.

CMS Response

For fiscal year 2001, we will conduct Contractor Performance Evaluation (CPE) reviews of accounts receivable activities at six Medicare contractors. The teams will be comprised of CMS central and regional office staff.

CMS hired an independent account firm (IPA) firm as CMS consultants to review contractor accounts receivable in order to validate (1) receivable amounts reported to CMS and (2) the adequacy of their internal controls. For FY 2001, the IPA firm conducted reviews at 12 contractors. Our decisions for determining which contractors would receive a CPE, National Team, or IPA consultant review were based on a documented risk assessment tool to identify the specific contractor and the financial area for review. This risk assessment allowed us to better direct and manage our resources to contractors and areas determined to be high risk.

In June 2001, we issued revised internal and contractor accounts receivable instructions and provided training to contractors and CMS regional staff to promote a uniform method for reporting and accounting for receivables. Also, for fiscal year 2001, we drafted a CPE review protocol, for the preparation and reconciliation of the HCFA 1522 report that contains information about contractor expenditures. This was completed September 2001.

GAO Recommendation 3

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to improve the agency's ability to detect irregular financial activities and identify high risk contractors by: (1) developing analysis and risk assessment procedures that detect unusual variances and patterns in the amounts of funds withdrawn, funds expended, bank balances, accounts receivable, accounts payable, and other key financial data reported by contractors; and (2) coordinating and sharing analysis and risk assessment methodologies with central and regional office staff responsible for contractor monitoring and oversight.

CMS Response

During fiscal years (FYs) 2000 and 2001, CMS hired consultants to assist us in developing analytical tools necessary to perform more expansive trend analysis of critical financial and related data, specifically account receivables. These tools provide the steps necessary to identify unusual variances and potential areas of risk. Additionally, the tools allow CMS to readily perform more extensive data analyses, follow up with Medicare contractors, and determine the need for additional actions to ensure that problems are adequately resolved. These enhancements along with additional staff members hired during FY 2000, allowed us to conduct trend analysis starting with quarter ending June 30, 2000. CMS is now performing a more structured and robust financial analysis and review each quarter. During FY 2001, we issued instructions to CMS regional offices to perform trending analysis on their own accounts receivable data, starting with the quarter ending June 30, 2001. This was completed September 2001.

CMS issued formal instruction/guidance to Medicare contractors to perform quarterly trend analysis procedures. This was completed July 2002.

CMS developed and maintain review procedures for CMS regional offices to review Medicare contractors' quarterly trend analysis submissions. This was completed December 2002.

GAO Recommendation 4

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to improve guidance to contractors for executing Medicare financial activities by ensuring that the current initiative to develop a comprehensive contractor financial management manual: (1) solicits input from contractors on the areas where better guidance is needed to address long-standing internal control weaknesses, such as specific instructions on allocation of cash receipts between the two Medicare trust funds; (2) includes steps for ongoing updating of guidance; (3) articulates how the manual will be used and implemented; (4) uses the results of audit findings and oversight reviews to determine areas where more complete and detailed guidance to contractors is needed; and (5) reviews the contractor fiscal intermediary and carrier manuals to determine which sections need updating.

CMS Response

We contracted with a consulting services firm for development of a database that will contain all financial management guidance and instructions that HCFA components have provided to contractors. The CMS received a final product from KPMG on February 2001 with the database/manual providing a comprehensive approach for contractor internal control duties and responsibilities. The OFM management decided to concentrate its efforts in developing a manual specifically tied to instructions issued by OFM. In addition, the project was split into two separate tracks—one is the Financial Management Instructions Database (FMID) and the other is the development of the

Internal Control manual section. The FMID is currently in a beta test mode and provides OFM's instruction on a searchable website. This was completed in FY 2001.

We revised the Financial Management Manual for Medicare Contractors and made it available to the internet. The CMS is committed to updating and revising the manual on a periodic basis, while incorporating the results from oversight activities, such as the CFO audit, SAS-70 reviews, self-certification reviews, Office of Inspector General (OIG) and GAO reviews to enhance and refine our guidance. This was completed August 2002.

GAO Recommendation 5

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to improve internal financial reporting processes by developing comprehensive policies and procedures that clearly define: (1) the process to be followed in preparing the financial statements; (2) the routine accounting procedures performed by the Office of Financial Management; and (3) the number of staff and skills needed to carry out responsibilities.

CMS Response

We hired a consultant to develop desk procedures for OFM's accounting staff. These procedures have been incorporated into an accounting manual that provides detailed instructions on many of the routine accounting procedures that are performed by OFM. Phase I of the manual is complete, with final revisions expected by September 2001. Phase II of the manual will include drafting sections of OFM's processes that are less routine, such as the preparation of the financial statements. Phase II is expected to be completed early 2002. This was completed August 2002.

GAO Recommendation 6

To improve financial management and accountability in the Medicare program, the Administrator, HCFA, should direct the Chief Financial Officer to develop a comprehensive financial management strategy that clearly: (1) defines financial management objectives and goals; (2) specifies corrective actions to address financial management weaknesses; (3) include target dates and resources necessary to implement corrective actions; (4) identifies offices and staff responsible for carrying out the corrective actions; (5) provides clear implementation plans that link the various financial management improvement initiatives underway and alternative plans in the event these reviews cannot be continued; (6) provides details on the systems architecture and requirements needed for its integrated financial management systems; and (7) includes a human capital needs assessment.

CMS Response

We issued in November 2000, CMS's Chief Financial Officer Comprehensive Plan for Financial Management, which was revised in FY 2001. The plan contains 10 goals and

25 initiatives, all of which support our overall strategic vision to improve financial reporting, design and implement effective financial management systems, improve debt collection and internal accounting operations, and validate financial data. Project plan for FY 2001 has been developed that provides for each initiative appropriate milestones and detail tasks, resource requirements and responsible entities, and interdependencies that will help manage performance.

CMS's financial management goals and initiatives are consistent with the Federal financial management vision articulated by the U.S. Government CFO's Council which focuses on shaping an environment in which Government officials use highest-quality financial and performance information to make and implement effective policy, management, stewardship, and program decisions. This was completed in November 2000.

Information Technology and Management Challenges

SUMMARY OF ISSUE: The CMS' major information systems are aged and often incompatible with each other. Auditors of FY 2001 financial systems noted numerous weaknesses in the security of Medicare information systems that compromise the security of sensitive Medicare data. CMS' IT planning and management processes have shortcomings that may undermine its modernization efforts.

CMS Response

Secure Systems: The CMS acknowledges that its systems are aged and fragile, however it is devoting significant efforts to remediate critical data and systems security vulnerabilities. The President's budget for FY 2004 includes $65 million for IT modernization and a more secure system environment is a key component of the IT modernization plan. A first-level goal that underlies all aspects of the CMS IT Modernization Implementation Strategy is to strengthen the security of CMS data and systems. A key component f the modernization program is for CMS to pursue a strategy to build security into the agency's modernized infrastructure through capital investments to reduce our current security perimeter and to reduce our exposure to unnecessary risk.

At the planned FY 2004 $65 million funding level, CMS will spend at least one of every two dollars of IT modernization funding on improving systems security. Not only will investments in the security infrastructure dramatically improve our security posture, it will support secure access capability to other critical investments in fee-for-service claims processing modernization, data warehousing, and IT infrastructure development. All of these initiatives are ultimately built on a modernized systems security foundation.

CMS's IT Planning and Management Processes

The CMS IT Investment Management Process continues to mature. CMS has established formal reviews throughout a project's life cycle and has established standards for systems development reviews and deliverables (tailored from IEEE 12207). CMS has also established an IT investment management process that is designed to meet the requirements of the Clinger Cohen Act, monitor performance and insure successful IT investment.

We continue to update and validate the current enterprise architecture. The target architecture and a migration strategies are being developed as part of the CMS IT modernization program.

GAO Recommendation

CMS needs to use current and reliable data to make payment policy decisions; for example, outpatient drugs. VA has access to detailed information on market prices that

would assist Medicare in setting appropriate, efficient payment amounts for covered drugs.

CMS Response

The current (legacy) data environment, which supports CMS business operations, has become increasingly difficult and costly to support. Furthermore, these legacy data files and databases do not satisfy the current data management policy and program assessment needs. The FY 2005 budget includes $18.0 million to support implementation of an integrated, relational data environment to specifically address these issues including the dual eligibles under Medicare and Medicaid.

Management Challenge from Medicare Contracting Reform

SUMMARY OF ISSUE: Medicare's contracting authority and practices differ from those embodied in standard Federal contracting regulations. Medicare could benefit from a removal of CMS' contracting limitations and use of open competition in the selection of claims administration contractors. The House passed a bill giving CMS greater flexibility in its contracting arrangements, and, if CMS is granted this authority effectively managing a transition to the new system will be a major new challenge.

GAO Recommendations

The GAO notes that Medicare's contracting authority and practices differ from those embodied in standard federal contracting regulations, and that it has testified that Medicare could benefit from Congress removing CMS' contracting limitations.

The GAO further notes that, should CMS be granted competitive contracting authority, managing the transition to a different contracting environment will challenge CMS. Federal agencies that manage large procurements of contracted services have experienced difficulties with contract acquisition and management, such as cost and schedule overruns and the failure to hold contractors accountable. The GAO states that CMS needs to carefully plan its contracting reform efforts, and be attentive to best practices, to avoid the problems experienced by other agencies.

CMS Response

The CMS agrees with GAO that Medicare contracting reform will present significant implementation challenges for the agency, as well as opportunities. While much work remains to be done, CMS has made significant progress in developing its program and procurement strategy for Medicare contracting reform. For instance, CMS has done considerable analysis on the scope, functions, and jurisdictions of the future Medicare claims processing contracts.

The CMS has reviewed several GAO reports about federal contracting problems, and is working to avoid repeating these problems. To this end, CMS staff has conducted a series of information exchanges with the TRICARE program, various large-volume health care purchasers, and current and potential contractors.

One CMS workgroup is considering how best to draft a performance-based work statement for the new contractors, while another is analyzing the challenge of transitioning many Medicare workloads in a short period of time.

To gain familiarity with how incentive contracting might work in the Medicare environment, CMS has piloted award-fee arrangements with 3 contractors. The CMS has engaged consultants with significant experience in federal acquisition challenges to assist

it in developing the contract work statement, as well as a program plan and procurement strategy for contracting reform.

The CMS believes that most aspects of the proposed legislation will be beneficial, but has some concern with one requirement: that all Medicare contracts be re-competed every five years. This limitation may result in higher CMS and contractor costs.

Inappropriate State Financing Schemes

SUMMARY OF ISSUE: According to GAO, states use various financing schemes to inappropriately generate excessive federal Medicaid matching funds while their own share of expenditures remained unchanged or decreased. The CMS and Congress act repeatedly to curtail inappropriate financing, but states consistently develop new variations. The GAO recommends that Congress prohibit Medicaid payments to government-owned facilities in excess of the facility's cost. Also, new CMS requirements on UPL-related payments do not provide information required to determine whether local government health facilities transfer the federal funds back to the State.

CMS Response

In an effort to improve national consistency in the issuance and application of Medicaid reimbursement policy, CMS has put together two teams of Central and Regional Office staff who are responsible for reviewing all Medicaid reimbursement state plan amendments. These teams are the National Institutional Reimbursement Team (NIRT) and the Non-Institutional Payment Team (NIPT). The NIRT is responsible for reviewing all institutional reimbursement state plan amendments, providing technical assistance to the states, and developing Medicaid institutional reimbursement regulations and policy. In FY 2004, the NIRT will issue guidance on appropriate rate setting methods for UPL and other payments, and will establish more rigorous review and approval processes for state plan amendments involving rate increases to providers. The NIPT functions similarly to the NIRT, but for non-institutional providers, such as outpatient hospital departments, physicians and clinics. Both teams are currently using a standard set of questions that must be answered by the states before a state plan amendment will be approved. These questions help ensure that the payment methodology is clear. Through these team efforts state plan amendments are receiving greater scrutiny and Medicaid reimbursement policy is being implemented in a much more consistent manner. As an example, the NIPT halted the approval of questionable physician supplemental payment state plan amendments and thus far three such amendments have been disapproved. The NIPT is currently working to identify potentially acceptable payment methodologies for publicly employed physicians and to confirm that the providers retain 100 percent of the payments rather than recycling a portion through intergovernmental transfers.

The CMS plans to hire 100 new financial management (FM) staff in FY 2004, using Health Care Fraud and Abuse Control (HCFAC) Program funds, to change the focus of our FM reviews from an after-the-fact review to an upfront review modeled after the Medicaid Partnership Plan negotiated last year with Missouri. Before the beginning of each fiscal year (FY), every state would present for CMS review and approval an operating plan that identifies the state's estimated expenditures in the upcoming FY and the sources of the required non-federal share. The new FM staff will be primarily responsible for reviewing the non-federal share amounts and related expenditures, so that any problems can be resolved before the FY starts. They would also perform in-depth reviews of funding sources such as donations, taxes, certified public expenditures,

intergovernmental transfers, and state and local appropriations, to verify that they are allowable non-federal funding sources. Ninety of the new staff will be assigned to specific states, based upon the magnitude of Medicaid/SCHIP expenditures at risk and the complexity of the state's programs and FM issues. The remaining ten staff will be assigned to the NIRT.

Budget Neutrality of Waiver Demonstration Programs

SUMMARY OF ISSUE: Adherences to budget neutrality requirements has eroded as HHS and OMB have permitted States to use questionable methods that in GAO's view do not demonstrate budget neutrality. For example: HHS and OMB have allowed State(s) to disregard substantial new costs that would be incurred under the waiver, making it easier to demonstrate budget neutrality. In another case, HHS and OMB allowed a State to include impermissible costs to raise the level of costs estimated without the waiver.

CMS Response

In July 2002, the GAO issued a report titled "Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns" that indicates CMS approved demonstrations using budget neutrality methodologies the GAO deemed to be questionable. In the response to the draft report, CMS strongly disagreed with GAO's recommendation to modify the criteria used to review budget neutrality and to reconsider recently approved demonstrations that used budget neutrality agreements the GAO found questionable. We have attached a copy of the response. The CMS continues to believe that the methods currently used to assure budget neutrality are valid.

Before a section 1115 demonstration is approved, CMS, the Department and OMB carefully review the data submitted by the state to assure that the demonstration will be budget neutral over the life of the project. The CMS does not agree that budget neutrality requirements have eroded, or that HHS and OMB have approved questionable methods.

There have not been significant changes to the procedure whereby the Department, CMS and OMB give careful scrutiny to each State's request for Section 1115 waivers. A major component of that review is a thorough analysis of the demonstration's budget neutrality. CMS, the Department and OMB do not provide approval of a demonstration until we are satisfied that the demonstration's cost to the federal government is no more than would have occurred in its absence. Each demonstration's budget parameters and monitoring protocol are determined prospectively and state acceptance is a prerequisite for a project's implementation.

We are placing increased emphasis on reporting and monitoring of actual expenditures under the demonstration. The CMS has developed internal staff training focusing on state financial reporting and waiver monitoring capabilities through the MBES/CBES system. Our goal is to continually monitor current financial reporting to assess whether State's actual expenditures remain within their budget neutrality limits. When a Section 1115 demonstration renewal request is received, particular attention is paid to the project's budget neutrality limit and actual expenditure experience to determine whether the State has remained within the project budget limit, and to determine whether trends rates need to be modified to be consistent with State historical experience.

Oversight of Routine State Medicaid Financial Transactions

SUMMARY ISSUE: CMS lacks important policies and procedures to guide either its own or States' financial oversight activities and it has not provided consistent guidance to the States on appropriate payment practices. Specifically, CMS lacks (1) a sound method for identifying areas at high risk for improper payments; (2) performance standards for review of State expenditures; (3) analysis of trend information on the amount and type of Medicaid expenditures deferred or disallowed to monitor performance of this oversight activity. Medicaid services provided to children through their schools are one example of why CMS needs to increase scrutiny of Medicaid expenditures.

CMS Response

In FY 2002, CMS instituted an annual FM work planning and reporting process that includes targeting of high-risk areas for focused financial reviews performed by CMS regional staff. An extensive audit program carried out by the HHS Office of Inspector General supplements these reviews. Starting in FY 2002, CMSO has secured HCFAC funding to contract with the OIG to perform additional auditing, above and beyond what it otherwise could undertake, in high-risk areas identified by CMSO. CMSO standards for review of quarterly state expenditure and budget reports are contained in the Regional Office Manual. In addition, CMSO to date has prepared more than 20 Financial Review Guides on specific topical areas, each of which includes review standards. The FM work plan that CMSO approves each year specifies the number of focused financial reviews to be conducted by each regional office.

The CMSO's Division of Financial Management conducts a monthly conference call with all ten regional office FM branch chiefs, to discuss policy and procedural issues of common concern, and facilitate consistent financial oversight of the Medicaid and SCHIP program. Financial management issues and policies also are regularly discussed on weekly CMSO conference calls with the ten Associate Regional Administrators for Medicaid and State Operations. In both venues, CMSO discusses emerging financial policy issues, and sets the priorities for regional office quarterly and ad hoc expenditure reviews. In September, 2003, CMSO hosted a weeklong FM training session in Baltimore in which more than 80 financial staff from all ten regional offices participated. The training focused on UPL, DSH and school based claiming, but also covered such topics as targeted case management services, procurement policy, and the new managed care regulations. Finally, CMSO recently instituted a formal process under which the regions are required to obtain advance CMSO clearance of every deferral, disallowance or financial review report they propose to issue to a state, as well as of every state plan amendment, procurement or other action that states submit for CMS approval. This process has markedly enhanced CMSO's ability to timely identify emerging issues, make or clarify related policy, and ensure consistent financial oversight of state claiming practices.

In FY 2000, CMS adopted a Government Performance and Results Act goal to explore the feasibility of developing a methodology to estimate improper Medicaid payments on a state-specific and national basis. Working collaboratively with nine interested states, CMS and our outside technical consultant developed in 2002 a Payment Accuracy Measurement (PAM) methodology to estimate payment accuracy for both the fee-for-service and managed care components of the Medicaid program. The methodology is designed to produce state-specific estimates that are within +/- 3 percent of the true population accuracy rate with 95 percent confidence. Through weighted aggregation, the state-specific estimates can be used to make national level payment accuracy estimates for the program. In FY 2003, twelve states volunteered to test our PAM model in the Medicaid program. Pursuant to the Improper Payments Information Act of 2002 and related guidance issued by OMB, CMS modified the model to include in-depth reviews of beneficiary eligibility, and to account for under- as well as overpayments. In FY 2004, the final year of the PAM pilot, 27 states applied to test the CMS model in their Medicaid or SCHIP programs, or both. CMSO is now drafting a regulation to require all states to regularly estimate Medicaid and SCHIP improper payments using the CMS methodology. The proposed rule is scheduled to be published in April 2004.

Providers Are Surveyed Infrequently and Deficiencies Are Understated In Nursing Homes, Home Health Agencies, and Kidney Dialysis Facilities

SUMMARY OF ISSUE:

Nursing Homes – State surveyors often missed or understated serious deficiencies, making the actual extent to which residents are harmed or endangered. Survey process is not rigorous enough and nursing homes are able to predict the timing of surveys. CMS response to date has limited effectiveness.

Home Health Agencies – Surveys are less frequent, less comprehensive and miss many locations (branch offices). States appear to have disparate survey practices (e.g. in determining seriousness of deficiencies), so the process does not consistently capture the actual status of quality. CMS is improving oversight by assigning ID numbers to branch offices.

Kidney Dialysis Facilities – No statutory requirements for frequency of surveys. Limited frequency of surveys makes it difficult to determine exact extent to which facilities were in compliance with Federal quality requirements.

Nursing Homes

Because of weaknesses in the survey process, state surveyors often missed or understated serious deficiencies, masking the actual extent to which residents are harmed or placed in danger. The 1.6 million elderly and disabled nursing home residents, often very dependent or incapacitated, may be totally reliant on nursing home staff for medical care as well as assistance with basic activities of daily living, such as dressing, grooming, and eating. Our work since 1998 has demonstrated that state surveyors failed to identify serious nursing home care deficiencies or classified such deficiencies, including weight loss, dehydration, pressure sores, and incontinence, at an inappropriately low severity level. In independent reviews conducted to evaluate the quality of state survey agencies' performance, CMS' surveyors often identified serious deficiencies where state surveyors did not. Factors contributing to the understatement of deficiencies included lack of sufficient rigor in the survey process and nursing homes' ability to predict the timing of their surveys so that, if a home chooses to do so, it may conceal problems. In response to our recommendations, CMS has introduced strengthened survey methods to spot serious deficiencies, but is still developing important additional steps. To reduce survey predictability, CMS has varied the starting times of surveys, but this change has had limited effectiveness.

CMS Response

We expect that with greater emphasis on training and more consistent CMS and Regional Office oversight we will continue to see a reduction in the variability of citing deficiencies. On Oct 1, 2002, new Standards of Performance for State Survey Agencies went into effect, using a uniform set of protocols to monitor State performance and identify variations and changes on an ongoing basis.

A contract is currently in place to review and revise interpretive guidance for surveyors at selected tags (e.g., weight loss, dehydration, pressure sores, and incontinence), and to develop severity guidance at those tags.

Regarding the predictability of surveys, data showed that CMS has reached a goal of 10% staggered surveys for the year 2000.

The CMS is committed to a number of specific actions that will help build upon the progress made during the Nursing Home Initiative. These include: examining how to make optimal use of available remedies and the possible need for additional authorities; continuing to work with the states not meeting the goal for off-hour surveys; developing more streamlined methods for investigating complaints and the implementation of a complaint tracking system; development and implementation of the PDQ data system to provide more timely, useful and customer-friendly information.

Home Health Agencies

Patients receiving home health care are homebound, may have little contact with anyone except home health staff, and are therefore often isolated and vulnerable to poor care. Surveys of home health agencies are required less frequently than those of nursing homes—a minimum of once every 3 years as opposed to annually—and branch offices, constituting about one-quarter of home health locations, generally escape routine scrutiny. Some agencies must be surveyed annually if, for example, they have had prior serious deficiencies, but about half of these agencies did not receive required annual surveys. A home health agency survey is less comprehensive than a nursing home survey in that CMS does not require surveyors to review about half of the conditions for participating in Medicare, including assessing the quality of skilled nursing care. Although state surveyors identified a small proportion of home health agencies with deficiencies that either harmed or could harm patients, we found evidence that such problems also were understated. Moreover, two states accounted for over two-thirds of serious deficiencies reported nationwide, suggesting that states have disparate survey practices that may not consistently capture the actual status of quality. We found deficiencies in some states documented at a lower level of seriousness than similar deficiencies in other states that were documented as harming or potentially harming patients. In July 2002, we recommended several steps CMS could take to improve the home health agency survey process, including strengthening reviews of branch offices. The following month CMS began assigning these offices identification numbers to improve oversight.

CMS Response

The CMS concurs with GAO's finding and is taking steps to improve our oversight of home health agencies and their branch offices. In addition, we are currently exploring how to incorporate branches into the HHA survey schedule. With the advent of the branch specific outcome information, we anticipate being able to provide guidance to surveyors on how to investigate "unusual" findings or patterns present in the OASIS-derived reports. As we develop new survey protocols, we will be able to help state survey agencies target resources towards "poor performers," invest fewer resources on providers with good quality of care, and conduct ongoing off-site monitoring. We also believe that if we have sufficient resources, we will be able to direct the surveyors to visit those branches whose outcome reports are well below the national reference point and investigate the care practices that are producing the poor outcomes.

While surveyors have the option to conduct a standard survey at an HHA's branch office, we are currently testing ways to more formalize the inclusion of branch offices during a survey. CMS is assigning unique branch identifiers for all Medicare-approved HHAs and will complete this assignment by the end of CY 2003. The CMS will also be developing policies to more effectively integrate branch reviews into the survey tasks.
Once we know the location of every branch , we will develop a more systematic approach to evaluating the parent/branch relationship and assess the quality of care delivered by the entire provider. We will also be better able to explore ways to implement our policy in the most cost effective manner

The CMS issued specific guidance as part of the first phase to refine the home health survey process which consisted of a series of enhanced survey protocols that include specific guidance on how surveyors will utilize the OBQM and OBQI to help identify areas of focus in individual HHA surveys or the types of patients to include in the sample selection. The CMS expects that the enhanced survey protocols will promote consistency of survey activities.

The CMS clarified our policy (see survey and certification memorandum 02-30) on approving branch offices. The policies outlined in this memorandum focus on the ability of the HHA to demonstrate how it can monitor all services provided by the branch to ensure compliance with the conditions of participation found at 42 CFR 484. We believe that the decision to approve a branch should be based on the HHA's ability to meet the regulatory requirements and adequately supervise the branch to assure that the quality and scope of items and services provided to all patients is of the highest practicable functional capacity for each patient so as to meet their medical, nursing, and rehabilitative needs

The target completion date for our contract "Improving Protocols For Home Health Agency Assessment In The Survey Process" with the University of Colorado Health Services Research Center is June 2005. This contract will make recommendations to CMS on improved survey protocols, which effectively and efficiently measure the quality of care delivered in HHAs, as well as continue to promote consistency in the survey

process. With the establishment of the OASIS national repository, we now have the opportunity to more effectively use the patient specific outcome information to direct and supplement onsite surveys and to initiate data analysis necessary to help us explore ways to build a process that is more focused on patient outcomes and less focused on agency process.

Our current contract to improve on the home health survey process may generate some ways with which we can better ensure compliance with all home health COPs. Because there are resource implications in simply changing our policies to include survey of all COPs on all surveys, we are investigating the possibility of redefining what COPs constitute a standard survey, whether to survey for all COPs on every initial certification survey, or to grant states the flexibility to randomly conduct routine recertification surveys that include determination of compliance with all COPs, in lieu of the traditional standard survey. We will, of course, change the definition of the standard survey when the new CoPs are published.

The CMS has awarded a contract on September 29, 2002 to inventory all the home health data related to the management and survey and certification activities. The purpose of this contract is to identify and create an inventory of home health data to make this data accessible to CMS management and staff in a single program. The CMS will then be able to validate, analyze and assess the data to determine its utility in overseeing survey and certification activities at the state, regional, and national levels.

This will assist CMS in managing and monitoring all survey and certification activities for HHAs, as well as increase the efficiency and effectiveness of survey and certification processes. As part of the deliverables, we expect to receive recommendations on types of reports that CMS staff and management need to effectively and efficiently manage and monitor survey and certification activities of the states as well as the ability to easily gain access to these reports from individual desktops. The CMS has also developed standards for adequate state survey agency performance that hold states accountable for certain program requirements. While the impetus of developing these standards was to improve our nursing home survey and certification program, the standards do include evaluations of such things as timely planning, scheduling and conducting of surveys as well as timely data entry of survey results. As we improve our methods for collecting oversight information, we expect to be able to use this process to focus on oversight of HHAs.

Kidney Dialysis Facilities

Dialysis facilities treat more than 280,000 patients suffering from end-stage renal disease, an irreversible state of kidney impairment that requires either a transplant or regular dialysis. If performed improperly, dialysis can cause serious complications or even death; many dialysis patients are especially vulnerable because they are elderly and have other conditions, such as diabetes. No statutory requirements exist for the frequency of state surveys of dialysis facilities, and the number of facilities surveyed each year declined steadily during the 1990s. For instance, in 1999, only 11 percent of existing facilities

received a recertification survey, compared with 52 percent in 1993. The limited frequency of surveys made it impossible for us to determine the exact extent to which dialysis facilities were in compliance with federal quality requirements. However, 15 percent of the most recent surveys conducted at the time of our 2000 review identified deficiencies severe enough, if uncorrected, to warrant terminating participation in Medicare. In fiscal year 2001, CMS received additional funding that resulted in its increasing the number of facilities surveyed annually to one-third and indicated that, again, 15 percent of the facilities surveyed had at least one deficiency severe enough to lead to termination, if uncorrected.

Between 1998 and 2002, CMS more than doubled the aggregate funding for ESRD surveys and reduced the goal for the maximum time required between surveys, from six years to three years. The CMS also built some flexibility into the budget call letter to allow states to better target facilities with quality issues; and, provided a series of tool to assist state agency efforts with targeting. Annually, CMS issues an outcomes report that includes key patient quality indicators for all ESRD provider in the State. The outcomes list is positively correlated with survey deficiencies, making the list a supportive tool to be used in conjunction with key survey and certification information, such as past survey findings and complaints. In conjunction with the University of Michigan and the Colorado Foundation for Medical Care, CMS issues facility-specific reports to providers, state agencies, and ESRD networks. These reports include comparative data on facility characteristics, practice patterns, and outcomes. The reports are used to inform each entity so that they can better achieve their respective goal(s) whether it is improved care, improved monitoring, or improved technical assistance. The CMS is also taking steps to enhance surveyor skills and improve the survey process. Surveyor training courses have been updated and improved. Additional courses have been added to the schedule. Under contract with Lewin Associates, CMS is developing an automated survey tool, the Surveyor Technical Assistant for Renal Disease (STAR) which CMS believes will lead to more consistent survey data nationally.

CMS Response

In October 2002, CMS brought together 154 representatives from the State Survey Agencies and the ESRD Networks in order to help them understand each other's roles and responsibilities and to discuss collaboration and information sharing. The CMS is working with the ESRD community to develop and implement the ESRD Core Data Set and the VISION software system, both of which will include the standardized clinical performance measures (CPMs).

States Complaint Intake and Investigation Processes Ineffective

SUMMARY OF ISSUE: GAO found continuing weaknesses with complaint investigation practices in many States, including problems with the filing of complaints and the timelines of State investigations. CMS has a complaint improvement project underway.

Complaint investigations are an important opportunity for state survey agencies to intervene promptly when care problems are reported. This is especially true given the varying frequency with which surveys are conducted for different types of providers. The ability to lodge complaints against providers—whether by patients, family members, or caregivers themselves—and to have them resolved promptly is an essential aspect of protecting patient health and safety. Our reviews of nursing home and home health agency oversight revealed continuing weaknesses with complaint investigation practices in many states, including problems with the filing of complaints and the timeliness of state investigations. In reviewing the nursing home and home health agency complaint investigation processes for several states, we identified numerous shortcomings, including complaint hotlines that were not easily accessible, not publicized, limited to in-state callers, or that had no voice mail capability; states that required or encouraged written complaints over telephone calls; investigations of apparently serious complaints that were delayed because they were assigned a low investigation priority; and information systems that were inadequate for properly monitoring the status of complaint investigations. The CMS currently has a complaint improvement project under way that is designed to strengthen and improve the nursing home complaint process. The CMS expects to determine how the findings from this project can be applied to other providers as well and to issue guidance for states' complaint investigation processes.

CMS Response

On October 1, 2002, new Standards for Performance of State Survey Agencies went into effect, with the Regional Offices using a uniform set of protocols to monitor State performance and identify variations and changes on an ongoing basis. Among the new requirements are that the conduct of complaint investigations is timely and accurate.

The complaint improvement project (CIP) mentioned in the summary has been concluded and made several recommendations. The report was forwarded to the GAO on March 22, 2003. We are in the process of implementing several of the recommendations.

In addition CMS has redesigned the data system that captures survey and certification information. A sub-component of the national system will assist state agencies in the processing and tracking of complaints/incidents. The system is called the ASPEN Complaints/Incidents Tracking System (ACTS) and it collects more comprehensive information than the current information collected on complaints. Analysis of the data will assist CMS in its monitoring and oversight efforts. The CMS is in the process of implementing this system nationally.

Sanctions Do Not Ensure Provider Compliance

SUMMARY OF ISSUE: CMS uses a broad array of penalties for nursing homes, but limits its sanctions for home health agencies and kidney dialysis facilities to termination from the program despite statutory authority to do more.

CMS Response

Although sanctions can be an important enforcement tool, CMS does not use the full array of sanctions available. The CMS uses a broad array of sanctions to penalize nursing homes that repeatedly harm residents or fail to correct deficiencies within certain time frames. Sanction options for nursing homes include, among others, assessing monetary penalties and denying Medicare payments for new admissions, in addition to termination from the program. In contrast, CMS limits its sanctions for home health agencies and kidney dialysis facilities to termination from the program, despite statutory authority and direction to do more. Termination—or, in reality, the threat of termination—is an all-or-nothing option that is limited in effectiveness. Under this sanction, a provider can avoid termination by taking short-term corrective action to show compliance when a surveyor revisits the facility, thus stopping the termination process. Deficient facilities often temporarily return to, but do not necessarily remain in, compliance. We believe that using termination as the sole sanction option does not prevent a cycle of recurring noncompliance. In many states, we found home health agencies that had corrected their deficiencies, but were found to have serious problems shortly afterward. Some of these home health agencies had serious deficiencies cited in the same quality-of-care category on three of four surveys, yet were still participating in Medicare. Although the length of time between surveys of dialysis facilities makes it difficult to determine how quickly and how often they slip out of compliance, the results of our review suggested a similar pattern. For instance, almost 40 percent of dialysis facilities with deficiencies on their most recent survey also had a deficiency with at least one of the same requirements on their last survey. More than half of them had two or more such repeat deficiencies. Since 1987, CMS has had statutory authority to use an array of sanctions other than termination for home health agencies comparable to those used for nursing homes. However, CMS has not implemented this authority, as it was required to do by 1989, nor followed our 1997 recommendation to implement additional sanctions for home health agencies that are repeatedly out of compliance with Medicare participation requirements. Thus, we suggested in 2002 that the Congress consider giving CMS a new deadline for implementing additional sanctions for home health agencies. Although CMS also has broad authority to implement most sanctions for dialysis facilities, it does not have the authority to assess civil monetary penalties, except under one specific condition. In 2000, we suggested that the Congress consider authorizing CMS to assess similar monetary penalties on dialysis facilities as are imposed on nursing homes that have severe or repeated deficiencies. For its part, CMS is in the process of developing a rule and procedures to strengthen sanction procedures for one quality standard associated with dialysis care.

The CMS agreed with the recommendations of this report and has been taking steps to improve the oversight and quality of care in dialysis facilities participating in the Medicare program including working on publishing new conditions for coverage that will strengthen requirements, and increasing funding level for surveys of ESRD facilities in order to increase the survey frequency.

The CMS recently awarded a contract to evaluate the effectiveness of sanctions and remedies for improving nursing home resident care. We believe that this information derived from this contract will help us better understand what directions to take in working with the ESRD community to improve quality outcomes for beneficiaries and sustained compliance for providers.

The CMS is committed to taking appropriate actions against facilities that have condition-level problems, especially on an ongoing basis. The purpose of our actions must be to provider either a strong incentive for the provider to come back into compliance and furnish quality care to our beneficiaries, or provide a mechanism to remove the provider from the program.

Oversight of State Survey Agencies Is Inadequate

SUMMARY OF ISSUES:

Nursing Homes – CMS relies heavily on State self-evaluations instead of using available data monitor State performance of nursing home surveys. CMS has responded to GAO recommendations by initiating annual assessments of each State's compliance with specific performance requirements and making greater use of survey data.

Home Health Agencies – CMS does not routinely review whether States are complying with key statutory, regulatory, or other requirements, such as annually surveying home health agencies with serious deficiencies. Moreover, CMS does not assess the adequacy of State agency surveys of home health agencies by conducting its own comparative studies.

CMS Response

The CMS and its 10 regional offices are responsible for ensuring that state survey agencies effectively identify and resolve problems with provider quality of care. Our work has consistently identified weaknesses in CMS's monitoring efforts. Although CMS had data available to assist in monitoring state performance of nursing home surveys, it instead relied heavily on states' self-evaluation—essentially allowing states to write their own report cards on the adequacy of surveyors' inspections or complaint investigations. CMS has responded to our recommendations to strengthen its state nursing home oversight by initiating annual assessments of each state's compliance with specific performance requirements and by making greater use of survey data. Additional management attention would further strengthen these efforts and ensure greater consistency across CMS's regional offices. The CMS's oversight of home health agencies has been less stringent, with limited use of the numerous tools it has available for monitoring states' nursing home surveys. To improve its monitoring of state nursing home survey activities, in 2001, CMS began producing and using reports from its numerous databases and established an annual state performance review process. As part of the annual performance review, it identified seven specific performance standards that states are required to meet, for example, survey timing, deficiency documentation, and complaint investigation criteria, and assessed each state's compliance with each standard. Our ongoing work is examining the results of this review, and we will comment on it in a future report. Another important component of CMS's oversight activities is monitoring its new January 2000 requirement that states refer to CMS for immediate sanction those nursing homes that were found on successive surveys to have harmed one or more residents. This policy was implemented at our recommendation to eliminate the practice of continually allowing such homes a grace period to correct deficiencies and thus escape sanctions indefinitely. Our ongoing work also will address the extent to which CMS has monitored states' compliance with this new policy. The CMS's oversight of states' home health agency surveys is particularly important because a new prospective payment

system introduced in October 2000 not only encouraged home health agencies to provide care more efficiently but also created a situation in which reducing services increases net revenues. Yet, CMS does not routinely review whether states are complying with key statutory, regulatory, or other requirements, such as annually surveying home health agencies with serious deficiencies and ensuring that sample sizes of medical records and patient visits meet minimum federal standards. Moreover, CMS does not assess the adequacy of state agency surveys of home health agencies by conducting its own onsite comparative survey at a sample of agencies shortly after the state's survey. The CMS is statutorily required to perform such surveys for nursing homes and is currently planning to more than double the number of these surveys. We recently suggested to the Congress that it require CMS to perform similar surveys of home health agencies. Although CMS is poised to conduct annual reviews of state compliance with federal home health survey requirements, the limited areas it selected for its first such review in 2002 did not focus on critical issues requiring more immediate attention, such as ensuring that home health agencies with serious deficiencies are surveyed annually and that states assign complaints to appropriate categories so that investigations are timely. In response to our recommendations, CMS has proposed taking some limited steps to improve oversight of home health agency surveys.

On October 1, 2002, new Standards for Performance of State Survey Agencies went into effect, with the Regional Offices using a uniform set of protocols to monitor State performance and identify variations and changes on an ongoing basis. The new standards include requirements to ensure: that surveys are planned, scheduled and conducted timely; that survey findings are supportable; that survey findings are supportable; that certifications are fully documented, and consistent with applicable regulations and instructions; that applicable instructions are adhered to in certifying non-compliance; and that the conduct of complaint investigations is timely and accurate, and complies with general instructions.

The CMS has also developed standards for adequate State Survey Agency performance that hold states accountable for certain program requirements. While the impetus of developing these standards was to improve our nursing home survey and certification program, the standards do include evaluations of such things as timely planning, scheduling and conducting of surveys as well as timely data entry of survey results. As we improve our methods for collecting oversight information, we expect to be able to use this process to focus on oversight of HHAs.

The State Performance standards were updated for FY 2003 and FY 2004.

Staffing Issues Create Human Capital Challenges to Meeting Survey Quality Requirements

SUMMARY OF ISSUE: CMS and State survey agencies face an increasingly difficult challenge to ensure that experienced survey staff are available to assess quality of care across the multitude of providers serving Medicare and Medicaid beneficiaries. States plan to hire additional surveyors but States are hindered by budget constraints and it could take up to 3 years for new surveyors to gain sufficient knowledge and experience.

CMS Response

The CMS and state survey agencies face an increasingly difficult challenge to ensure that experienced survey staff—generally registered nurses—are available to assess quality of care across the multitude of providers serving Medicare and Medicaid beneficiaries. Some states indicated that the numbers of their survey staff were inadequate to meet expanding survey requirements, including complaint investigations, and therefore planned to hire additional surveyors. However, we were informed that it could take as long as 3 years for newly hired surveyor staff to gain sufficient knowledge and experience to perform their jobs well and independently. We found that, for home health agencies, a substantial number of surveyors assigned during 2000 in some states we reviewed had neither taken the basic training course that CMS offers nor acquired substantial on-the-job experience by conducting home health agency surveys. State officials cited surveyor turnover as a reason they must often rely on relatively inexperienced surveyors to conduct surveys. In addition, CMS has expressed concern that the economic downturn in the past 2 years may have affected state budgets, to the extent that states are unable to ensure that sufficient numbers of skilled staff are available to survey providers as required. We have ongoing work that addresses, among other things, states' ability to maintain a well-trained and experienced surveyor workforce in order to meet their obligations to the federal government to assess the quality of care provided to public beneficiaries.

The CMS does not disagree with the summary findings. However, CMS notes that in FY 2003 the Agency moved forward with efforts towards strengthening our ability to track the number of state surveyor staff, including their federal training course status.

Each fiscal year, CMS issues to state survey agencies, federal survey and certification program priorities and guidance that states are required to meet, including survey training requirements as well as statutorily mandated survey requirements.

The CMS established a Classroom Learning System (CLS) that keeps individual records of all staff that participate in any training provided by CMS and State. A procedure is in place to put training materials on internal websites for Providers, Federal Oversight Support and Survey and other program requirements such as the State Operations Manual. The website links to nationally recognized groups for policy and training materials.

On January 22, 2003, CMS issued to each State survey agency a request for the purpose of assessing State staffing capacity dedicated to the Federal survey and certification program. Responses from nearly all States indicated that state economic conditions and state hiring freezes would not adversely impact the ability of states to meet statutorily mandated federal survey workload requirements

In FY04, we will conduct 56 on-site courses which include: 19 Basic courses (LTC, HHA, ICF/MR, Psych Hospital, LSC, Hospital, Hospice and ESRD); and -35 specialty courses. In advance of the schedule, surveys are done to determine training locations that would most efficiently provide training to those states in need. In addition to the 56 on-site courses, we will broadcast 26 satellite programs on a variety of survey and certification issues which are accessible to surveyors and the public and available for rebroadcast for a year on the internet.

Program Effectiveness

SUMMARY OF ISSUE: States do not have reliable or complete data on the extent to which individuals are getting care, like EPSDT services.

CMS Response

The CMS has taken several steps to assist states in compiling more accurate and consistent data. In January 2001, CMS sent a memorandum to its Associate Regional Administrators highlighting the need to assure access to care for Medicaid-eligible children. In that memorandum, CMS acknowledged that data collection was an issue that needed to be addressed at the federal level, by states, and by providers, since the data is dependent on what is reported by providers. The CMS encouraged our regional offices to work with states to understand the strengths and limitations of the EPSDT reporting system. This is especially difficult in states where there are large pediatric populations in managed care where claims data is not generally available under these arrangements.

The CMS held a national EPSDT meeting in Philadelphia in August 2002 that was attended by 22 state Medicaid representatives. One of the three major topics of discussion was data reporting. States shared their experiences, both successes and failures, in their attempts to collect accurate and consistent data.

The CMS also continues to meet with outside parties and organizations interested in reporting issues. For example, we have met with the National Association of Urban HMOs, most recently on October 21, to discuss EPSDT data reporting issues and quality indicators. The CMS continues to be open to discussions on how best to collect data that is a true indicator of children receiving the services to which they are entitled.

The CMS believes that as a result of these efforts both CMS and the states have a better understanding of the strengths and weaknesses of the EPSDT reporting requirements and process. In addition, by providing a forum for states to share best practices, CMS has initiated a federal-state and state-to-state dialogue on this important issue.

SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS HEARING ENTITLED: "DOES CMS HAVE THE RIGHT PRESCRIPTION? IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM" APRIL 8, 2004

Senator Durbin:

Question 1:

The Medicare bill provided $1.5 billion for FYs 2004 and 2005 for implementation of the entire bill, all 176 provisions. This includes $1 billion for CMS and $0.5 billion for the Social Security Agency. Part of this money is for education and outreach but the final bill did not specify what portion of the money should go for education and outreach or how much should be used for appeals cases, claims payment, computer systems, etc.

How do you plan to spend the money? Do you have enough funds to promulgate the rules, set up new systems, build a mechanism for dealing with PMBs and the new Prescription Drug Plans; and ensure that seniors understand the bill?

Answer:

CMS Response: CMS is working to develop a detailed Medicare Modernization Act implementation plan for FY04 and FY05. The development of this plan will be an evolving process as business requirements and implementation plans are developed and refined.

As we embark on this modernization effort, we anticipate that education and outreach activities for beneficiaries and providers will be critical and we have planned on spending at least a quarter of our resources on these efforts. This program expansion will also require modifications in our operating systems and we expect to spend another quarter of our funds on information technology and contractor system changes. Another portion of our funding will be directed to support various research and demonstration projects and related program administration activities. Given the magnitude of this effort and our desire to be flexible in order to meet changing program needs, we have created a contingency reserve with the remaining funds to cover changes in cost estimates or changes in program needs over the next two years.

We can say that even without all of the details of our spending plan being nailed down, we have released some funds, within a broad framework of what must be done, to address the immediate needs of implementing MMA. We will need flexibility, as we work with the Department and the Office of Management and Budget, to modify the implementation plan to handle future implementation issues and to best meet the needs of our beneficiaries.

Question 2:

What happens to CMS's budget on October 1, 2005, three months before the serious stuff starts and the $1 billion runs out? Does anyone at OMB or elsewhere have a strategic plan for funding in FY 2006?

Answer:

CMS Response: CMS has already begun to formulate its FY 2006 budget requirements for the Medicare Modernization Act (MMA). We have been working for the past few months to develop a detailed workload and spending plan for the $1 billion that was appropriated for FY 2004 and FY 2005. The estimates in this plan will provide a framework for our FY 2006 estimate since we expect that many MMA activities will be ongoing. We are also developing estimates for provisions, such as contracting reform, which we expect to implement beginning in FY 2006. Together with the Department, we plan to work closely with OMB to ensure that we have adequate resources to support all of the work associated with the many new provisions required by the Medicare Modernization Act, in addition to CMS' other ongoing baseline activities.

Question 3:

As you know, despite years of work and millions of dollars spent on outreach, the level of participation in the Medicare Savings Program (MSP) is very low. The millions of eligible low-income Medicare beneficiaries who are not enrolled in the MSP program miss out on the Part A and Part B deductible, co-pay, and premium assistance provided by these MSP programs. In 2004, this assistance is worth a minimum of $799 and for Qualified Medicare Beneficiaries who live on incomes under 100 percent of the poverty level, it can easily be worth much more than that.

Many of my colleagues have urged CMS to automatically enroll all current MSP beneficiaries in the transitional assistance program so as to avoid requiring a separate time-consuming enrollment process for the $600 per year.

When will you make a decision on automatic enrollment?

Answer:

CMS Response: We committed to doing everything we can to enroll eligible people with Medicare in the $600 transitional assistance program. We are working with sponsors and others to reach out to this population so they can benefit fully from the Medicare-approved drug discount card. In addition, we are working with community-based organizations and States to educate low-income beneficiaries about the opportunity to save on their outpatient drugs and to get the credit. We will monitor enrollment in transitional assistance and if we

find that enrollment is lagging we will work with States on options to enroll people with Medicare for whom the States pay Medicare premiums.

SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE AND THE DISTRICT OF COLUMBIA OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS HEARING ENTITLED: "DOES CMS HAVE THE RIGHT PRESCRIPTION? IMPLEMENTING THE MEDICARE PRESCRIPTION DRUG PROGRAM" APRIL 8, 2004

Senator Akaka:

Question 1:

You testified on behalf of the Centers for Medicare and Medicaid Services (CMS) that your agency will use contractors to staff the Medicare Prescription Drug Program's six call centers and to carry out other administrative activities.

Please describe how CMS will ensure that contractors preserve patient rights under the Health Insurance Portability and Accountability Act Privacy Rule?

Answer:

CMS Response: CMS is committed to protecting the information we manage on behalf of the millions of beneficiaries that we serve. Currently, CMS' 1-800-MEDICARE call centers that answer questions about Medicare-Approved Drug Discount Cards do not have access to a beneficiary's protected health information. Any information that a beneficiary discloses about him or herself in a call to1-800-MEDICARE is not kept by the call center. In order to ensure the protection of any information that an individual may disclose, call center employees are required to sign a "Statement of Understanding and Non-Disclosure." This statement lists the call center employees' privacy and security responsibilities and prohibitions.

CMS includes the business associate contract provisions of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in the contracts of Medicare contractor call centers that have access to beneficiary protected health information. These provisions include the obligation for call centers to safeguard the use or disclosure of protected health information and to only use the information as permitted under the contract or as required by law. Call centers, as business associates, also agree to ensure that any agent, including any subcontractor, to whom they provide protected health information are held to the same obligations and activities as the call centers. These same privacy protections will be extended under the Medicare Prescription Drug Program.

CMS has issued guidelines for the Medicare contractors' call centers regarding the disclosure of beneficiary-specific information over the telephone. These guidelines apply to requests for information from beneficiaries and providers and are consistent with federal privacy requirements, including the Health Insurance Portability and

Accountability Act Privacy Rule. As a part of the agency's commitment to privacy, CMS created web-based privacy training for the contractor call centers. The training informs personnel about their roles and responsibilities for protecting health information that is used and disclosed in the day-to-day administration of the Medicare program.

Question 2:

Many of CMS's challenges, under its new prescription drug program, are similar to those of the SSA. Both entities rely on strong institutional knowledge and efficient service to deliver critical benefits successfully. At the Social Security Administration, it takes a field representative an average of three years to acquire the administrative and technical knowledge that is needed to ensure proper benefit delivery.

Please specify how long CMS anticipates it will take to train contractors to perform successfully and independently?

Answer:

CMS Response: The functions being performed by SSA and 1-800 Medicare are two different and distinct functions. At SSA, the CSR has to know the full set of rules, regulations and technical details so that they can apply them to the individual situation of a caller. At 1-800 Medicare, the questions are more general and do not contain personal health information. The CSRs are assisted by a desktop (NGD) that contains an extensive set of scripts that they can use to answer questions. The CSR has to know how to get to the correct information that they have to read to the beneficiary. They do not have to know all of the rules and regulations and apply them to individual personal situations. The training period needed for 1-800 Medicare Customer Service Representatives in order to get them into a fully functional state (including drug card material) is 12 days. The 12 days includes training on Medicare content, the Medicare Modernization Act, Quality Call Monitoring, Customer Service Skills, website navigation, and the Customer Service Representative NGD desktop application. Every CSR participates in one hour refresher training per week. Refresher training may include review of new and updated content, desktop scripts, and a review of quality call monitoring techniques.

Question 3:

What criteria will CMS use to assess the proficiency of contractors?

Answer:

CMS Response: We use a variety of techniques to assess the proficiency of the contractors such as:

1) Blind monitoring – listening in on ongoing calls for quality and coaching purposes.

2) Recording calls (% of CSR calls). Both CSR and Beneficiary voices are included on the recording along with the computer screens accessed by the CSR. These recordings can be played back at a later date, scored, used to mentor the CSR for performance improvement.

3) Performing test calls – call in to the help line as a beneficiary and present a question or situation to the CSR to see how they perform.

A standard scorecard is used to evaluate the elements of each of the types of calls. The results of the scorecard are collected and analyzed. The results are reported to the CSR, the call center contractor Pearson Government Solutions to CMS management. On a regular basis, we hold calibration sessions with those responsible to score the call in order to ensure a consistency and fairness of scores.

Question 4:

What are the projected contractor training costs CMS will incur as it implements and executes its new Medicare Part D prescription drug program?

Answer:

CMS Response: Medicare Part D prescription drug program training costs are about $4 million.

Question 5:

Furthermore, please describe what human capital strategies CMS intends to utilize to recruit and to retain contractor services.

Answer:

CMS has a service contract with Pearson Government Solutions to establish, maintain and operate 1-800-MEDICARE call center Help lines. Within the contract we have a service level agreement to answer 80% of the calls within 30 seconds. Pearson uses Industry Best Practices on hiring and retaining CSRs. The industry best practices include elements such as offering competitive wages and providing extensive ongoing training.

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