PATIENTS FIRST: A 21ST CENTURY PROMISE TO ENSURE QUALITY AND AFFORDABLE HEALTH COVERAGE

JOINT HEARINGS

BEFORE THE

SUBCOMMITTEE ON HEALTH

AND THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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PATIENTS FIRST: A 21ST CENTURY PROMISE TO ENSURE QUALITY AND AFFORDABLE HEALTH COVERAGE

THURSDAY, MARCH 1, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH, JOINT WITH THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittees met, pursuant to notice, at 10:07 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman, Subcommittee on Health) and Hon. James C. Greenwood (chairman, Subcommittee on Oversight and Investigations) presiding.

Members present Subcommittee on Health: Representatives Bilirakis, Upton, Greenwood, Burr, Whitfield, Wilson, Shadegg, Bryant, Pitts, Tauzin (ex officio), Brown, Barrett, Capps, Deutsch, Eshoo, Stupak, Engel, Wynn, and Green.

Members present Subcommittee on Oversight and Investigations: Greenwood, Bilirakis, Burr, Whitfield, Tauzin (ex officio), Stupak, and Rush.

Staff present: Tom Giles, majority counsel; Marc Wheat, majority counsel; Kristi Gillis, legislative clerk; Amy Droskoski, minority professional staff; and Bridget Taylor, minority professional staff.

Mr. BILIRAKIS. Good morning. I now call to order this first joint hearing in this 107th Congress of the Health Subcommittee and the Oversight Investigation Subcommittee, and I would like to start, of course, by welcoming our witnesses and all of the members of both subcommittees. I particularly appreciate this opportunity to work with the Oversight and Investigations Subcommittee and its chairman, Jim Greenwood, as well as the ranking member, my Florida colleague, Congressman Peter Deutsch.

Today, along with Mr. Brown, we launch the first hearing in a series entitled "Patients First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage."

Millions of seniors rely on Medicare for their health care needs, but few are familiar with the agency that administers this important program, and that is the Health Care Financing Administration, or HCFA, as we fondly refer to it. And yet this agency has a very real and sometimes negative impact on the quality of care delivered to patients through Federal health programs.

Reform of the agency that administers Medicare is a critical step in our efforts to protect and strengthen this vital program for the

future. Too often HCFA is inflexible and unresponsive to patient needs.

A recent report by the Lewin Group indicated that beneficiaries have been denied access to some medical technologies for up to 5 years or more after approval by the Food and Drug Administration.

HCFA's processes for determining coverage, assigning billing codes, and setting payment levels are causing serious delays in the availability of these breakthrough treatments for patients. These delays cause serious harm to patients in need of treatment, and patient care will continue to suffer unless HCFA's coverage policies are reformed.

We will address those issues today while recognizing that we must constantly keep the fiscal health of the Medicare program at the forefront of all of our efforts. Today, an estimated 130,000 pages of laws and regulations govern the Medicare program. Many providers are forced to spend as much time negotiating the maze of HCFA's bureaucracy as they do treating patients.

To improve the quality of patient care, therefore, we must first conduct a top to bottom review of HCFA's structure, operations, and regulations. A similar effort by our committee to overhaul the Food and Drug Administration led to enactment of the Food and Drug Modernization Act in 1997. This critical measure removed bureaucratic obstacles which had blocked the timely approval of life-saving medications and medical devices for patients.

Under the leadership of our new full committee chairman, Congressman Billy Tauzin, we will now tackle an even greater challenge: ensuring quality and affordable health coverage for patients through Federal health programs. Together, we have launched an ambitious initiative to reform HCFA and to put patients first.

On February 13, I had the opportunity to visit HCFA's facilities in Baltimore with Chairmen Tauzin, Greenwood, and several committee members. The tour underscored the agency's complexity and the incredibly broad range of its responsibilities. Our discussions with HCFA staff were productive, and we did have frank conversations about the problems facing the agency.

Following our visit, Chairman Tauzin, Chairman Greenwood and I wrote to Health and Human Services Secretary Tommy Thompson to underscore our commitment to improving patients' access to quality health care through Federal programs.

As a former Governor, Secretary Thompson will bring a wealth of practical experience to bear in solving this problem, and we have solicited his active participation in support of this initiative.

Clearly, patients deserve better access to the most technologically-advanced devices and services. This is just one example of the many areas in which we will focus over the next several months. We will work to ensure patients receive quality affordable health care through Federal programs. I am confident that we will succeed in our efforts to put patients first.

The Chair will recognize Mr. Brown, Mr. Greenwood and Mr. Deutsch for the usual 5 minute opening statements, and then, with unanimous consent, I would like to either limit other members' opening statements to 1 minute or else they may choose to defer their opening statements until after we have completed this first

panel. That being the case, the Chair now recognizes Mr. Brown for an opening statement.

Mr. BROWN. I thank the chairman. I am pleased to welcome our witnesses this morning. This is an important hearing because there are questions about certain aspects of Medicare coverage and payment rules. If these rules are inappropriately delaying or restricting access to certain medical devices, we must do something about it.

This hearing is also important because it is the first of several focusing on HCFA operations, and it happens to be taking place at a critical point in the history of Medicare. Before we get started, I believe it is important to clarify our intentions for this and for future HCFA hearings and place our review of HCFA operations in the proper context. Otherwise, our decision to focus on the details of HCFA's current operations could be misperceived as a statement for or against complete overhaul of HCFA or as a statement for or against Medicare privatization. As I understand it, that is not what these hearings are about.

Last year, the chairman and I along with other subcommittee members met with then acting HCFA Administrator Mike Hash. We asked him to tell us what HCFA could do and what Congress could do to improve program operations and ensure that beneficiaries are protected. As I see it, identifying what Congress can do and what HCFA can do to improve program operations and keep our promises to seniors is the sole purpose of these hearings.

The goal is not today, should not be today, to demonize HCFA. If we are going to dole out blame for incremental problems in the Medicare program, Congress, not HCFA, should bear the brunt of it. The goal is to make sure that the program is running as smoothly as possible. That means looking at each of the major variables that influence operations.

Last Friday, four HCFA administrators representing both Democratic and Republican administrations participated in a roundtable discussion about HCFA. All four administrators agreed on two points: the Health Care Financing Administration is severely overburdened and chronically underfunded.

When managed care plans were asked to share data on how they spend the billions of Trust Fund dollars that Medicare pays them each year, they screamed too complicated, too much work, overregulation. HCFA is not allowed to scream when we codify arcane details about how providers are to be paid without regard to the operational requirements of those payment systems, without regard to the resources and time needed to fulfil those requirements, and sometimes frankly without regard to logic.

When over a 3-year period, Medicare Plus Choice plans systematically and unceremoniously dropped 1.7 million Medicare beneficiaries from coverage instead of cross-subsidizing between more and less profitable counties and staying in, remaining in those counties and serving those seniors, when they underprojected the cost of providing supplemental benefits, made bad business decisions, under projected the cost of providing supplemental benefits like prescription drugs, and then they blamed their missed profit goals on a shortfall on reimbursement for basic benefits, what did Congress do? Nothing.

Did we discuss overhauling the Plus Choice program or abandoning it in favor of the more stable and reliable Medicare fee-for-service program? No. In the great old big government tradition, this government, this Congress, threw money at the Plus Choice plans. We did not even require that they address beneficiary concerns as a condition of receiving the money.

As we scrutinize HCFA's overtaxed and underfunded operations, maybe, just maybe, we should think about giving HCFA the resources it needs to do its job. Maybe we should see about removing statutory constraints that hold the agency back. This is not to say that HCFA is perfect and could not benefit from close evaluation of its practices. But in doing so, HCFA and Congress must work together to perform a better balancing act, making sure beneficiaries are getting quality care, protecting the program from fraud, and ensuring that the program is responsive and responsible. In this context, Mr. Chairman, this hearing is a positive step. I thank the chairman.

Mr. BILIRAKIS. I thank the gentleman. Chairman Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman. I would ask unanimous consent to submit my written statement for the record.

Mr. BILIRAKIS. Without objection, the written statements of all members of the two subcommittees may be made a part of the record.

Mr. GREENWOOD. And I would like to forgo my written statement, in part, to respond to Mr. Brown's comments, if I may.

Mr. BILIRAKIS. Yes.

Mr. GREENWOOD. In part to set the tone for what is going to be a series of these hearings on the Health Care Financing Agency. I hope none of us or none of the witnesses demonize HCFA, nor the extraordinary people who work for HCFA. That would be a mistake. They have had, I think, 17 directors in 23 years, and frankly it has been the senior staff of HCFA that has been trying to make a go of it.

And what we are all about here is trying to figure out in the interest of the 70 some million Medicare and Medicaid beneficiaries and the kids in the CHIP program whether there is a better way after 23 years of HCFA to structure it, to organize it to make it respond to the needs of the seniors and kids and the others and the disabled in the country. And that is what we ought to be about, particularly as a health subcommittee and as an oversight subcommittee.

I think it is equally destructive and nonproductive to demonize the Medicare Plus Choice plans, and, frankly, I think that is what you are doing a little bit there, Mr. Brown.

We should not demonize HCFA. We should not demonize the plans. I do agree with you that the reason the Medicare Plus Choice plans have not functioned very well is our fault. It is the Congress' fault. We did not give them enough money. We should not expect them to provide a service that we are not willing to pay for. So I am hopeful that in this hearing today and in the hearings that follow, let us not demonize anybody. Let us not demonize HCFA. Let us not demonize the Medicare Plus Choice plans. Let us do what we get paid to do, and that is to constructively oversee

this agency and see if we can come up with a better result. I yield back, Mr. Chairman.

Mr. BILIRAKIS. And amen to those comments. Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman. Mr. Chairman, today's hearing is about how to bring certain reforms to the Health Care Financing Administration's efforts to bring new medical technologies to market. While I do not dispute the importance of today's topic, and I fully believe that you and the rest of the committee members on this panel appreciate its importance as well, I am concerned that it is somewhat premature for the Oversight and Investigations Subcommittee to be holding this hearing at this time.

As you know, the oversight panel is an investigatory body. We do investigations. We are set up to conduct lengthy examinations designed to explore not only what is dysfunctional about a particular government program, but also to explore what possible solutions might be used to address whatever shortcomings are uncovered.

But we generally do our investigation first, then hold a hearing to report what we have found. What is somewhat frustrating about today's meeting is that we have not yet completed or even really begun a cursory investigation into this matter.

Instead, what we are doing in this room is really a process of opinion gathering. But it should not be construed as a presentation of the subcommittee's investigative findings. Consider the resources or lack thereof that we have dedicated to the investigating of this matter thus far.

To my knowledge, there has not even been a single bipartisan staff interview with HCFA officials in an attempt to examine what is broken at the agency as it relates to today's topic. Moreover, we are at this hearing with virtually no agency documents because thus far we haven't sent out a request to HCFA for such information.

That information is critical if we are going to independently assess whether the agency is doing a competent job or incompetent job at bringing new technologies to Medicare beneficiaries. In virtually every other investigation conducted by this subcommittee involving the previous administration, we made numerous document requests, often highly burdensome ones at that, but why not here?

Is it because we are just starting out with investigation or is it because we already know the conclusions of the inquiry? I do not know, but it leaves me and I would guess some of my colleagues in a rather awkward position. It is awkward because we have not conducted our own careful analysis of these matters. Instead, we have spent much of this last week scrambling to find last minute information to pull together this hearing, which is not a very satisfying process.

Mr. Chairman, please do not think I am trying to be partisan or even unconstructive here. That is not my intent. I am indeed committed to working with you on this and other important issues, but what I do not want to see is a continuation of a practice that sometimes occurred in the last Congress, which was to hold an oversight hearing prematurely before an investigation was complete or noteworthy findings made.

In other words, if you want support from our side, we should work together to conduct a detailed subcommittee investigation. Then, put our heads together to determine if we are ready to schedule a hearing.

Let me give you an example of what I mean. The last hearing involving the oversight investigation staff examined whether TV networks deliberately biased the coverage of the 2000 Presidential elections. That investigation alone involved hundreds of subcommittee staff hours and took several months' work.

It also required document reviews and countless staff interviews, many of which required staff travel. It was not until considerable work was undertaken and significant analysis expended that this hearing was even scheduled. I would only hope that if this subcommittee now finds this subject as important, it will dedicate the same amount of resources and attention.

Mr. Chairman, let me underscore again that I am willing to support you in making all necessary document requests to HCFA or the providers regarding the subject. To that end, let me also say that I will support you in conducting whatever meetings are necessary at the staff level with HCFA or industry officials.

I will even support you in requesting that the General Accounting Office assist us should we find it necessary. But if we are going to investigate the processes and procedures HCFA uses to approve or reject certain medical technologies for Medicare beneficiaries, a highly complex and technical matter, then we need to spend significantly more time behind the scenes before we gather in this room.

That being said, Mr. Chairman, let me conclude by saying the following: I do want to stress the importance of improving access to medical technologies for our seniors. Overall, our country's health care system has gone from one of intervention to one of prevention. The entrance of new medical technologies into the health care arena is allowing millions of Americans to live longer, healthier lives.

It is imperative that our seniors have access to these same innovations in a timely fashion. We in Congress must ensure that the system designed to provide this access works in the most expedient and efficient manner possible. I look forward to learning more about HCFA's role in this process and ways in which we can better the system to take advantage and give advantage to the nation's seniors.

Again, Mr. Chairman, I look forward to working with you constructively in the future and I hope you will take my concerns into consideration. With that, I welcome our witnesses and I thank them in advance for their thoughtful testimony.

Mr. BILIRAKIS. The Chair thanks the gentleman and recognizes the chairman of the full committee, Mr. Tauzin, for an opening statement.

Chairman TAUZIN. Thank you, Mr. Chairman. Mr. Bilirakis and Mr. Greenwood, let me congratulate you on this, the first of, I hope, what will be many efforts of joint O&I and substantive subcommittee work at examining the problems that the Federal agencies which do govern some of the most important programs that provide health care services to patients across America.

Let me comment quickly on what I know and what I hope this effort will achieve. Let me first indicate that we could wait until we do a great deal more investigation on a staff level. We could have many meetings with HCFA. We could have many exchanges of letters. We could do a lot of things, but the first and most important thing we do is gather, as members of these two subcommittees, and begin to take testimony on the record so that we can get into these subject matters as quickly as possible.

I want to commend you for not waiting but moving. This committee has waited too long. There have been too many months and too many years where this committee has not engaged the serious concerns of Americans as we have heard them in letters and calls to this committee regarding the administration of these vital programs.

And I am pleased that the focus is going to be on patients first. I am pleased that you are going to put a human face on this question: how well are patients in America being served by the Federal bureaucracies that manage these critical programs that are critical to their lives, that make a great difference in how long and what kind of quality of life Americans enjoy?

And this objective, to make sure that seniors will have access to the best technologies that our country can offer, that the government is not standing in the way but always assisting in moving new technologies out into the marketplace where they have been properly tested and properly prepared to save lives and extend the quality of life, and I want to again commend you for not waiting but for moving.

And I want to commend all of you on the two committees for taking this as seriously as I know you are. This is serious business, and it is not, I hope, going to bog down in partisan concerns and complaints or fingerpointings. We are not here to score points at each other's expense. We are here to learn, to learn what is wrong with the system, what is right with it, and then to fix those things that are wrong, not in the interest again of politics, but in the interest of patients, and the fact that you have put patients first in this inquiry, in this project, is something I know Americans will appreciate.

And the fact that the two of you can cooperate in this inquiry, because there will be many hearings before we are through—a lot of cooperation is going to be required between O&I and the committee you chair, Mr. Bilirakis—as chairman of the full committee, I want to thank you.

The full committee will appreciate the work you do. We look forward to the results of your hearings of what you find out. We do not come with preconceived notions about what is right and what is wrong and what can be fixed and what cannot be fixed. We come with a very open mind and open inquiry, and I hope that is the way all of us approach it on both sides of the aisle.

This committee, as I said in the first organizational meeting, is going to be a very key and active player in the very important health care decisions that are being made in the Congress in the next 2 years. This set of inquiries will set the stage for us, will tell us what we in Washington can do to make sure that the best

health care delivery system in the world is even better because we have put patients first. Thank you, Mr. Chairman.

Mr. BILIRAKIS. And I thank you very much, Mr. Chairman, and I would like to suggest that it is not just the two of us, but the four of us in terms of working together and, of course, the members of both subcommittees on both sides of the aisle.

Mr. Linkletter will have to leave at 11 o'clock, we are advised. That being the case, I have already received unanimous consent that members can have the choice of either limiting their opening statement to 1 minute now, if they choose to do so, or else deferring their opening statement until after this first panel has been completed.

That being the case, I will go right on down the aisle. Mr. Bryant, what is your choice?

Mr. BRYANT. Mr. Chairman, I will defer.

Mr. BILIRAKIS. Defer. Ms. Capps?

Ms. CAPPS. Defer.

Mr. BILIRAKIS. You will defer. Mr. Shadegg?

Mr. SHADEGG. Defer.

Mr. BILIRAKIS. You will defer. Let us see who is next here. Mr. Rush?

Mr. RUSH. Defer.

Mr. BILIRAKIS. You will defer. Mr. Pitts? One minute now or defer your opening statement until later?

Mr. PITTS. Thank you, Mr. Chairman. I will submit my written statement for the record, but, first of all, Chairman Bilirakis and Chairman Greenwood, I would like to than you for undertaking——

Mr. BILIRAKIS. One minute, please, sir.

Mr. PITTS. I understand—such in-depth review of HCFA's major programs, policies, and operations. I think the review is long overdue, but with your strong leadership, I think that will start us on the path of improving the quality of care for our nation's beneficiaries.

I am pleased with the topic of the first year, which will look into the complexities of the Medicare system. I look forward to learning more about the processes for reimbursement for medical devices and new technologies, and how these processes will affect patient care.

I have one company, Centocor, in my district that has had a lot of experience with a drug called ReoPro through the years. It was approved by FDA in 1994. There have been problems, roadblocks that have delayed access, so I am looking forward to the information we receive in the hearing. Thank you.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Engel, 1 minute now or defer?

Mr. ENGEL. I will take the minute now, Mr. Chairman.

Mr. BILIRAKIS. Take the minute now.

Mr. ENGEL. Thank you, Mr. Chairman. There are so many areas in which we need to improve how we care for our nation's seniors, one of which is to provide beneficiaries with the most advanced medical technologies when they become available. The fact that many are suffering simply because of the lengthy Medicare approval process is just not tolerable.

New technologies are emerging everyday that enhance the quality of life for so many. New medical treatments and devices are eliminating the need for intrusive surgery or painful procedures. However, many seniors do not have access to these new methods even though they have been approved by FDA because Medicare will not pay for them.

We will hear testimony today illustrating the fact that many seniors are denied access to specific treatments, for several years in some instances, due to the lengthy Medicare approval process. In some cases, physicians may not offer new services despite the benefit to patients because of the administrative burden in dealing with HCFA.

Without an improved process that allows companies to get their new devices on the market in a timely manner, we run the risk of discouraging research and development into new technology. So I am glad we are doing this today. I welcome the panel, particularly Mr. Linkletter, who has been a hero of mine for so many years. I want to thank the panel for coming and I thank you, Mr. Chairman.

Mr. BILIRAKIS. And I thank the gentleman. Mr. Upton?

Mr. UPTON. Defer.

Mr. BILIRAKIS. Defer. Mr. Stupak?

Mr. STUPAK. Defer.

Mr. BILIRAKIS. Defer. Mr. Whitfield?

Mr. WHITFIELD. Defer.

Mr. BILIRAKIS. Defer. Mr. Green?

Mr. GREEN. Mr. Chairman, I will take my 1 minute and I will submit my total statement. Like my colleagues, I want to welcome, Mr. Linkletter. I rode over on the train with you or walked over with you and it is good to have you here.

Mr. BILIRAKIS. The gentleman has 1 minute.

Mr. GREEN. I agree with Mr. Greenwood that hopefully our effort is to modernize HCFA and to provide the resources for HCFA to be able to put these technologies on the market quicker, provide not only resources, but also I noticed, and if the witnesses will address it, it is not just with Medicare, it is also with third-party reimbursement, but also private insurance for some of the new technologies, and so it is not just HCFA that is a problem. I think it is lots of third parties. Thank you, Mr. Chairman. I yield back.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Speaker: Thank you for holding a hearing on the need to create a stronger and more efficient Health Care Finance Administration. I have heard from a number of doctors in my district about the problems they have encountered with the agency, and am eager to discuss ways to resolve those problems.

HCFA approval and coverage for new technologies is a timely issue. Congress has debated for years the need to modernize Medicare to include a prescription drug benefit. But we cannot stop there. The program must be modernized to utilize the best of all technologies—not just prescription drugs.

Health care technologies have improved the quality of our health care for all Americans. Advancements in medical technology have had many benefits, from providing information systems that monitor patient treatment data, to new diagnostics tests that detect diseases at earlier stages, when they are less expensive to treat, and more likely to be cured.

I am troubled by reports that new technologies are taking too long to approve. None of us would want to wait 3 to 5 years for a life-saving technological advancement, and we don't want our seniors to wait that long either.

Like my colleagues, I am committed to streamlining HCFA's process. This hearing presents an excellent opportunity to examine the problems that exist and discuss solutions for them.

I look forward to the testimony of our witnesses, especially our physicians who are working with new technologies. Houston Medical Center is near my district, and I am constantly amazed by the work that they are doing at the various hospitals there.

PREPARED STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Thank you Mr. Chairmen.

Chairman Bilirakis and Chairman Greenwood, I would like to thank you for undertaking such an in depth review of HCFA's major programs, policies, and operations. This review is long overdue; but with your strong leadership, will start us on the path of finally improving the quality of care for our nation's beneficiaries.

I am pleased with the topic of the first hearing in this series, which will look into specific complexities in the Medicare system. I look forward to learning more about Medicare's processes for reimbursement of medical devices and new technologies, and how these processes affect patient care.

In fact, Centocor, an innovative biotechnology company based in Chester County, Pennsylvania, has a perfect example of how frustrating it is to have new drugs and technologies adopted and reimbursed by HCFA.

Centocor manufactures the drug ReoPro, part of a class of platelet inhibitors. ReoPro was approved by the FDA in 1994, and its clinical effectiveness is unquestioned.

However, it seemed that HCFA consistently created roadblocks that delayed access to this breakthrough therapy.

Over a period of years, HCFA insisted that it would not create a tracking code for platelet inhibitors. This means that costs for angioplasty cases in which ReoPro was administered could not be tracked for purposes of assessing the appropriate diagnostic related group ("DRG") these cases should be in for payment purposes. After significant Congressional pressure, HCFA finally began to grant tracking codes for these drugs. ReoPro's code was effective October 1, 1998—three years after it should have been, had HCFA responded more reasonably.

Even with a tracking code, it takes HCFA at least two years before making a DRG reclassification based on its own data. Therefore, pursuant to its own policy, HCFA would not make a reclassification for angioplasties with platelet inhibitor therapy until FY 2001 at the earliest. This is a six-year delay for a drug approved in 1994.

Because HCFA's originally failed to grant tracking codes for drugs, and because of the extended delay as HCFA waited for its own data on use of these codes, Congress twice urged HCFA to consider outside data in making DRG reclassifications. (First in BBA 97 Report Language and second in the FY 1999 Senate HHS-Labor Appropriations report.)

Centocor was one of the first to submit outside data to HCFA under this authority. The data showed that Medicare beneficiaries are 15 percent less likely to get the drug, and charges for Reopro cases are consistent with charges in DRG 116 and not its current DRG 112.

Nonetheless, HCFA rejected the data submitted to them.

To this day, if ReoPro is used during angioplasty in a hospital inpatient setting, hospitals are not receiving the extra payment for it. This seems to mean, Mr. Chairman, that hospitals have a "disincentive" to use ReoPro, as they won't receive proper payment from Medicare.

Further, failure to resolve this issue in FY 2000 seems to sends a message that HCFA will not utilize outside data.

Chairman Greenwood and Chairman Bilirakis, this is only one small example from my district—but I fear that many other new drugs and technologies are experiencing similar delays as they move through HCFA's coverage, coding, and payment processes.

This causes me to question how many years HCFA will be content to delay Medicare beneficiaries' access to new technologies.

Again, Mr. Chairman, thank you for holding this hearing. And I thank the witnesses for sharing with us today. I look forward hearing your testimony.

Mr. GREENWOOD I believe everyone has either been recognized or deferred; is that correct? Okay. For those of you who are witnesses and wondering why the chairman and I just changed places, I am the chairman of the Oversight and Investigations Subcommittee, and I think you are aware that the committee is holding an investigative hearing and that when doing so has had the practice of taking testimony under oath. Do any of you have objections to testifying under oath?

[No response.]

Mr. GREENWOOD. Let me introduce to the audience, first, who our witnesses are before I swear them in. Mr. Art Linkletter is the national spokesperson for United Seniors Association and a hero to all of us who grew up watching him on television. I was going to say "Subcommittee chairmen say the darndest things" this morning, but I chose not to.

Dr. Paul Shreve is the Director of General Nuclear Imaging Section at the University of Michigan Medial Center in Ann Arbor. He is accompanied by Ms. Kathleen Dziuba.

And Dr. Jeffrey Popma is the Director of Interventional Cardiology at Brigham and Women's Hospital in Boston, Massachusetts, accompanied by Mr. Donald Latulippe.

Mr. LATULIPPE. Latulippe.

Mr. GREENWOOD. Latulippe. Okay. And do we swear in all five of these witnesses, as they may all be testifying? Okay. The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

[No response.]

Mr. GREENWOOD. I will take that silence as a no.

In that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Very well. You are now under oath and you may give a 5-minute summary of your written statement. I will excuse myself while I go introduce my Governor at another hearing and turn the meeting back to the chairman.

Mr. BILIRAKIS. Your written testimony is already a part of the record, so we would hope that you would complement that. I will set the clock at 5 minutes, but obviously if it looks like you are rolling pretty well and will not take too much very much longer, we will let you go a little while longer. Mr. Linkletter, you are first in our hearts and first here this morning. So please proceed, sir. Make sure you have that mike close to you and on. I guess it is on. Is it on?

TESTIMONY OF ART LINKLETTER, NATIONAL SPOKESPERSON, UNITED SENIORS ASSOCIATION; PAUL SHREVE, DIRECTOR, GENERAL NUCLEAR IMAGING SECTION, UNIVERSITY OF MICHIGAN MEDICAL CENTER, ACCOMPANIED BY KATHLEEN DZIUBA; AND JEFFREY J. POPMA, DIRECTOR, INTERNATIONAL CARDIOLOGY, BRIGHAM AND WOMEN'S HOSPITAL, ACCOMPANIED BY DONALD LATULIPPE

Mr. LINKLETTER. I have had a little experience with these.

Mr. BILIRAKIS. Yes, you have had.

Mr. LINKLETTER. Since 1933. Mr. Chairman and members of the committee, thank you very much for inviting me to be here with you today to testify on behalf of the United Seniors Association. It is a nationwide grassroots senior advocacy group. We have over 550,000 members.

I have struck out already?

As we were saying earlier in the program, I am Art Linkletter and I am the National Spokesman for United Seniors. It was founded in 1991, and, as a matter of fact, I was with Senator Murphy at the Bohemian Club in San Francisco before he even began to think of founding USA, which is for the purpose for letting the seniors of America, a large and growing group, to express their opinions. And now our present president and CEO, Charlie Jarvis, is a powerful voice in Washington and across the Nation to bring hope and prosperity and health and freedom for all Americans who believe in lower taxes, smaller government, a strong free enterprise system, and the power of united generations, not just old, but old and young.

And I might add I am not here only as a spokesman and a member of the USA, but I am past president of the Center on Aging at the UCLA Geriatric School. I am the chairman of the board of the John Douglas French Alzheimer's Research Foundation, an international fundraising group for the Alzheimer's group. I have been a spokesman for Humana, a large HMO, and a PPO called PAP Care, and I lecture across the country at senior citizen places, bringing information and asking questions of seniors across the United States.

I am also a Medicare beneficiary, and like all other members of USA, we are concerned about the long-term solvency of the program. But USA members are not only worried about the fiscal health of the program. According to the Mayo foundation, this taxpayer-funded program has now amassed over 130,000 pages of laws, rules, regulations, guidelines and paperwork. And this crushing regulatory burden makes care more costly and delays patient access to the new diagnostic tests and treatments.

I am very pleased today that this committee is reviewing the policy and procedures which govern how the new and innovative medical technologies are adopted by Medicare. USA members appreciate your attention to these processes, and as a person who has been witnessing a lot of them lately at our advanced technical places at UCLA, I can assure you that we are at a gigantic revolutionary moment in the history of medicine.

Just a week ago, 2000 scientists met in San Francisco to discuss how the gene program is going to revolutionize medicine in the next few years, and it is so startling that I can't even believe what I heard.

But we are concerned that today's Medicare program remains a structure made for another time and an earlier understanding of Medicine. The program has changed little in the 35 years since it began and it has not kept pace with profound advancements. It couldn't. It is impossible. And yet these very advances will play an important role in keeping Medicare solvent.

Think of DNA-based tests to detect diseases before they even appear in the body, take the tissue engineered technologies to replace

failing hearts and livers, the less invasive surgeries that let people get back to work, and palm-held computers to reduce medical errors and information technologies to streamline administration.

Now, ladies and gentlemen, seniors are aware of these new technologies, like the PET scan, the Positron Emission Tomography, which I have seen work, and which can detect diseases earlier when they are cheaper and more effective to treat. And then new devices like pacemakers, neural brain stimulators, allowing seniors to live productive, happy retirement days. Progress in surgical options like angioplasty, being coupled with new devices like stents, which allow doctors to address a deadly blocked artery through a very tiny incision. Now, these advances are not only amazing, they are less invasive, less painful, less expensive, staving off long hospital stays.

I am not an expert on the coverage and coding process for the new medical technologies and treatments, but over my TV and radio days and in writing my many books, one thing I know something about is people, especially seniors. In writing my most recent best seller, Old Age is Not for Sissies, I travel all over the country with focus groups, trying to understand the world in which we seniors live today, and I know that seniors greatly appreciate the Medicare program, but they worry about a myriad of Medicare-related issues, especially coverage issues.

Now, as Members of Congress, who have probably gotten dozens of calls from concerned seniors, you here at the committee could probably help me put together a new television special called "HICF Does the Darndest Things."

I have read briefly through the summary of the Lewin Report that Mr. Goodman will testify about in the panel today, and I while I have not memorized the complexities of the coding systems or the various steps in the coverage program, I am struck by the fact that it can take 15 months to 5 years or longer for HCFA to integrate new medical technologies.

As a matter of fact, as an owner and a partner in a new chain of new ideas on curing incontinence, I just went through the bankruptcy of our program 2 months ago due to problems we had with payments and okays and delays by Medicare, so I am speaking from the purse now, not from the mind.

Truth be told, it is not all HCFA's fault that the system has difficulties in deciding how to handle all this new stuff. Some of these technologies not only did not exist when the program began, they were not even imagined. It is not unimaginable that the current processes for reviewing these miracles of science and medicine need to be updated to allow the hardworking people at HCFA to integrate them into the Medicare program.

Now, I know that the oversight plan for this committee for the year outlines how you will all continue efforts to identify and expose instances or patterns of waste, fraud, and abuse in the Medicare and Medicaid programs, or opportunities for activities due to inadequate policies or procedures or controls.

The coverage, coding and payment process system is ripe for review, and USA, our group, thanks all members of the committee who are working to make the process and the program overall more

efficient and effective for America's 39 million Medicare beneficiaries.

One more word on behalf of all of us seniors that I would like to have you remember: it is better to be over the hill than under it.

Thank you.

Mr. BILIRAKIS. Some of us need to be reminded of that, Mr. Linkletter. Thank you, sir. Thank you for testifying and, of course, for having served all of us in so many happy ways over the years. You are continuing to do so now in your later years, and may God bless you for it.

[The prepared statement of Art Linkletter follows:]

PREPARED STATEMENT OF ART LINKLETTER ON BEHALF OF THE UNITED SENIORS ASSOCIATION

Mr. Chairmen, Ranking Members, and Members of the Committee, thank you very much for inviting me to be here with you today to testify on behalf of the United Seniors Association, a nationwide grassroots Senior advocacy group with over 550,000 members.

I am Art Linkletter and I am the National Spokesman for United Seniors Association (USA). USA was founded in 1991, and under the leadership of President and CEO Charles W. Jarvis, provides a powerful voice in Washington, D.C. and across the nation to bring hope, prosperity, and health freedom for all Americans who believe in lower taxes, smaller government, a strong free enterprise system, and the power of united generations.

But I am here today not only as the spokesman and member of USA. As a senior American, I am also a Medicare beneficiary myself. Like all other members of USA, we are concerned about the long-term solvency of the program, as well as patient choice and access within the system.

USA members are not only worried about the fiscal health of the program. According to the Mayo Foundation, this tax-payer funded program has amassed over 130,000 pages of laws, rules, regulations, guidelines and paperwork. This crushing regulatory burden makes care more costly for everyone, and frequently delays patient access to important new diagnostic tests and treatments.

I am pleased that today the Committee is reviewing the policies and procedures which govern how new, innovative medical technologies are adopted by Medicare. USA members appreciate your attention to these processes, because we believe that seniors should have timely access to many of the lifesaving and life-enhancing advances that are being developed today.

We are concerned that today's Medicare program remains a structure made for another time and an earlier understanding of medicine. The program has changed little in the 35 years since its inception and has not kept pace with profound advancements in health care technology or delivery.

Yet these very advances will play an important role in keeping Medicare solvent. A host of exciting new breakthroughs will improve the efficiency and effectiveness of our health care system:

- Technologies like DNA-based tests to detect diseases before they even appear,
- tissue-engineered technologies to replace failing hearts and livers,
- less-invasive surgeries that allow people to return to work quickly, and
- palm-held computers to reduce medical errors, information technologies to streamline health care administration.

Seniors are aware of the new technologies—like the PET scan discussed here today, which can detect diseases earlier, when they are cheaper and more effective to treat. New devices, like pacemakers and neural brain stimulators, are allowing seniors to live productive, happy retirement days. Progress in surgical options, like angioplasty, are being coupled with new devices like stents and allow doctors to address a deadly blocked artery through a small incision! These advances are not only amazing—they are less invasive, less painful, and often less expensive to the overall health care system by staving off long hospital stays and rehabilitations.

I am not an expert on the coverage and coding process for new medical technologies and treatments, but over my television and radio days, and in writing my many books, one thing I do know about is people—including seniors. In writing my most recent best seller, "Old Age is Not for Sissies," I spent a lot of time trying to understand the world in which we seniors live today. I know that seniors greatly

appreciate the Medicare program, but do worry about a myriad of Medicare-related issues, especially coverage issues.

As Members of Congress who have probably gotten dozens of calls from concerned seniors and baffled health care providers trying to navigate the Medicare system, you could probably help me put together a television special entitled "HCFA Says the Darndest Things."

I've read briefly through the summary of the Lewin Report that Mr. Goodman will testify about in the next panel today. While I have not memorized the complexities of the coding systems or the various steps in the coverage process, I am struck by the fact that it can take 15 months to 5 years—or longer—for the Health Care Financing Administration (HCFA) to integrate new medical technologies into Medicare. As major consumers of health care services, it is disconcerting that a senior may have to wait 5 years to have access to a technology that is already saving lives in other healthcare settings.

As we stand at the forefront of amazing advances in health care, we cannot even imagine what medical miracles will emerge in the coming years. But we do know that money spent researching and developing all the latest advances is money well spent—whether it helps find a drug to cure Alzheimer's, track medications to prevent a patient from mixing deadly combinations for differing ailments, or a mechanical heart to save the life of someone on a transplant list.

And, truth be told, it's not all HCFA's fault that the system often has difficulties in deciding how best to handle new technologies. Some of these technologies not only didn't exist when the program began, they weren't even imagined! It is not unimaginable that the current processes for reviewing these miracles of science and medicine need to be updated to allow the hardworking people at HCFA to effectively integrate them into the Medicare program.

I know that the oversight plan for this committee for the year outlines how you will all continue efforts to identify and expose instances or patterns of waste, fraud, and abuse in the Medicare and Medicaid programs, or opportunities for such activities due to inadequate policies, procedures, or controls. The coverage, coding and payment process seem ripe for review and USA thanks all members of this Committee who are working to make the process, and the program overall, more efficient and effective for Americas 39 million Medicare beneficiaries.

Again, thank you for your work on these important issues, and for inviting me to speak on behalf of USA today.

Mr. BILIRAKIS. Dr. Shreve and Ms. Dziuba. Please proceed, Doctor.

TESTIMONY OF PAUL SHREVE

Mr. SHREVE. Thank you. It is a pleasure to be here this morning. I did not realize I would have a hard act to follow here, but I am certainly pleased to be here. My name is Dr. Paul Shreve, and I am a diagnostic radiologist at the University of Michigan Health System.

This morning I would like to discuss a medical imaging technology known as Positron Emission Tomography, or PET. In the last decade, this technology has become an indispensable tool in medical diagnostic imaging, yet it remains unavailable to Medicare patients for many key indications still.

All of us here this morning are well aware of the remarkable advances in medical technology. This U.S. Congress continues a long and noble tradition of medical research funding that has made our nation the world leader in medicine. I am sure that we can all agree that our goal is to bring these lifesaving medical advancements to patients as quickly and efficiently as possible.

PET is an example of a major advancement in medical technology, an outgrowth of federally supported medical research, that has been kept from our patients for too long due to disorganized and indifferent Federal agencies. PET scans like CAT scans are cross-sectional images of the body. Unlike the CAT scans and MRI scans you may be familiar with, however, PET scans are images

not just of the body's internal anatomy but of tissue, organ and biochemistry. PET images are literally slices of life.

This is the molecular imaging for the era of molecular medicine. With PET we can identify cancer earlier and with greater certainty than any other imaging technology. We can determine when a cancer is responding to therapy before the tumor shrinks. We can even diagnose Alzheimer's disease before it can be done by clinical exam.

PET is a prime example of what is right about Federal support of research. We have taken a basic understanding of the molecular basis of disease in the laboratory at the bench and moved it to the patient at the bedside, something we refer to as from bench to bedside.

Yet for the past 10 years, PET has largely been on hold due to regulatory and reimbursement issues centered largely here in Washington. While private insurance carriers began paying for PET scans over 10 years ago, consideration of payment by HCFA remains stalled.

First, it was not clear which government agency should regulate the production and compounding of the molecular probes known as positron radiopharmaceuticals used in the PET scans and exactly how the production and use of these agents would be regulated.

Without FDA approval, a positron radiopharmaceutical use for PET imaging was considered experimental by HCFA and not eligible for reimbursement consideration. A single very limited indication of heart disease made it through the regulatory morass only by the mid-'90's. It literally took an act of Congress, the Food and Drug Administration Modernization and Accountability Act of 1997 to clear this impasse.

Repeated efforts to bring PET to Medicare beneficiaries have been met with delay and indifference from HCFA. Each small increment in coverage has required pressure from Congress. In 1998, we finally received limited coverage for lung cancer. Three more cancers were introduced a year later after continued pressure from Congress. This past fall, a massive document requesting broad coverage of PET for cancer diagnoses of all cancers and for coverage of such important diseases as Alzheimer's disease was submitted to HCFA.

This included analyses of over 400 published articles in some 15,000 patients that underwent PET scans. The request for broad coverage was strongly supported by the National Cancer Institute of the NIH. The FDA itself had concluded broad indications for FDG used with PET scans were justified. Some 19 senators from both political parties urged broad coverage by HCFA in a letter to Secretary Shalala.

The final coverage decision announced in December provided additional coverage for two more cancers, limited coverage for refractory seizures and myocardial viability under certain circumstances. Coverage of breast cancer and Alzheimer's disease was referred to the MCAC Diagnostic Imaging Panel for review this May.

We find ourselves now in a disturbing situation. While Medicare coverage for several cancers now exists—a total of six actually—no cancers uniquely affecting women are covered. Breast cancer is not covered. Ovarian cancer is not covered. Cervical cancer is not covered nor is uterine cancer. Alzheimer's disease is not covered. How

many iterations must we go through with HCFA to get coverage for these important diseases? How long will this take? How many more years will women covered by Medicare have to wait before they can add PET to their battle with diseases they must fight?

HCFA has not established clear standards which new technologies must meet for reimbursement so decisions become arbitrary and painfully slow. I believe we all want to ensure quality and affordable health care for all Americans. We should not fear new technology, reflexively seeing such as expensive.

As a practicing physician, I can assure you that it is mistakes that are expensive. It is the missed diagnosis and the missed diagnoses that end up costing everyone. All Americans should benefit from the knowledge and technology our federally supported medical research provides. Everyday now at our medical center we are avoiding unnecessary surgery, invasive procedures, and useless treatments due to the improved accuracy possible with PET.

We are more accurately directing therapies using PET. Medicare patients should not have to wait 10 years to have access to PET. Women today should not have to wait additional years for HCFA coverage of diseases they must battle. The road from the laboratory research bench to the patient's bedside should not be filled with potholes, detours and dead ends. Technology as groundbreaking and useful as PET should not be held back for years because HCFA has not established standards which new technologies must meet and consequently must resort to decisions which are often arbitrary.

We must untangle the web of regulations and agency infighting and establish a clear intent within our Federal Government to improve patient access to new technologies in the Medicare program. I should like to urge the committee today to take steps to require HCFA to integrate PET and other new life saving technologies into Medicare on a timely basis. Thank you.

[The prepared statement of Paul Shreve follows:]

PREPARED STATEMENT OF PAUL SHREVE, DIRECTOR, GENERAL NUCLEAR IMAGING SECTION, UNIVERSITY OF MICHIGAN MEDICAL CENTER

Thank you for inviting me to testify before The Committee on Energy and Commerce of the U.S. House of Representatives. My name is Dr. Paul Shreve, and I am a diagnostic radiologist at The University of Michigan Health System, where I am Associate Professor of Radiology and Director of the Clinical PET Imaging Service. I am trained in both diagnostic radiology and nuclear medicine, and have been in practice for nearly 10 years. This morning I should like to discuss a medical imaging technology known as Positron Emission Tomography, or PET. In the last decade this technology has become an indispensable tool in medical diagnostic imaging, yet it remains unavailable to Medicare patients for many key indications due to regulatory overlap among government agencies and lack of clear standards and standardized mechanisms governing coverage decisions in the Health Care Financing Administration.

All of us here this morning are well aware of the remarkable advances in medical technology. Many of these advances originated in academic laboratories here in the United States supported by federal research funding over the years. This U.S. Congress continues a long and noble tradition of medical research funding that has made our nation the world leader in medicine. I am sure we can all agree that our goal is to bring these life saving medical advancements to patients as quickly and efficiently as possible.

PET is an example of a major advance in medical technology, an outgrowth of federally supported medical research, that has been kept from our patients far too long due to disorganized and indifferent federal agencies such as HCFA. First allow me to explain what PET is, and why it represents a major advance in medice. I am sure

most of you are familiar with a CAT scan. This is a type of X-ray machine that makes pictures of the body's internal anatomy, which are not unlike a series of slices of bread. This technology has become common in medical practice today, as are other methods of medical imaging such as ultrasound and magnetic resonance imaging (MRI). All of these methods largely depict only the internal anatomy of the body and have become immensely useful in medical practice. Prior to such cross-sectional imaging technology, we were often left with only the option of surgery; literally cutting people open to see what was going on inside. These methods of making pictures of the body's internal anatomy began with Roentgen's discover of the X-ray, and served us well in the last century given our crude understanding of biology and human health and disease. I say crude because we are now on the verge of a revolution in biology and medicine, the beginning of an era of molecular medicine. Health and disease in the post human genome project era will be assessed, diagnosed and treated at the molecular level. PET is a method of molecular imaging, a medical technology for 21st century medicine.

PET scans of the body actually look somewhat like CAT scans, except the PET scans depict the body's tissue metabolism, not just the anatomy. The images are literally "slices of life". Images of the biochemical and fundamental molecular events of organs and tissues reveal disease at their earliest, and hence, most curable stages. Equally important, there are numerous abnormalities inside our bodies detected by conventional medical imaging, which are inconsequential, but often indistinguishable from serious disease. A significant contribution to accelerating health care expenditures is the "diagnostic detour" frequently pursued as a consequence of the exquisitely depicted, but frequently non-specific abnormalities we find when we put patients in a CT or MRI machine. PET allows us to avoid many of these expensive detours because PET directly depicts the underlying biological basis of disease.

This "biological imaging" has been under development for over twenty-five years. The ability to perform the "molecular assays" of the research laboratory in a living human subject safely and non-invasively using short lived positron radioisotopes began in the 1970s with the construction of full ring PET scan devices and the application of molecular imaging probes such as fluorodeoxyglucose (FDG). This early work occurred almost exclusively in U.S. government and academic research laboratories, funded by federal research grants from agencies such as the NIH and DOE. As one would expect, the initial focus of PET imaging was scientific research. PET allowed us to answer many fundamental questions regarding the true nature of human health and disease by looking directly at the molecular events as they occurred in the patient. By the 1980s, it became increasingly clear to physicians and scientists this molecular imaging approach would be a powerful diagnostic tool in the clinic, allowing for earlier and more accurate imaging diagnosis of cancer, heart disease and neurologic diseases.

By the early 1990s, clinical research studies using PET, many again funded by federal research dollars, had shown remarkable advantages over conventional medical imaging in the detection of cancer, reversible heart failure and even Alzheimer's disease. For example, our medical imaging approach to cancer in the chest and abdomen until then had been essentially based on size. If something is abnormally enlarged on CAT scan, it may be bad, maybe even cancer, while if it is small, it more likely is not cancer. It sounds crude because it is, and consequently limited. Cancer starts out small—nothing abnormal on conventional medical imaging—but that is precisely when it is most curable. Further, we all have things in our bodies that get a bit out of proportion as we age—but by and large we live with this. By making images of the fundamental biochemical abnormalities that underlie most cancers, PET allows us to diagnosis cancer very early, before it becomes an identifiable mass. Further, PET allows us to determine which of those masses we may have inside our bodies really are serious, and which are best left alone. Another example is Alzheimer's disease. CAT scans and MRI scans of the brain show us remarkable anatomic detail, yet these images of the brain of a normal patient and a patient with Alzheimer's disease of roughly the same age are indistinguishable at any given time. Changes in the biochemistry of the brain occur very early in Alzheimer's disease in a predictable pattern; this has been known for nearly twenty years now. We now also know these changes can be clearly depicted by PET. PET can detect the disease up to 3 years before diagnosis by any other means.

In many ways PET represents what is right and what is wrong with our federal government's involvement in medicine. PET embodies a central principal of modern medical research, pioneered in this country, known as the "from the bench to the bedside" Basic medical research performed at the laboratory bench is eventually transferred to patient care, to the bedside. Federally supported basic research has given us extraordinary insights into the molecular basis of disease, and a tool, PET, to bring this insight to patient care. Yet due to regulatory overlap and uncertainty,

a lack of clear standards and standardized mechanisms governing coverage, and an absence of timely decisions, many Medicare patients have been denied access to PET for a decade.

For the past 10 years, however, PET has largely been on hold due to regulatory and reimbursement issues, centered largely here in Washington. While private insurance carriers began paying for PET scans over 10 years ago, consideration of payment by HCFA remained stalled. First it was not clear what government agency should regulate the production and compounding of the molecular probes known as positron radiopharmaceuticals used for PET scans, and exactly how the production and use of these agents would be regulated. Without FDA approval, a positron radiopharmaceutical used for PET imaging was considered experimental by HCFA, and not eligible for reimbursement consideration. In a single very limited indication of heart disease made it through the regulatory morass by the mid 1990s. It literally took an act of Congress, The Food and Drug Administration Modernization and Accountability Act (FDAMA) of 1997, to clear this impasse. Once directed to understand the unique nature of PET and the positron radiopharmaceuticals used in PET imaging, the FDA made rapid progress in its regulatory oversight duties. Indeed, after a recent review of the world's scientific peer-reviewed literature covering the clinical use of PET, FDG, presently the most important radiopharmaceutical used for PET imaging, has been broadly approved for all cancers, as well as certain cardiovascular and neurologic disorders.

Despite FDAMA, HCFA, there was an addition reluctance for HCFA to approve reimbursement for PET. PET was viewed as "high tech" medical imaging, perceived as expensive and likely to further drive up health care costs. HCFA had been criticized for what, in retrospect, appeared to be a pre-mature approval for payment for MRI scans in the 1980s, and did not want to repeat such a scenario. Finally, with increasing coverage by private insurance carriers, particularly for lung cancer, and pressure from members of the U.S. Congress, HCFA developed coverage policies for two limited indications in cancer: the evaluation of the solitary pulmonary nodule, and the initial staging of non-small cell lung cancer, effective January 1998.

The broad use of FDG PET in cancer diagnosis, staging, and re-staging for several major cancers was already widely established in the medical literature. Ironically, due to the slow movement of PET from the "bench to the bedside" here in the U.S., a good deal of the application of PET to routine patient care in the later 1990s was occurring in Europe and Asia. Motivated by the need to bring the advantages of PET to their patients, various medical and surgical specialties presented data in support of reimbursement of additional indications in oncology and for Alzheimer's disease at a HCFA Town Hall Meeting held in Baltimore, Maryland in January of 1999. In July of 1999, HCFA did finally develop coverage policies for three additional limited indications: the detection of colorectal cancer with rising serum CEA, detection of recurrent melanoma, and the staging and re-staging of lymphoma.

Still, so many other cancers where PET was making a difference in patient's lives remained not covered. For example, while some women fighting breast or ovarian cancer could get PET scans paid by private insurance, Medicare beneficiaries would have to pay out of pocket or forgo the advantages of an earlier and more accurate diagnosis using PET. Early memory problems common to both Alzheimer's disease and depression could be sorted out using PET for those with the money to pay for the scans (about the same cost as an MRI), but not those covered by Medicare. Again, various medical and surgical specialties made a case to HCFA to expand the coverage of PET, and bring the full benefits of this technology to those covered by the Medicare. A massive document requesting broad coverage of PET for oncology, cardiovascular disease, epilepsy and Alzheimer's disease was assembled which included analysis of approximately 450 scientific articles involving studies of 16,000 (now 27,000) patients. Among the findings overall, for cancer diagnosis in general FDG PET is 8 to 43% more accurate than CT or MRI, and depending on the clinical question, PET changes treatment decisions in 15-50% of patients over existing diagnostic imaging methods. It is also notable that neither CT nor MRI, used and reimbursed routinely for evaluation of a patient suspected of Alzheimer's disease, can provide a diagnosis; these anatomy based methods can only rule out a mass or bleed as a source of a patient's cognitive problems. In contrast, FDG PET has a 93% accuracy 3 years before the clinical diagnosis of Alzheimer's can be established. A town hall meeting was again convened by HCFA in Baltimore on November 7, 2000 and included many representatives from both physician and patient advocacy groups as well as representatives from HCFA and the Executive Committee of HCFA's Medicare Coverage Advisory Committee.

This request for broad coverage was additionally strongly supported by NCI of the NIH. Indeed, the NCI has identified molecular imaging as an area of "extraordinary opportunity" warranting special funding. Committed to moving medical discoveries

from the bench to the bedside, the physicians and scientists of NCI strongly supported the broad coverage request for PET scans of all cancers. The FDA had concluded broad indications for FDG used with PET scans were justified. Some 19 U.S. Senators from both political parties urged broad coverage by HCFA in a letter to Secretary Shalala dated December 5, 2000. The final coverage decision, announced December 15, 2000 provided coverage of for diagnosis, staging, and re-staging of six cancers, including non-small cell lung cancer, esophageal cancer, colorectal cancer, lymphoma, melanoma, and head and neck cancers excluding thyroid and CNS. Refractory seizure and myocardial viability assessment were also included. Coverage of breast cancer and Alzheimer's disease were deferred to the MCAC Diagnostic Imaging Panel for review in May 2001.

Because broad coverage, the same coverage we have had for years for CAT scans and MRI scans, for example, was not given, for all cancer and the evaluation of Alzheimer's disease, we find ourselves in a disturbing situation. While Medicare coverage for several cancers now exists, no cancers uniquely afflicting women are covered. Breast cancer is not covered, ovarian cancer is not covered, cervical cancer is not covered, nor is uterine cancer covered. Too, Alzheimer's disease afflicts women much more commonly than men owing to their longer average lifespan, and women are disproportionately burdened by the care of relatives with this devastating disease. Alzheimer's disease is not covered. How many iterations must we go through with HCFA to get coverage? How long will this take? How many more years will women covered by Medicare have to wait before they can add PET to the battle with diseases they must fight? HCFA has not established clear standards which new technologies must meet for reimbursement, so decisions can become arbitrary and painfully slow.

I fully understand HCFA's concern over payment for new and "expensive" technologies, and the need to fully access such before payment decisions. There is endless talk of technology assessment and cost effectiveness analysis as if these were mature, fool-proof disaplines. They are not. Different "experts" routinely come to different conclusions. For example this past fall, a group of "technology assessment experts" hired by HCFA to analyze the broad coverage request document came to a completely different conclusion as the FDA technology assessment team and the NCI technology assessment experts. Perhaps even more important, and frequently overlooked, is the reality that in the five years or so that a comprehensive multicenter evaluation of a medical technology is completed and published, the technology in question has changed to such a degree, and the applications expanded or shifted, that the conclusion of the study becomes largely irrelevant. In the meantime, our Medicare patients have been waiting 10 years for PET. It is noteworthy that currently one the biggest purchasers of PET scanners is U.S. Oncology, a private capitated provider of cancer treatment that is convinced by its own analysis that PET is an essential cost-effective tool in the overall delivery of care to cancer patients.

I believe we all want to insure quality and affordable health coverage for all Americans. We should not fear new technology, reflexively seeing such as expensive. As a practicing physician, I can assure you that it is mistakes that are expensive. It is the misdiagnosis, and the missed diagnosis that end up costing everyone. All Americans should benefit from the knowledge and technology our federally supported medical research provides. Everyday now at our medical center we are avoiding unnecessary surgery, invasive proceeds, and useless treatments due to the improved accuracy of PET. We are more accurately directing treatments by using PET. Medicare patients should not have had to wait 10 years to have access to PET. Women today should not have to wait for more years for HCFA coverage of the diseases they must battle. The road from the bench to the bedside should not be filled with potholes, detours and dead ends. Technology as groundbreaking and useful as PET should not be held back for years because HCFA has not established standards which new technologies must meet and consequently must resort to decisions which are often arbitrary. We must untangle the web of regulations and agency infighting, and establish a clear intent within our federal government to improve patient access to new technologies in the Medicare program. I should like today to urge this Committee to take steps to require HCFA to integrate PET and other new, life saving technologies into Medicare on a timely basis.

Mr. BILIRAKIS. Thank you very much, Dr. Shreve.

Mr. BILIRAKIS. Dr. Popma. Well, Ms. Dziuba, do you have a very brief supplementary statement to the doctor's?

Ms. DZIUBA. Yes.

Mr. BILIRAKIS. Please make it brief, though, because the intent was it would be a 5-minute total for the both of you.

TESTIMONY OF KATLEEN DZIUBA

Ms. DZIUBA. Good morning.

Mr. BILIRAKIS. Good morning.

Ms. DZIUBA. My name is Kathy Dziuba. I live in Rochester Hills, Michigan.

Mr. BILIRAKIS. Please pull that closer.

Ms. DZIUBA. And I am a breast cancer survivor. I feel honored to speak to you this morning. I ask that as you listen to my testimony, you keep in mind that this is more than a one woman's story with breast cancer. There are thousands of women, young or old, perhaps your wife or daughter, who will be diagnosed with breast cancer this year alone.

What is even more frightening is that there are women who have cancer and don't yet know it. I hope that by sharing my experiences with you, that you will be able to soften the blow and decrease the pain of which these women will experience in their life long battle with breast cancer.

In 1992, I was diagnosed with breast cancer. My treatment consisted of a bilateral mastectomy. My doctors and I hoped at that time that I had been cured. Unfortunately, that was not to be. In 1998, I discovered a lump in my breast in the same area where my previous cancer had resided. A biopsy proved this to be a recurrence of the cancer. A more intensive treatment program of chemotherapy and radiation was recommended.

At that point, I chose to pursue my care at the University of Michigan. My oncologist utilized PET scanning at the outset, as his primary diagnostic tool, to determine the extent and spread of my cancer. My doctor explained to me that PET scanning displayed images of the biology of the disease rather than pictures of my anatomy. It guided him in selecting the best treatment and protocol for me.

I then undertook a series of chemotherapy and radiation therapy sessions lasting 8 long months. During this process, PET scanning was used to monitor the effectiveness of my treatments. There is nothing experimental regarding the use of PET scanning in my care. It has been integral, valuable and vital.

It continues that way through today. In the summer of 2000, I had an MRI scan which revealed abnormalities in my right lung. It was a real concern that the cancer had metastasized. The conventional approach, I was told, was to have a thoracic surgeon perform an exploratory operation and biopsy. This is a painful, expensive procedure, which requires a long recuperation period. My doctors at the University of Michigan were able to utilize PET scanning to identify that my lung abnormality was due to my radiation treatment and not a spread of my cancer. I did not have to undergo surgery, which would have disabled me from my work and removed me from my family.

The inaccurate results of my MRI have continued to cause great anxiety and doubt in my mind. I will continue to be forever grateful for my physicians who possess the savvy, foresight and belief in the diagnostic capability of PET scanning to accurately identify my

state of remission. I am currently on medication and considered cancer free. I have no guarantees about my future. I have been told that I am in a phase of my illness where I am at high risk for return of cancer. PET scanning is now used in my treatment to monitor for recurrence and metastasis.

In my opinion, breast cancer is not simple, common or predictable. It does not necessarily respond logically to treatment. There is not yet a blueprint for women to follow to assure that they will remain cancer free in their lifetime. Sure, we talk about healthy diet and exercise, not smoking, and just living a healthy lifestyle. Unfortunately, many breast cancer survivors who have followed these guidelines are asking themselves where did I go wrong? What did I do to receive a diagnosis of breast cancer?

Until we have answers to these vital questions, this disease will continue to haunt us. It is because of the uncertainty of the disease, and having asked myself these same questions, that I again ask that Medicare provide reimbursement for advanced diagnostic testing, including PET scans, in the standard treatment of breast cancer patients. My hope is that from today forward, you will put your faith in the physicians we call upon when encountering life threatening illnesses such as cancer and allow them to use the skills and knowledge they possess to effectively treat all women's cancers regardless of insurance. Thank you.

Mr. BILIRAKIS. Thank you very much, Dziuba. I am very happy and pleased that we allowed you to give your statement.

Ms. DZIUBA. Thank you.

[The prepared statement of Kathleen Dziuba follows:]

PREPARED STATEMENT OF KATHY DZIUBA

Good morning, my name is Kathy Dziuba and I live in Rochester Hills, Michigan. I am a breast cancer survivor, and I feel honored to speak to this committee on how PET scanning, continues to play a life saving role, in my battle with breast cancer. I ask that as you listen to my testimony, you keep in mind that this is more then a one woman's story with breast cancer. There are thousands of women, young and old, perhaps your wife or daughter, who will be diagnosed with breast cancer this year alone. What is even more frightening, is that there are women who have cancer, and don't yet know it. I hope that by sharing my experiences with you, that you will be able to soften the blow and decrease the pain, of which these women will experience, in their lifelong battle with breast cancer.

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At that point, I chose to pursue my care at The University of Michigan. My oncologist utilized PET scanning, at the outset, as his primary diagnostic tool, to determine the extent and spread of my cancer. My doctor explained to me that PET scanning displayed images of the biology of the disease, rather than just pictures of my anatomy. It guided him in selecting the best treatment protocol for me. I then undertook a series of chemotherapy and radiation therapy sessions lasting eight long months. During this process, PET scanning was used to monitor the effectiveness of my treatments. There is nothing experimental regarding the use of PET scanning in my care. It has been integral, valuable and vital. It continues that way through today.

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PET scanning to identify that my lung abnormality was due to my radiation treatment and not a spread of my cancer. I did not have to undergo surgery which would have disabled me from work and removed me from my family.

The inaccurate results of my MRI have continued to cause great anxiety and doubt in my mind. I will continue to be forever grateful for my physicians, who possess the savvy, foresight and belief in the diagnostic capability of PET scanning, to accurately identify my state of remission.

I am currently on medication and considered "cancer free". I have no guarantees about my future. I have been told that I am in a phase of my illness where I am at high risk for another return of cancer. PET scanning is now used in my treatment, to monitor for recurrence and metastasis.

In my opinion, breast cancer is not simple, common or predictable. It does not necessarily respond logically to treatment. There is not yet a blueprint for women to follow, to assure that they will remain cancer free, in their lifetime. Sure we talk about healthy diet and exercise, not smoking, and just living a healthy life style. Unfortunately, many breast cancer survivors, who have followed these guidelines, are asking themselves where did I go wrong? What did I do to receive a diagnosis of breast cancer? Until we have answers to these vital questions, this disease will continue to haunt us. It is because of the uncertainty of the disease, and having asked myself these same questions, that I again ask that Medicare provide reimbursement for advanced diagnostic testing, including PET scans, in the standard treatment of breast cancer patients.

My hope is that from today forward, you will put your faith in the physicians we call upon when encountering life threatening illnesses, such as cancer, and allow them to use the skills and knowledge they possess, to effectively treat all women's cancers regardless of insurance.

Thank you

Mr. BILIRAKIS. This is very helpful.

Dr. Popma.

TESTIMONY OF JEFFREY J. POPMA

Mr. POPMA. Thank you, Mr. Chairman, and I appreciate the opportunity to speak before this committee about the need for governmental and third-party payers, and in particular Medicare, to fund proven life saving medical procedures that have become available as a result of advances in new technology.

I have submitted an extensive written statement. I will be very brief in my summary comments and I will use some specific examples here, if I may?

Mr. BILIRAKIS. Please do.

[Chart shown.]

Mr. POPMA. I would like to focus on one new technology, that is the use of radiation therapy for the patients who fail stent implantation, as one therapy that is approved by the Food and Drug Administration, but is not currently funded under the Medicare system.

This year we will perform 750,000 angioplasty procedures in this country to relieve obstructive disease that causes patients to have symptoms of heart disease. Of these, 70 to 80 percent of the patients will receive a new coronary stent.

The left panel shows the regulatory and reimbursement process that has resulted as a result of new stents. We received, based on randomized clinical trials, FDA approval in 1994 to implant stents in patients. There was a series that lasted over 3 years, during which time a code was developed and a differential reimbursement was developed for the stenting procedures which average between three and $5,000 a procedure.

During this period of time, hospitals were strapped for finances. They were strapped for finances because these incremental costs

were not reimbursed under the Medicare system. Now stents have worked and they have worked extremely well in our patients, but they sometimes fail. And in the 20 percent of patients or so that develop a failure of a stent due to scar tissue formation within the stent, we need other therapies. We have used balloon angioplasties. We have used drills. We have used a variety of different techniques, none of which have been effective in reducing the recurrence in the subset of patients who develop a failure of their stents.

We now have five randomized trials performed, presented to the FDA, and performed and resulted in the approval of two of these devices that have demonstrated that radiation therapy for patients that have stent restenosis is effective in reducing the recurrence rate by 30 to 50 percent.

[Chart shown.]

Mr. POPMA. On the right panel shows a diagrammatic example of the radiation catheter that is inserted into the coronary artery and delivers radiation over a three to 20 minute period of time, and then this catheter is removed from the body. This therapy works. We use it now in our patients. It is not reimbursed under the Medicare system.

In the table that I provided in my table outlines the incremental costs that our radiation oncology group has put together for our costs for doing these procedures. It ranges, depending upon the estimates, between three and $5,000. These numbers are summarized on the panel.

This is not reimbursed under the current systems and the hospitals are expected to take the loss. Now, I am very fortunate to be at the Brigham and Women's Hospital. We are a tertiary referral center, we are a teaching hospital for Harvard system, we have not turned away therapy at our hospital as a result of not being reimbursed by Medicare.

But what is assumed is that we will not be reimbursed and we have to bury these costs in the rest of our operational expenses. And while we can do that in our individual teaching hospital, this is not smart fiscal policy and certainly cannot expand. And you will hear in just a moment Mr. Donald Latulippe, one of my patients, who has experienced this from a personal level.

I would like to summarize. I do think that the dedicated staff at HCFA are working on this problem, and I agree with all the comments that say this is not something that we should be ascribing blame to one area or the other. I think the staff at HCFA is working on this, but the time delay is too long. It allows us to lose money, to not be able to effectively care for patients today, when the reimbursement processes may last up to 2 or 3 years more until we get adequate reimbursement.

I would have three suggestions for how this process might be improved. There needs to be better communication between the Food and Drug Administration and HCFA and there needs to be a better identification of which therapies are truly advances, truly things that will differentiate how we care for patients in the future. Those therapies need an expedited process.

Today, we need to have newer codes. We need to utilize the codes that are currently in place to allow there to be reimbursement for these newer therapies, and this is going to take some innovative

work on the part of HCFA. And finally, wearing my teaching institution hat, I am just pleading to you that we are already operating on very marginal budgets, and to ask the teaching institutions and other tertiary referral centers at this point to bear the cost of the new technology I think is something that we cannot have for the long term, and with that, I would like to turn this over to my patient, Mr. Donald Latulippe.

[The prepared statement of Jeffrey J. Popma follows:]

PREPARED STATEMENT OF JEFFREY J. POPMA, DIRECTOR, INTERVENTIONAL CARDIOLOGY, BRIGHAM AND WOMEN'S HOSPITAL

I appreciate the opportunity to speak briefly with you this morning about a critical aspect of health care, namely the *need for governmental and third-party payers, and in particular, Medicare, to fund proven, life-saving medical procedures that have become available as a result of new technological advances.* As an cardiologist who performs angioplasty and stenting in patients on a daily basis, I can tell you that it is critically important for Medicare to streamline its procedures for reimbursing hospitals and physicians for new technology that is available to treat patients with heart disease. I hope that after hearing my testimony today that you will share my sense of urgency about this problem.

To focus my discussion, I would like to provide you with one brief example of a new FDA approved technology that is not currently covered by HCFA, that is, radiation therapy for the treatment of patients who have failed a coronary stent procedure, but I should note that there are also other new technologies that should also undergo expedited reimbursement review by Medicare. I would hope that the current process for HCFA reimbursement for new technologies could be carefully examined, and that the reimbursement process for truly life saving therapies would be accelerated. I hope that this testimony will provide you with the understanding that this accelerated process is extremely important for patients and for the hospitals and physicians who care for them. The discussion will also focus on the reimbursement process for the technical aspects of the procedure—I would also state a review of the professional reimbursements for the physician who provide these highly specialized services will also be needed.

The State of Coronary Angioplasty. Cardiovascular disease is the major cause of death in this country. We have made many advances of the past decade—we have better medicine, more prevention, and we have developed newer methods to treated blocked coronary arteries. As a result, the mortality rate for coronary angioplasty has dropped 20% over the past 10 years.

One of these methods is called coronary angioplasty, or PTCA. Over three-quarters of a million patients in this country will undergo a coronary angioplasty this year, 50% more that the number of who will undergo coronary bypass surgery. Coronary angioplasty now often involves the use of coronary stents, which are small metal sleeves the are placed inside the artery and keep the artery wall from collapsing over time. Coronary stents are beneficial in preventing the chest pain and heart attacks that result from blocked coronary arteries. Through stenting, we have cut in half the number or patients whose arteries reclose after being opened with balloon angioplasty.

I should note that hospitals went through a similar reimbursement "crisis" when coronary stents became available in 1994. On average, the use of coronary stents cost the hospitals $3,000-5,000 more per procedure than a conventional balloon angioplasty. Because physicians felt that stents were so beneficial, they used the stents in patients, and one Midwest hospital reported that approximately $2 million was lost one year because of inadequate reimbursement for the use of coronary stents. This ultimately resulted in the creation of a new DRG code, DRG 116, which provides higher reimbursement for patients who receive a coronary stent.

Despite their benefit, the stents form scar tissue inside the metal sleeve in approximately 20% of patients, and when this occurs, it requires re-treatment with another angioplasty or with coronary bypass surgery. The recurrence rate with so called "in-stent" restenosis is higher than after the first time stent placement, and may occur in 30-80% of patients, depending on the degree of the scar tissue within the stent. Thus far, we have been unable to lower this recurrence rate with medicine, drilling devices, or additional stents. The impact on the lives of those patients who develop "stent" restenosis is profound and you will hear the testimony of one of my patients, Mr. Donald Latulippe, in just a moment.

Over the past 3 years, a new therapy has been developed for patients whose stents have failed. The therapy involves the use of delivering a small plastic tube into the coronary artery from the leg, and treating the artery with a brief exposure to radiation. To date, there have been five randomized clinical trials that have each demonstrated that this therapy reduces the recurrence rate by 30-50% in patients with this disease. Patient treated with this therapy require less repeat angioplasty, less hospitalization, less bypass surgery than if they are not treated with the radiation. These are real benefits to patients. Radiation therapy, or brachytherapy as it is know as, is different than a standard angioplasty procedure, as it involves additional specialized equipment and personnel, including the radiation source, a radiation oncologist, a radiation physicist, and a radiation safety officer to make certain that our personnel are not exposed to radiation. These impressive clinical results with radiation therapy resulted in the approval by the Food and Drug Administration this fall of two radiation systems. Currently at the Brigham and Women's hospital, we are treating between 5 and 10 patients per week with this radiation brachytherapy for in-stent restenosis.

Our problem is the following. Despite more intensive personnel requirement, catheters costs, and the specialized training that is needed to provide this therapy, there is no additional reimbursement by HCFA for this therapy. The hospital currently bill under DRG 112, which is the one used for a standard coronary angioplasty. We have estimated the approximate costs of the radiation procedure in Table 1. These estimates have also been validated in a randomized trial of radiation brachytherapy. At the current time, the hospital is simply expected to absorb these costs.

We have been fortunate so far in that the Brigham and Women's Hospital, as tertiary referral center and teaching hospital for Harvard Medical School, has allowed us to more forward with this program, despite its impact on the hospital's "bottom line". But it is clear that continuing to perform under-reimbursed procedures is not a healthy fiscal policy for the hospitals. We very much need to have reimbursement by HCFA and other third party payers for the costs associated with this type of programs. We believe that our patients deserve this in our health care system.

Table 1: Vascular Brachytherapy Costs

(Estimates Five Cases Per Week)

Expenses	Amount
Salaries and Fringe Benefits	
Physician Salary	$32,000
Physicist Salaries	1,200
Technical Physics	21,000
Nursing	14,400
Brachy Coordinator/Scheduling	8,000
Admin Exp (Chief of Physics, Admin Director)	13,750
Fringe Benefits	28,884
Total Salary & Fringe Benefits per Year	**$149,234**
Other Expenses	
Catheters ($2,500 per case)	$650,000
Isotope Sources (Beta & Gamma)	72,000
Miscellaneous (chambers, jigs, etc.	2,000
Overhead	52,232
Total Other Expenses	**$776,232**
Total Expenses	**$925,466**
Total Cases per Year	260
Cost per Case	**$3,559**

There is no question in my mind that the dedicated staff at HCFA are working diligently on this process right now, but the current cycle of review for financial reimbursement of these new therapies is long, and as you know, and it may take up to two more years before this reimbursement is available to hospitals. Yet our patients need the therapy today. I urge you to make certain that this remains a high priority for them.

I would emphasize that it is these kind of technologies that will support a continued decline in the death rate for heart disease, that improve the health care produc-

tivity, and enable patients to live active productive lives. As a practicing physician, I believe that we can't afford NOT to make these therapies available to patients who need them.

I have three suggestions for you to expedite this process. First, there needs to be effective pathways for HCFA to interact with the FDA to understand earlier about the cost-effectiveness and potential benefits of new technologies early in the process. Not all new approved FDA approved therapies are major advances in medicine. Some are small steps, but others, like radiation therapy in this example, are big steps forward and need to be available to patients. Second, Medicare needs to issue codes for new technologies in a more timely fashion. Temporary reimbursement should also be provided to cover the costs of important new advances in medicine. Finally, you no doubt understand that there are simply no margins left in the hospital budgets, particularly for teaching hospitals. We are doing our best to provide high quality, state of the art care for our patients—care that they deserve for living in this country. It is difficult, if not impossible for us to do so if there are not sufficient funds, particularly for our elderly population. We truly need your help.

Thank you for your attention.

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TESTIMONY OF DONALD LATULIPPE

Mr. LATULIPPE. Good morning. I am very honored and thrilled to be here. I really am honored because I have never been in such a situation. I saw the McCarthy hearings when I was 18 years old, and that was it.

But, however, and I am thrilled because I am alive. I will give a quick history and I won't take a long time. When I was 53 years old, I had my first bypass operation at Massachusetts General Hospital. I thought that was it. My father died at age 55 of this disease, my brother at 43, and my grandfather at 41. So I fully expected by the age 60 not to be here.

And I have been through three bypass operations, one 7 years after the first, and the last 5 years ago. After these operations, there is not much more they can do except what doctor just told you, to put in these graph stents, which I have five of them, and

also if they get scar tissue, which they have, there is not much they can do, until just recently.

Now, the past year, I have been through five angioplasties at New England Medical Center. My only salvation was to go through the therapy that doctor talked about with the radiation. I am very happy to say that by this time, since my last treatment with the radiation, I would have known if they were filling up again, and I am very happy to say that I outdid him walking here today. And I am feeling great and I am feeling just marvelous.

This suit that I am wearing, ladies and gentlemen—I don't want to be dramatic—I bought a year ago for my burial, and I am wearing it today never expecting to wear it in Washington, DC.

I have grandchildren that I love very dearly and I am trying to tell all my children, my own children and my grandchildren, about their diet and so forth because most of my problem is heredity. And you know a year ago, I was hoping to live to see the year 2000 and the Millennium. I saw it. I saw my birthday. That was the next goal. In July I turned 70. I can't believe I am 70, but here I am, and talking to you fine folk. I thank the government. I thank Medicare for its help because without it I would have been dead long ago.

And I am very happy to live in the Boston area because we have great medical facilities there, and I am very proud and happy again to be here this morning. Thank you.

[The prepared statement of Donald Latulippe follows:]

PREPARED STATEMENT OF DON LATULIPPE

I am a 70 year old male and have been in perfect health all my life except for plugged arteries to my heart. I have been very careful about my diet thru the years and doctors have discovered that my problems are created by my self. My Grandfather died at age 41, my father at age 55 and my younger brother at 43, all of the same thing. In 1983 I went through my first by-pass operation at the Massachusetts General Hospital in Boston. I had a second by-pass operation in 1990 at the same hospital. The third by-pass operation was performed at the New England Medical Center in 1995. Two years ago I volunteered for a new research procedure being done at the New England Medical Center by Dr. James Udelson, head of cardiology at the hospital. It was the growing of new veins around the heart with the introduction of some sort of stimulant. When the doctors were giving me the angioplasty that would lead to the injection of this substance they all agreed that the stints were the way to go for me. The study said that if there was any other way, then they had to go that way. So they performed angioplasty. Since that time I have been in the hospital 4 or 5 times to have further stints put in or the cleaning out of what is in there. I now have five stints. Up until recently I would start to have slight angina about a month after the angioplasty procedure. I really didn't think I was going to see the year 2000. I was hoping to live that long. I am totally resigned to my passing and have made all arrangements so that my family will not have to be concerned with that. I have also told my doctors that if my body can be of use in further research than its all theirs after my passing. My family know this. I had as many angioplasty procedures that I think are safe for me and my doctor at New England Medical Center suggested I go through the radiation treatment at Brigham and Women's Hospital in Boston. I did that and it was a wonderful experience.

By this time I should have felt some angina, slight at least, but haven't. So I am convinced that this new procedure has given me more time and a new outlook on life. My brother in Naples, Florida has asked me to visit him and I have decided to do that next week. Under ordinary conditions I wouldn't think of it because I didn't want to be that far away from my doctors in Boston. With this new treatment I feel very confident and I am going next week for ten days. My doctors know all about this and have given me the okay. I do want to thank Medicare for all the help I have received. I waited until I was 65 to take Social Security and Medicare and worked up until the day I received it. I am still working part time, on call and weekends at a Boston Radio station. I do an interview program in Boston and hope

to have the doctors in this project on my program very soon. They are busy people. I also do a cable tv show in the Boston area that is seen in about 30 communities. This keeps me busy as I live alone, my wife passed on a few years ago of cancer. I don't want to marry again, so being busy is sweet. This new radiation procedure has given me a new outlook on life and with their help and God's will I now expect a few more years to my life. I will do anything to further their cause because it may help others, including my own children and Grandchildren.

Mr. BILIRAKIS. Thank you, sir. That was good.

Well, I am going to start off the questioning. Dr. Shreve, you stated that women under Medicare still do not have access to PET scans for many uses. So what exactly are the women's health uses for which PET scans are not covered that are covered by private plans? I assume many of them are covered by private plans but not covered by Medicare. What are some of those?

Mr. SHREVE. Currently, Medicare covers, they have approved six cancers: lung cancer, esophageal cancer, colon cancer, melanoma, lymphoma, and head and neck cancer, with certain restrictions. They have not approved breast cancer, cervical cancer, uterine cancer or ovarian cancer. Both breast and ovarian, we do quite frequently on patients that have private insurance, and find it very useful, and increasingly with cervical cancer.

What was requested was broad coverage so that PET would be covered just like MRI and CT, and what has happened is we have had to nitpick disease by disease and that is how we got to where we are where only certain cancers are covered and not others.

Now, the arguments are, well, we don't have a huge convincing body of scientific literature. That is debatable, but the point is that you never can break it down disease for disease, indication for indication, and have complete comprehensive literature. There is some point where you make a broad coverage decision. You certainly don't make it at the onset when you have just shown you can make nice pictures.

But by the time you have four or 500 scientific articles predominantly covering cancer applications of PET, and I think in the latest revision, we have 20 some thousand patients in our review, you really are at that point of making a broad coverage decision. And the problem has been HCFA really doesn't have a guideline or a road map on how to do this, and so things have been touch and go, back and forth, and helter-skelter, and that is very frustrating when a patient comes in with ovarian cancer and we know that PET works just as good for that as it does for melanoma or colon cancer, why is this not covered by Medicare?

Mr. BILIRAKIS. And can it get covered by many private plans?

Mr. SHREVE. Depending on the private carrier. Sometimes it is a case by case. Sometimes flatly covering. Some of our carriers now flatly cover breast cancer for any indication. As you know, there is an interplay between HCFA and the private carriers. Some of them simply say, well, when HCFA pays for it, we will. That is an easy out.

Mr. BILIRAKIS. Yes. Ordinarily it is that way.

Mr. SHREVE. Yes. In other cases, Blue Cross/Blue Shield was always about a year ahead of HCFA in approving these indications.

Mr. BILIRAKIS. With this process that is taking place, do you have——

Mr. SHREVE. About 10 years.

Mr. BILIRAKIS. [continuing] any idea how long women may have to wait before that coverage is available?

Mr. SHREVE. That was my question. I don't know. We look at that it took 10 years to get here. I would imagine it is going to be more than 6 months. It could be years depending on whether they say, well, we need more papers and more outcome studies.

Another thing to keep in mind is it is very fashionable to talk about outcome studies and technology assessment, but in many areas of medicine, No. 1, that is not an exact science, and No. 2, the technology evolves so fast that by the time you do a comprehensive technology assessment, the technology has changed so much, it becomes irrelevant, and as we heard earlier, we really need a way to look at true advances, true fundamental advances and get them in an expedited means of reimbursement and dissemination in the population or we can be waiting.

The PET scanners haven't changed in 10 years. I mean they are just as capable now as they were 10 years ago. Now with some evolving reimbursement, that technology is starting to advance so we can find smaller cancers earlier, study more cancers and so on. That is really what we want is to move that technology forward, as I said from the bench to the bedside.

We have an explosion of molecular knowledge coming out now. PET is just one of the tools to apply that from patients, but we can't wait 10 years to apply that knowledge.

Mr. BILIRAKIS. When we finish up here, we will ask all of you to feel free, in fact, we would encourage you, to submit to us suggestions in writing as to what we can do to streamline the process. Hopefully you will take advantage of that, all of you, and submit it to us.

Dr. Popma, regarding the cardiac procedure that you shared with us, is there pressure building to cut back on the performance of the procedure because of its inadequate reimbursement?

Mr. POPMA. Mr. Chairman, it would probably be in the opposite way. As these new therapies become available, they begin to roll out into the community, and the cost considerations are definitely a factor in providing this therapy to further patients. They begin in a small circle of sites that did the investigative studies, and they slowly begin to move out into the community. And I think it is fair to say that there is a hesitation to adopt these in the community.

It simply means that patients are treated in a conventional way, and in that sense, they are denied the access to that.

Mr. BILIRAKIS. And because they are treated in a conventional way and because maybe they are not caught early enough and additional problems develop, might it not be costing Medicare a lot more than it would cost if the program had covered it initially?

Mr. POPMA. Mr. Chairman, that is an excellent point because the cost effectiveness analyses have suggested that by avoiding the repeat procedures in the future that these therapies are truly cost effective and would save Medicare less in the future.

Mr. BILIRAKIS. There you go. All right. I am now going to yield to Mr. Brown for questions. I would just say that I know that the sounding of these buzzers seems very rude, but it means there is a vote on the floor. So right after Mr. Brown finishes his inquiry,

we are going to break for a few minutes to run over to cast our votes and then return. Please proceed, sir.

Mr. BROWN. Thank you very much. Both Ms. Dziuba and Mr. Latulippe, thank you for your very, very moving testimony. Mr. Latulippe compared—I think he compared this panel to his younger days of watching McCarthy. I wonder if you have no decency saying such a thing, Mr. Latulippe?

Mr. LATULIPPE. No.

Mr. BROWN. Those of you who don't remember the McCarthy hearings——

Mr. LATULIPPE. It was my first experience in Washington.

Mr. BROWN. No. I understand.

Mr. LATULIPPE. I am very lucky. At 18, I got a job in a radio station, like Mr. Linkletter, in Quincy, Massachusetts, and the owner wanted me to carry his tape recorder, and we came during the Eisenhower administration to Washington, and I was thrilled—18 years old, come on. And staying at the Mayflower Hotel and all that jazz; it was great. I met John Cameron Swayzie. Hey. And I was very impressed, and we popped into the hearings. And Joe Welch was there, and, you know, he used, Mr. Senator, can you—you know, it was a wonderful experience.

I have had a great life. I am 70 years old. I have been all around the world with radio.

Mr. BROWN. I knew I shouldn't have asked you about this.

Mr. LATULIPPE. You know I have had a great life. And so I just—no, no mention of the committee compared to this one.

Mr. BROWN. No, I know.

Mr. LATULIPPE. I am just saying it was a great experience.

Mr. BROWN. We are not nearly as powerful either.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. BROWN. For asking such a stupid question. Never give a guy from Boston that opportunity with an open mike; right, sir?

No. Thank you very much for your testimony. I appreciate what you said about the role of government and the role of Medicare because some people in this Congress want to see this program privatized. They want to turn it over to insurance companies. Some of them didn't believe in Medicare when it passed in 1965 and don't believe the government can do things well, and I think that your testimony really did illustrate how important a program like that is.

I want to make one other comment before asking the two physicians a question. My friend from Pennsylvania, the chairman of Oversight and Investigations, made a comment about demonizing HCFA, demonizing Medicare Plus Choice, and my role is to do neither, as is his isn't. But I support the oversight and the examination of HCFA because I think the two physicians and the two patients brought up very real problems where HCFA does need to improve its operations. There is no doubt. I hope, though, we go over with the same fine-tooth comb an examination of managed care and Medicare Plus Choice where Congress threw $11 billion in Medicare Plus Choice without real oversight on what we are getting back for that $11 billion.

If we had thrown $11 billion, just a little extra here, for HCFA to run its programs, I think this Congress would have been looking

at HCFA doing oversight after oversight after oversight. So I just hope we apply the same standards, not to demonize either, but to learn something from them, and maybe not make some of the mistakes we have made in all cases, in both parties, and all of that for managed care and for traditional fee for service.

Dr. Shreve and Dr. Popma, I would like to hear your comments on both. You are advocating specific changes in coverage or payment with respect to a very particular procedure or service. What exactly at HCFA is broken regarding the issue of new technology approval? How do we make this better? Tell us that.

Mr. SHREVE. I think there is two issues. One is, as we mentioned earlier, and I don't mean to demonize HCFA either, that they are overburdened and there are no clear guidelines, and so it is difficult for them to put together a straightforward and consistent mechanism. There also are other agencies in the government, the FDA, for example, that approve both drugs and devices and analyze the data.

And there there are branches of the National Institutes of Health. As I mentioned, the National Cancer Institute was quite enthusiastic that PET be approved broadly for cancer to expedite its use in a variety of cancers as well as more clinical research.

So there are two things. One is there has to be a degree of reorganization or clearly defined areas of expertise. When we presented our document to HCFA, they farmed out an analysis of our analysis by a private group out of Boston, I think it was, and they came to completely different conclusions than the NCI did or the FDA did. So when you go to these experts, you get different answers, and sometimes you can kind of pick the experts and get the answer you want.

There has to be a consistent way of evaluating new technologies, and as we mentioned earlier, the second point is you have to make a distinction of some slightly new gizmo, some variation on a theme, and technologies that really are revolutionary, really are significant and a substantial departing from existing technologies, and those need to be pushed and encouraged.

The National Institutes of Health has been actually very responsive and very good at this. They have identified areas for research which they consider areas of extraordinary opportunity and they have been very good at pinpointing those areas and supporting those. Molecular imaging such as PET is one of those, but there are many others.

So some agencies in government have really come to grips with the pace and the dynamic range of medical research that is accelerating right now, and have been able to identify true advances and target those. And so that is the other thing that needs to be done.

Mr. BROWN. Yes, Dr. Popma.

Mr. POPMA. I will just give you a very brief answer, and that is that there is a time lag between the statement this therapy is safe and effective and then when we say this therapy has a mechanism for payment. And that time lag between the Food and Drug Administration accepting as safe and effective the therapy and the time that the governmental agencies will recommend payment for that can be up to 3 years.

I would certainly hope that with any kind of reform of HCFA that the questions about safe and effective and how are we going to pay for this are done simultaneously, which I think is a critical piece of the process.

Mr. BROWN. Thank you.

Mr. BILIRAKIS. All right. We are going to break now to cast these votes.

[Brief recess.]

Mr. GREENWOOD. We'll reconvene the hearing now, please. The witnesses could return to the witness table, and the spectators could return to their seats, members to their seats. And I believe that where we are in the process is that Mr. Brown has completed his questioning, and the Chair will now take his 5 minutes, and I would like to direct my questions to Dr. Shreve, if I could.

In your testimony, you talk about PET imaging technology, which is Positron Emission Tomography. It is called PET. My understanding is that that was developed as a direct result of work at the National Institutes of Health; is that correct, sir?

Mr. SHREVE. Yes. And at Malinkrat Institute under federally sponsored research.

Mr. GREENWOOD. So we in the Congress can take some pride in the fact that our funding of NIH has paid off in this respect and we have produced some pretty good technology that is instrumental—I think you called it indispensable medical tool—in medical diagnostic imaging?

Mr. SHREVE. Yes, and you can take credit for more than that. I mean the revolution in medicine and biology is largely because of this and preceding congresses' support of basic research, and PET is one facet of this revolution of molecular medicine that is now upon us. It is the way we look inside the body now at molecular processes rather than the old way which is to basically look at lump and bumps inside.

Mr. GREENWOOD. Dr. Shreve, for how long have you considered PET imaging technology to be state-of-the-art important, critical that you would use it on your patients with whom you practice?

Mr. SHREVE. I have been in practice, in academic practice, now about 10 years, and I would say beginning about 5 or 6 years ago, it became very clear that this was what we needed to make up for the shortcomings in CT and MR in certain given indications, but increasingly more and more and more indications.

Mr. GREENWOOD. And have you found, sir, that most of the private insurers covering your patients have covered the use of this technology?

Mr. SHREVE. It depends on the insurer. They have increasingly been covering. Some cover without question. Some cover on a case by case. Some look to HCFA, quite frankly, in their coverage. Blue Cross/Blue Shield's advisory board nationally has generally been a year ahead of HCFA in terms of reviewing indications. We have some private insurers now that pay for just about any indication.

It is variable. As you know, there are many insurers, and that is one of the complexities we have to deal with. We have a full-time staffer who just takes care of reimbursement, that gets the request for the scan, calls the insurance company to figure out if it is really

covered or not, and if it is not, we send them a letter, and usually they will cover it.

Probably one of the most telling things, I think, is a major provider of oncology services, a company called U.S. Oncology, is right now one of the biggest purchasers of PET scans. Now they operate on a capitated basis. They contract to take care of patients for a fixed price. They have become convinced that it is such an advantage in managing their cancer patients that it actually saves them money. They have just unilaterally made the investment. They are one of the largest purchasers of scanners right now.

Mr. GREENWOOD. Okay. Now, as you know, the central purpose for these hearings is to try to figure out how we can create a new paradigm, modernize the Health Care Financing Agency, and so this is a case example that causes us to wonder, causes me to wonder, why it is that you have known for 5 or 6 years and a number of insurers have known that is it not only the best state-of-the-art technology to diagnose the patient, avoid surgical procedures, basic procedures, and, as you just indicated, it has become obvious to certain insurers that it is in their economic interest.

We expect HCFA to have a fiduciary responsibility. We expect them not to carte blanche approve every technology because it may not be the most cost effective, and that is not prudent for the taxpayers, but, in your view, what is it about the way that HCFA operates that has caused this delay so that, in essence, the outcome is that Medicare patients have second-class health care compared to your patients who are able to have access to this technology?

Why has it taken them so long? And do you have any suggestions about how they could speed up the process?

Mr. SHREVE. Well, I don't pretend to understand the mind of HCFA, but one of the problems is the role of different agencies. You know, as was mentioned earlier, when the FDA approves something safe and effective, that really doesn't mean much to HCFA in terms of reimbursement. HCFA has increasingly taken on the task by itself of evaluating technology as to whether not only is it reasonable to use, but beyond that is it cost effective?

Now there are two problems with that. That is a complicated thing to do and, as I mentioned earlier, it is not an exact science, the notion that you can give a panel of experts a problem and they will tell you, yes, it is cost effective or not cost effective. It is a lot like economics. It is kind of a dismal science, I am afraid.

So, in many cases, I think it comes down to a political decision, look, this might cost us money; we can't really divine whether it is going to save us money by eliminating other procedures; we just don't want to pay for it. And I understand that. I understand there is a fiscal responsibility, but, surely, we have a great deal of problems with fraud and abuse, with self-referral, where new technologies are kind of ordered by the doctors that do them, and you suddenly see an explosion in utilization.

We don't want those problems to hold back technology that really is better for the patient and ultimately saves money in the long run in patient care. That is really the dilemma, and I don't propose to have a blueprint for that, but we have to have a clear delineation of what branches of government do what. And when, for example, the National Cancer Institute tells HCFA, look, you should pay for

this for all cancers, don't nickel and dime for cancer, that should have some weight. And HCFA should say, well, you guys are the cancer experts; Okay.

I am not sure exactly how that works, but there has to be clear delineations of who does what and there has to be a notion that there are new breakthrough technologies that are fundamentally different that have extraordinary promise, and those have to be put in a separate track versus something that is, say, a little bit better CAT scan or a little bit better surgical instrument.

Mr. GREENWOOD. Thank you, sir. My time has expired, and the Chair recognizes the gentleman from Florida, the ranking member of the Oversight and Investigations Committee, Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman. For each of the witnesses, if you could respond do you believe that HCFA has enough money to obtain the necessary resources to properly run the agency, and if no, what should they have, and if yes, what are you basing that conclusion on? Let me just go down the panel. Dr. Shreve.

Mr. SHREVE. You ask some pretty tough questions, sir. Again, I do not know. I am not intimately familiar with HCFA, but my guess is they are underfunded to do what they are being asked to do. I don't know what the numbers should be. I do know that they need some direction from Congress as to exactly what their role is. And is it a technology assessment agency? Is it a health insurance agency? Just what is their role? And then the proper funding to carry out that role needs to be provided.

Ms. DZIUBA. May I?

Mr. DEUTSCH. Yes.

Ms. DZIUBA. My thought is do they have the money? I think they do. My other thought——

Mr. GREENWOOD. Excuse me. Could you pull your microphone forward and make sure it is turned on, please?

Ms. DZIUBA. I am sorry. My other thought would be that not to open it up carte blanche to have all hospitals, all physicians doing PET scans, because it is advanced technology, and I certainly would not want my internist to be recommending a PET scan for me.

However, when we are dealing with life threatening illnesses such as cancer, it is a totally different situation, and that is why I switched to the University of Michigan, which is, you know, an accredited cancer center, and I have to put my trust in what they say. I mean obviously they have given me options, but my question is, and it would be the same to you, if your wife, mother, daughter had cancer, wouldn't you want her to have the best in terms of a diagnostic technology?

Would you want to send her for a CAT scan when really what she needs is a PET scan? Would you want to send her for a mammogram when really what she needs is a PET scan? Would you want her to have exploratory surgery when you can tell if she had cancer if she had a PET scan and then maybe we would move forward with that?

So, I guess, again, certainly not being a physician, but from a personal experience, I would not agree that all hospitals, all institutes, should be able, should have PET scans, or should be able to

receive reimbursement for them. But I do think that these type hospitals should.

Mr. DEUTSCH. Dr. Popma, in response to the HCFA financing?

Mr. POPMA. I have a puzzled look on my face here because I actually don't know what the right answer to your question is. I certainly think that every agency that has identified problems with efficiency and expedited process needs more money. But I am not sure—I think my statement would be that I am not sure it is solely a money problem. I think it may be a process problem, and I am not sure that you can solve the solutions that we are talking about today simply by just upping the budget for the whole HCFA agency, although that certainly would help, I am sure.

What we need to do is reexamine the process. We need to reexamine exactly what interactions occur early within the stage of the cycle. When does the FDA begin to speak with HCFA about the potential benefits of this therapy? When do we begin discussions about reimbursements for these techniques that are clearly safe and effective benefits to patients?

And so I think in addition to money, which everything always comes down to, you can do more with more money than what you currently have, much more important is going to be a fundamental change in the process. And I hope that would be as result of this hearing.

Mr. DEUTSCH. Did you want to respond as well?

Mr. LATULIPPE. I can't add much to that, but all I can say is that the radiation therapy works. I am a living example of it, and if I can help in future funding of it through my fine doctor and so forth, I am all for it. I wouldn't be here now if it wasn't for that treatment.

Mr. GREENWOOD. The time of the gentleman has expired.

Mr. DEUTSCH. Okay.

Mr. GREENWOOD. The Chair recognizes the gentleman from Pennsylvania, Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. Dr. Shreve, setting aside the funding issue, in your testimony you state: "Once directed to understand the unique nature of PET and the positron radiopharmaceuticals used in PET imaging, the FDA made rapid progress in its regulatory oversight duties." Could you please expand on that? How can we bring such efficiencies which did not previously exist in FDA to HCFA?

Mr. SHREVE. Just to clarify, what I was talking about there, prior to the modernization act, the FDA had to approve these radiopharmaceuticals we use in PET, in particular, FDG, fluorodeoxyglucose. The FDA saw that as a drug, did not understand exactly what was involved in making these. These are made locally and compounded and used regionally, not sent out over the whole country. And so there was a big battle over whether the FDA had jurisdiction or it was considered the practice of pharmacy regulated by states.

With the act, and I think it was 1997, the FDA was forced to actually talk to the PET community and find out exactly what we were doing. They visited our facilities. They saw just exactly what the technology was and what we were using, and that changed everything. They said, oh, now we understand what you are doing

and why you said it was absurd to handle these as conventional drugs.

And we are still working with the FDA right now to write down the regulations for PET radiopharmaceuticals. They have had a 4-year period under the law to do that. And it is not a perfect process, but without that, we would have gotten nowhere because they would have just said, well, this is a drug, you got to handle it just like a drug.

Now, how that can be applied to HCFA, I am not sure, but I think there has to be a distinction, as I mentioned earlier, between evolutionary technologies that cost more money, say, and major revolutionary changes in the way we do things, because those things are going to be happening more and more rapidly with this revolution that this Congress has brought us with post-genomic medicine in the next 20 years.

And we really have to have a mechanism to look at things that are new and different and fundamentally revolutionary and get that through the regulatory process so that technology can evolve, and it doesn't evolve until it gets into practice and industry starts making investments and so on. And that is when the real benefit comes to patients.

Mr. PITTS. You also indicated that PET can actually reduce health care costs. Can you elaborate on how it does that?

Mr. SHREVE. Well, there are many publications referenced in the document we sent to HCFA. Basically, as I say in my written testimony, and as I said in my oral testimony, it is mistakes that are expensive. As a radiologist, I am always finding things on CAT scans that really aren't a problem, it is not cancer, but I can't be sure, and so we have to do a biopsy or do surgery, and so we go on these diagnostic detours, which are very expensive, because our technology is imperfect.

The more accurate your diagnostic technology, the fewer of those detours and mistakes you make. This saves a lot of money. In the last week, we found metastacies in a patient with esophageal cancer that would have made major surgery fruitless and we prevented that surgery and that expense from happening.

Another patient with colon cancer, with rising serum markers, we found a single metastasis in one part of the liver, completely not seen on CT, that allows us to take that little part out and substantially prolong that patient's life. Had the metastasis been elsewhere, it would be a waste of time. So that increment—and PET isn't perfect; it has limitations, too, like anything—those increments in accuracy have an enormous effect on the downstream costs and on patient's lives. So it is not perfect, but each major increment can make a substantial difference in cost.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank the gentleman. I believe we should next recognize the gentlelady, Ms. Capps.

Ms. CAPPS. Thank you, Mr. Chairman, and I want to thank our witnesses for their testimony today, and you, Chairman Bilirakis, for holding this hearing. The relationship between HCFA's policies and new medical technologies is indeed a very important one. Medicare is a sacred program to many seniors and people with dis-

abilities, counting on Medicare for their health care, and we want them to be able to do that.

Administering Medicare involves HCFA in a delicate balancing act. We don't want HCFA to compromise patient care or medical advances with excessive regulation, but we also want to make sure that the agency preserves the high level of program integrity and works to reduce fraud, waste and abuse.

That being said, I know there are many areas that need improvement when it comes to Medicare's management, and am particularly concerned, as you are, about patient access to medical technologies. I have heard so often from device manufacturers who are unhappy with HCFA's coding and payment system. These systems make it difficult for beneficiaries to gain access to innovative technologies and procedures, even if Medicare covers these therapies. The concern is that technologies are reaching Medicare patients much too slowly.

This really troubles me. I believe we are standing in the way of lifesaving treatments that are already available being able to be used. Everyday new technologies come along. Many companies have already spent years navigating the rigorous FDA approval process. Then to be subjected to long and unnecessary waiting periods by HCFA for administrative reasons, to me, seems wasteful, at the least, and potentially irresponsible in terms of health care.

Sadly, by the time they are registered or given approval, many of these devices and technologies are already out of date and have been superseded. Overregulation hurts the manufacturers, but in the end it really does hurt patients. I am committed to working closely with HCFA to create an environment in which medical device manufacturers and entrepreneurs can bring safe and effective devices to the public.

We have to keep pace with innovation. Not to do that is to shortchange patients across this country. But I want to see if you will—I know you have been responding already to many concerns—but the very topics that you brought up, the PET scan, and my own daughter's experience with lung cancer, and then to see it being denied, I can't stress enough, also the devices used in the cardiovascular arena, that these are often cost-saving devices. The very mechanism put in place by HCFA to prevent waste is a barricade to saving, to not just saving lives but saving costs, too.

You were eloquent, both of you, in your testimony, and I want to see if you would explore for me just briefly how you see Medicare's denial affecting other health care providers, the effect, the trigger effect that it has on that? I have had some impressions on it myself, but if you would answer, please.

Mr. POPMA. We would certainly encourage all the third-party payers to understand the cost effectiveness of these new therapies, and ultimately I suspect that they will understand the cost effectiveness of the new therapies, particularly if it truly prevents subsequent procedures for us, whether they be diagnostic procedures or whether they be invasive procedures.

It is a slow process and I have to say that HCFA really leads the way with a lot of these things, and I think the example that you can set in place by helping HCFA reform and expedite that will clearly have secondary benefits to the other managed care payers.

You would certainly not want to have a competitive framework at least in our Boston environment where the coverage was better for Medicare patients than it was for the third-party premium payers, and I think that they will follow an example that you would provide for them with what happens with HCFA.

So I would agree with your statement that these therapies oftentimes are cost effective, if not cost savings, although that is always a risky word.

Ms. CAPPS. Yes.

Mr. POPMA. But they could potentially be cost savings for the health care payers, and we would hope that they would follow the example of what is put in place here with HCFA.

Ms. CAPPS. In other words, do you see HCFA or Medicare reimbursement as being a standard then? That the third-party payers are watching to see if HCFA will cover it, and if they don't, then they won't either?

Mr. POPMA. I can't speak for that in a specific example of our radiation therapy programs per se. Certainly, there has been no third-party payer that has come forth today and said we are going to pay an incremental cost for these. We are hopeful that—this is new therapy—this will evolve. But I think the example can be put in place with HCFA.

Ms. CAPPS. Okay. Thank you.

Mr. GREENWOOD. The Chair recognizes the gentleman from North Carolina, Mr. Burr.

Mr. BURR. I thank the chairman. I apologize to the panel for my tardiness, but I have had an opportunity to go over testimonies. Let me ask you, Dr. Shreve, what impact do you think technology will ultimately have on health care, especially as it relates to medical devices? Where do you see this going? Where is the endpoint?

Mr. SHREVE. Could you repeat that just one more time, a little more specific?

Mr. BURR. What impact is technology going to have on health care in general and technology specifically as it relates to medical devices? Where is the endpoint? What are we ultimately going to see?

Mr. SHREVE. We are going to see far less hospitalization, far less morbidity, that is people that can't function in their daily lives be it because of a bad joint or severe ischemic heart disease or even Alzheimer's disease. I mean the goal, as we understand it in the medical community, of the continued funding for medical research is to have people live very healthy lives late into their expected lifetime and then die and not spend a lot of time dying slowly of chronic diseases. That is the ultimate goal.

Mr. BURR. Layman's terms of what you said is that the quality of care will be better, and because there is less hospitalization, the cost will be significantly less?

Mr. SHREVE. The key word is understanding diseases at a fundamental level allows us to treat diseases at a fundamental level. So understanding them and detecting them early, if you detect cancer early enough, you can cure it. That saves a lot of money and it makes lives better.

If you can prevent atherosclerotic disease, you can prevent coronary heart/ischemic heart disease, and if you can prevent degenera-

tive diseases of the brain, if you understand it, you can prevent Alzheimer's disease. So that is our goal is to prevent these diseases or cure them in a very early state, treat them at a very early state, even before they become apparent.

As I said earlier, we can see the metabolic profile of Alzheimer's disease on a PET scan before it is really obvious clinically.

Mr. BURR. Dr. Popma—is it Popma?

Mr. POPMA. Yes.

Mr. BURR. Is it safe to say that the culture within our reimbursement system today cannot evaluate long-term savings versus initial costs as it relates to devices?

Mr. POPMA. If I understand your question, is it fair to say that the long term—over the period that we see long term in our trials is 1 year to 2 years, and you may be thinking about long-term in terms of decades—we certainly know that over the past 10 years, there has been a 20 percent drop in the cardiovascular mortality rate, that we know that that has a long-term benefit for patients because they are living longer.

We attribute those better mortality rates over the long term to two factors. One factor is early detection and treatment. So we want to support new technologies that will allow us to detect disease, particularly atherosclerotic disease, at an early stage.

Mr. BURR. Do you ever envision possibly a non-invasive way to remove artery blockage?

Mr. POPMA. I do think that these therapies are certainly being developed; they are being discussed. There is a whole new industry that is being created around the vulnerable atherosclerotic plaque. People, not patients, who are in their 20's and 30's begin to have these atherosclerotic narrowings, and there is an industry that is developing about detecting these in their early stage.

Mr. BURR. If that were developed and we were able to eliminate the hospitalization of bypass surgery or catheterization, and we were able to eliminate the recovery time, from a quality of care standpoint, would one not have to assess the initial cost of that non-invasive procedure in relation to what the savings are——

Mr. POPMA. Absolutely.

Mr. BURR. [continuing] per incident rate?

Mr. POPMA. We have a specific example of that, and that is a cholesterol lowering therapy in patients who have heart disease, and that therapy is likely beneficial in an absolute level at age 20 or 30, just to lower the cholesterol as low as we can to prevent the heart disease.

But its highest cost effectiveness ratio, where it really benefits people the most, are in people who have established disease and you are describing a gradient of threshold about how much we put in at this point in time with how much we will gain in the future, and there are numbers for that.

Mr. BURR. Is the culture such that that assessment can be made today in the process that they go through at the Health Care Financing Administration?

Mr. POPMA. I think the answer to your question is yes, that there are models that can be created. If you are asking me are there specific data——

Mr. BURR. Could be, but does the model exist today?

Mr. POPMA. Most of our models now, most of our clinical trials now, when we evaluate the safety and efficacy of our new therapies, incorporate a cost effectiveness limb to that, where the hospital bills, the true hospital costs, the utilization of resources are collected prospectively as part of the clinical trials. And one of the radiation trials that was done was done with very effective, if you will, cost effectiveness analysis that was done prospectively.

So the short answer to your question is, yes, I think this data is available. We certainly will be able to understand the short-term costs, the costs over 1 to 3 years. It is a little bit more difficult to predict what our costs are going to be like 10 to 20 years later.

Mr. BURR. My time has run out and I guess my question should have been do they use that data to go through the calculations at HCFA that they do today? I just want to read for the record—Mr. Chairman, I had the opportunity to talk to a number of physicians before this hearing in North Carolina. I want to read one of their quotes. I won't tell you who it was. And it dealt with Medicare reimbursements, device reimbursements.

And it said, "Medicare might as well put an asterisk by reimbursement, and the asterisk will read if you hold your breath, stand on the moon on Monday, you will be reimbursed."

And the purpose for reading that is to say that if we are to enjoy the benefits that technology can bring to devices or pharmaceuticals or to any area of the health care industry, there has to be a belief within the ranks of the individuals who will discover that new technology that they will go through a predictable approval process, that their products will be reimbursed fairly, and that as long as we put an asterisk by it that you have to hold your breath and stand on the moon on Monday and hope for reimbursement, we will not have the type of effort that we could have in health care developing new technologies that do save us money and do increase the quality of care.

Mr. POPMA. I agree.

Mr. BURR. If you disagree with that, I would be glad for you to state it.

Mr. POPMA. No.

Mr. BURR. Thank you, Mr. Chairman.

Mr. GREENWOOD. The gentleman's time has expired and the Chair recognizes the gentlelady from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. Let me start out by congratulating you on chairing this very important subcommittee. You know I respect you, we are friends, and I wish you every success in your leadership here. Together with our distinguished ranking member, Sherrod Brown, we can really make a difference in some areas, given the jurisdiction and the role of this subcommittee.

So thank you for holding this hearing. I think it is a very important one. As the co-chair of the Medical Technology Caucus here in the House of Representatives, I have a strong interest in medical technology issues, and I am committed to improving patient access to the marvels of modern medicine, as we know them today. Of course, several members have made reference to several parts of our health care system, and the breakthroughs in technology that represent the high end of our health care system and make us second to none in the world today.

Over the past couple of years, I have repeatedly expressed my concern that bureaucratic barriers at HCFA are inhibiting access to new technologies. According to the Lewin Group, it often takes as long as 5 years for a product to make its way through the HCFA maze, yet it only takes now 18 months to get FDA approval.

The Federal Government can determine whether a product is safe and effective in 18 months, but it takes 5 years to decide whether we are going to pay for it. And delays are really not the only problem. Illogical coding decisions are commonplace. Over the last handful of months alone, I have had to intervene repeatedly at HCFA to address coverage decisions that didn't make sense and inhibited access.

One example was the pass-through payment list. In putting together the list, HCFA listed specific product brands rather than categories. And they really got themselves into a mess by doing it this way. The result was that one company got lucky because their product got reimbursed while their competitor's product was not.

In another example, HCFA mistakenly crosswalked a test for preterm labor to the wrong code, which resulted in an unreasonably low reimbursement rate. My staff and I have spent, again, an inordinate amount of time calling and writing HCFA about these kinds of problems, and rather than continuing to micromanage the agency, what I think we should be doing is addressing the structural inefficiencies that produce what I just described.

I led the effort in this committee last year to include in the BBA give-back package two provisions aimed at streamlining the coverage process at HCFA. I am very pleased that we were successful in that effort, but it wasn't enough obviously. More work needs to be done. I am committed to taking a comprehensive approach to streamlining HCFA in much the same way that we did with FDA in 1997.

It is a source of pride to me the work that not only the Commerce Committee did, the work I was able to achieve as the Democratic lead on the FDA reform bill along with Joe Barton and many other members of the committee. Prior to that legislation, FDA had many of the same problems that HCFA currently suffers from. By modernizing the agency in a very comprehensive way, we were able to dramatically improve the approval times.

So, again, this is a source of pride. For those that say it can't be done, it can. There are fiscal funding problems with HCFA which we need to recognize, but I don't think the money should come first. I think that we should streamline and modernize the agency and then look at what that streamlining actually is going to cost. Then the Congress needs to step up to homeplate to provide the funding. I don't think it should be done the other way around.

I don't think that we can continue to allow a two-tiered system of health care where senior citizens are concerned. They just shouldn't be subjected to that in the autumn of their lives. The technologies that are coming out today are really quite revolutionary. So if, in fact, they are not paid for, they are not quote "reimbursed," it is a double whammy for them.

So I think that we have a ways to go. I have spent a lot of legislative time and energy on these issues, and I really think that this hearing and whatever else the I&O Subcommittee can do, Mr.

Chairman, in this area is going to serve the full committee and its members really very well. I look forward to working with you, our ranking member, and all the members here, on this. I think this is an exciting time to be on the committee and to move ahead with this. I think we are ready for prime time on it. Thank you.

Mr. GREENWOOD. I thank the gentlelady for her comments and for her general good nature, and the Chair recognizes the gentlelady from New Mexico, Mrs. Wilson.

Mrs. WILSON. Thank you, Mr. Chairman. I also wanted to thank you for holding this hearing, and while I was not able to be here the first hour, I have read your testimony, which I find interesting and also troubling, but the sad thing to me is that the examples that you give of PET scans and radiation therapy are not the exceptions. They are the rule, and I see it in my own district.

I recently visited Rio Grande Medical Technologies, which had developed detection technology for glucometers, for people who have diabetes, and there are 7 million diabetics in this country, more and more instances of juvenile diabetes and Type II diabetes at younger ages. At least in my State of New Mexico, with a high percentage of Hispanic Americans and Native Americans, we are disproportionately affected by diabetes in New Mexico.

That is 7 million people who are pricking their fingers everyday when they don't need to, and maybe for adults that is not a big deal, but if you have a child with diabetes, that daily or twice daily or even three times daily pricking of your fingers, to find one that doesn't hurt today so that you can take that blood sample, matters. And it matters financially as well.

The cost of diabetes in this country is astronomical, and yet it takes forever to get a non-invasive infrared scanner that looks through the tissue with an infrared beam that has been approved by the FDA, to get a code from HCFA to be able to use it. People spend $400 a year just on those little glucose strips that you have to put the blood on. We should be able to do this.

And the same is true for other technologies that are just on the cusp and being developed even in my district in Sandia National Laboratories and being transferred to the private sector. We are about to be able to have smart scalpels that will be able to detect cancerous cells from non-cancerous cells while the surgeon is doing his surgery. What a marvelous advance in health care, but we can't get HCFA to move fast enough to give us the codes.

[Chart shown.]

Mrs. WILSON. There is a chart I think the staff has, and the thing that concerns me about this is that HCFA and Champus seem to use one of the same organizations—it is called TEC—to evaluate the effectiveness of certain medical technologies, and it is also used, interestingly, by private industry, Blue Cross/Blue Shield, Prudential, Humana, all the major health insurance companies, and they also use the same studies to decide whether to cover it in private insurance.

Certainly, this will be a question for HCFA, but from your perspective why is it—why is it—that HCFA takes so much longer to approve a new technology than its counterparts in the private sector? I mean from your perspective in working with these folks, why?

Mr. SHREVE. I think part of the answer is they haven't been told they have to do that, that Congress has to tell them, look, this is important, this is important for Americans on Medicare, you have to come up with a streamlined way of doing this and you have to make it work. If you are not told to do it, you are not compelled to do it. It is not simple; this business of technology assessment, as I said, is not an exact science, and it is in evolution. But if there is a mechanism of recognizing new technologies, in moving that through, similar to what was done with FDA, and the FDA reform. I mean it was done there. HCFA may be more complicated. I don't know. But we know we can do this and we know we can streamline and get technology and drugs to the market faster, to the patients faster.

Mr. POPMA. I am risking being at odds with some of the members with this because I actually think that the process is a quantitative process that was based on sound reason about why one would establish a code, accumulate what physicians are doing and what the incremental costs of hospitals are, and then prospectively reimbursing that.

I don't disagree personally with that concept of paying the hospitals back for the codes based on their incremental benefit. Where I think we would all agree the problem has been is in how rapidly the codes are established, how rapidly there is a provisional reimbursement for codes based on our best guess, and whether or not there can be a reevaluation system as time goes on about whether that truly reflects the incremental costs that the hospitals are actually bearing.

So I think, to answer your question, there is a delay, and it can't go on for—my opinion—and it has to be expedited in a very, very rapid way, and there are some temporary measures that I think we would all like to propose to do that.

But the process has been a quantitative one that has been based on the real hospital expenditures, not on the value of the agents, but what has been spent with that money. And I think it would be not correct to criticize HCFA for what they have done in the past because that process has been set up to be fair and to be quantitative and to reimburse the hospitals exactly what they spent.

I think the only criticism that I could personally make is that the time lag has been entirely too long, and we need some immediate relief, almost within the timeframe of the FDA approval, to provide reimbursement, but I think a reevaluation process almost similar to what HCFA has established is not necessarily a bad thing.

Mrs. WILSON. Thank you.

Mr. GREENWOOD. The Chair recognizes the gentleman, Mr. Whitfield, for questions.

Mr. WHITFIELD. Thank you very much, Mr. Chairman. This question is for Dr. Shreve regarding PET. Now, it is my understanding that utilizing PET in helping to diagnose certain women-exclusive diseases like breast cancer, ovarian cancer, cervical cancer, so forth, is not covered by Medicare; is that correct?

Mr. SHREVE. Not by Medicare, yes.

Mr. WHITFIELD. But there are certain diseases that both men and women contract that is covered?

Mr. SHREVE. Yes, there are currently six cancers that are covered which are relatively common cancers to both men and women.

Mr. WHITFIELD. Okay.

Mr. SHREVE. They are major cancers, and for that reason, there is more data on those cancers. By major, I mean they——

Mr. WHITFIELD. And I notice that you say that HCFA has deferred to the MCAC Diagnostic Imaging Panel for review in May of 2001 the use of this for Alzheimer's disease only? Is that right?

Mr. SHREVE. And breast cancer.

Mr. WHITFIELD. And breast cancer.

Mr. SHREVE. They picked two out. We asked for broad coverage for cancer, for example.

Mr. WHITFIELD. Right.

Mr. SHREVE. And we are still on this path of cancer by cancer. So let us say they approve breast cancer in the spring of 2001, we will not really have coverage probably toward the end of the year. It usually takes them awhile to get to the point, okay, reimbursement starts. Then how long is it going to take for ovarian cancer?

You see the biological principle of PET is the same. I mean these are different cancers from different parts of the body, but the aberrations in metabolism are the same. So in practice, I mean I use PET for ovarian cancer all the time.

Mr. WHITFIELD. Right.

Mr. SHREVE. Just like I do for colon cancer so this doesn't make sense that we have all of this information dating back over two decades of the basis of metabolism changes in cancer. We have a technology that detects that. So there is this commonality to these cancers, and we proposed that to HCFA. We said, look, we can't spend 10 years going disease by disease by disease by disease. We have to reach a point somewhere, not when you make the first picture, not when you do the first hundred patients, but somewhere, and we thought 15 to 20,000 patients was a pretty reasonable number, where we say, look, the general underlying principles here indicate this should be used for all the cancers.

Now, it doesn't work in every cancer. I already know that. There are certain cancers that PET doesn't work very well, at least with FDG. But we already know where that principle applies with FDG. And another thing is with reimbursement, the technology starts to evolve. The scanners get better. We have tracers now that are better for breast cancer than FDG that we are working on. All of this is accelerated, and instead of waiting 10 years for an improvement in diagnosing breast cancer, it could be 3 years.

So that is the real problem. These breakthrough technologies, we cannot wait for this slow process. This road from bench to bedside cannot be curvy with detours and potholes. We got to get there because this really changes people's lives.

Mr. WHITFIELD. Well, in these co-called breakthrough technologies that you and Dr. Popma have both referred to, while it may be breakthrough technology, it is relatively old now in both instances, I assume. I mean PET has been used—what—10 years or so?

Mr. SHREVE. Well, yes and no. I mean the principle is old. The principles of biochemistry we have understood for quite awhile. The scanner technology has been basically going nowhere for 10 years.

The scanners have not changed much because industry didn't feel like it was worth investing.

Mr. WHITFIELD. Right.

Mr. SHREVE. Now, already with some reimbursement, investments are being made and the capability of these devices will move to much higher levels and give us much more accuracy. Furthermore, at least with PET, because it is a molecular form of imaging, it is not just FDG, this one tracer, that we are using in general for cancer. We can look at virtually any metabolic pathway, and so with investment there are other tracers and other things we can look at in other diseases.

For example, Parkinson's disease, we can detect it very early and detect the effective treatment. So, again, a breakthrough technology is something that is a fundamentally new principle. And once you have identified that, you have identified there is tremendous potential. The National Institutes of Health has said molecular imaging such as PET is an area of extraordinary potential, and so they set aside a lot of money for research.

The NIH has been able to do this. And if HCFA could do this and streamline this process, there would be tremendous benefits for the whole country.

Mr. WHITFIELD. Like we said, a lot of private insurance companies reimburse for the use of this technology. So I would not be oversimplistic in saying that perhaps one reason HCFA is not doing it is simply cost?

Mr. SHREVE. That is probably a reasonable assumption. As I said in my written statement, there is a problem of we view anything "new" expensive, as something that will cost more, and I can understand that, because there is what we call the "woodwork effect": when something new comes out, everybody wants it. And there is a piling on effect, at least in my specialty, where we tend to do one thing and add something on and add something on, and sometimes it doesn't make sense.

But there are bigger problems in self-referral and fraud in terms of costs. Please don't slow down the movement of new technology into patient care just because it is perceived as being expensive. There are other places where there is an awful lot money to be saved.

Mr. WHITFIELD. Did you want to say something, Dr. Popma?

Mr. POPMA. I was just going to note that the radiation brachytherapy piece is relatively new technology in terms of its advancement. The stents that we have been using now, we have really only had available for the last couple of years, and this therapy has been only available for 6 months.

We do need immediate relief for this therapy because before it is implemented within programs outside of the initial sites that did this as investigation, it has to make sense financially for the hospitals to invest in this program and currently right now it doesn't make sense to do that.

Mr. WHITFIELD. Yes.

Mr. POPMA. So I think patients are, in fact, being denied care because the institution of these programs has not been forthcoming. So I think that they may be two technologies that are different,

PET versus radiation brachytherapy. Radiation brachytherapy is new and I think that we do need immediate relief for that.

Mr. WHITFIELD. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman. The Chair thanks the panelists for your testimony and hope that you feel assured that we will use the testimony that you have offered today and the answers to the questions you have provided to helpfully improve HCFA. And you are dismissed.

And we would call forward the second panel. It consists of Dr. Jeffrey Kang, Director of the Office of Clinical Standards and Quality at the Health Care Financing Administration; Murray N. Ross, Ph.D., Executive Director of Medicare Payment Advisory Commission; and Clifford Goodman, Ph.D., Senior Scientist for Medical Technology at the Lewin Group.

Good afternoon, gentlemen. Thank you for your presence. I am assuming that you are aware that the committee is holding an investigative hearing and in doing so has had the practice of taking testimony under oath. Do any of you have objections to testifying under oath?

[No response.]

Mr. GREENWOOD. And I notice, Dr. Kang that you have with you Dr. Miller who is not on the witness list. Dr. Miller, will you be testifying as well?

Mr. MILLER. I will be taking questions, yes.

Mr. GREENWOOD. You will be taking questions. Then you have no objection to being sworn in as well.

Mr. MILLER. No, I don't have an objection.

Mr. GREENWOOD. The Chair advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Now do you desire to be advised by counsel during your testimony today?

[No response.]

Mr. GREENWOOD. I take that as a negative. In that case, would you please rise and raise your right hand and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Thank you. You are now under oath and you may now give your 5 minute summary of your written statement, and we will begin by Dr. Kang. Thank you for being here.

TESTIMONY OF JEFFREY KANG, DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY, ACCOMPANIED BY MARK MILLER, ACTING DIRECTOR, CENTER FOR HEALTH PLANS AND PROVIDERS, HEALTH CARE FINANCING ADMINISTRATION; CLIFFORD GOODMAN, SENIOR SCIENTIST FOR MEDICAL TECHNOLOGY, THE LEWIN GROUP; AND MURRAY N. ROSS, EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION

Mr. KANG. Chairman Greenwood, Chairman Bilirakis, Mr. Brown, Mr. Deutsch, distinguished committee members, thank you very much for inviting us here today to discuss Medicare coverage issues. Ensuring beneficiaries have access to high quality health care including access to new, proven, medically beneficial technologies is a key goal for our agency.

And I want to assure you that we at the Health Care Financing Administration care deeply about our beneficiaries. On a personal note, that is especially true for me as a practicing geriatrician of 10 years from Boston at the Harvard Medical School at Beth Israel Hospital.

We know that as we have heard from the previous testimonies that there is very real impact to every decision that we make, and I want to thank each of them for personally sharing their stories.

Our goal in the Medicare coverage process is that it is evidence-based, as well as more open, understandable and predictable for beneficiaries, providers, manufacturers, Congress and the public. We are proud of the success that we have achieved thus far in achieving that innovations in health care are readily available for our more than 39 million Medicare beneficiaries, and we look forward to working cooperatively with Congress as we implement important modifications to the Medicare coverage process that were recently enacted in the Benefits Improvement and Protection Act last year.

We face a difficult challenge as we strive to assure high quality health care for our beneficiaries. We must balance multiple and sometimes competing interests as we work toward this goal. We must act as a prudent purchaser on behalf of our beneficiaries and hundreds and millions of taxpayers. We must pay providers adequately and fairly under the law while protecting the Medicare trust funds and ensuring quality care for the Medicare beneficiaries.

We also must consider and incorporate the views and interests of many stakeholders. At the same time, we must carefully assess the potential impact of our coverage decisions. For example, we must ensure that decisions do not discourage the use of valuable new technology or, on the other hand, encourage the use of technologies that are unproven, ineffective or harmful. And we must be careful to ensure that decisions do not create unique advantages or financial incentives that encourage the use of a particular technology simply because it is new.

We firmly believe that Medicare's coverage process must be clear and understandable to beneficiaries, providers, manufacturers and the public, and we have taken a number of positive steps in the last 2 years in achieving this shared goal. They include creating new administrative procedures, allowing any member of the public to request a national coverage policy decision, and instructing our contractors to do the same.

I have attached for the committee's consideration a list of the 23 national coverage decisions that we have made under this new process that has been in existence for the last 1½ years.

We also established a Medicare Coverage Advisory Committee consisting of 100 members including nationally recognized experts in a broad range of medical, scientific and professional disciplines as well as consumer and industry representatives. The committee helps us facilitate public input as well as scientific and medical expertise into our national coverage decisions, particularly on very complex issues.

Finally, we created an internet website where the public can get updated information on the status of any pending national cov-

erage decision including information when a determination is expected and the rationale behind every coverage decision.

We firmly believe that Medicare coverage process must be clear, understandable and predictable for all those involved. We continue to make important progress toward this goal and we look forward to continuing to work cooperatively with all of you on this critical issue.

We thank you for holding this hearing, and we are happy to answer any of your questions. I will answer the coverage and clinical questions, and Dr. Mark Miller, the Acting Director of our Center for Health Plans and Providers, will answer questions related to coding and payment.

[The prepared statement of Jeffrey Kang follows:]

PREPARED STATEMENT OF JEFF KANG, DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Chairman Greenwood, Ranking Member Brown, Ranking Member Deutsch, thank you for inviting me here today to discuss Medicare coverage policy. I appreciate the opportunity to discuss with you this critically important aspect of the Medicare program. Ensuring beneficiaries have access to high quality health care, including access to new, proven, medically beneficial technologies, is a key goal for our Agency.

Many medical device manufacturers and providers have complained that our coverage process has failed them and we are preventing beneficiaries from getting the best care available. They see it as being slow, unresponsive, and full of unnecessary barriers. We recognize that our process is not perfect and in the past we have, at times, been slower than necessary to incorporate new technology into the Medicare program. We also know that our contractors' involvement in the coverage process has been closed, confusing, and contradictory. We have listened to these criticisms from the provider community and Members of Congress. As a response to these critics, we evaluated where the coverage process was difficult to understand or unpredictable and have taken appropriate steps to address these criticisms.

Our goal is a Medicare coverage process that is evidence-based, as well as more open, understandable, and predictable for beneficiaries, providers, manufacturers, Congress, and the public. We are proud of the success we have achieved thus far in assuring that innovations in health care are readily available for our more than 39 million Medicare beneficiaries. In addition, we will be implementing important modifications to the Medicare coverage process that were included in the recently enacted Medicare, Medicaid, and State Children's Health Insurance Benefits Improvement and Protection Act of 2000 (BIPA). We look forward to working cooperatively with the Congress as we implement these improvements.

BACKGROUND

Medicare law provides for broad coverage of many medical and health care services. Rather than providing an all-inclusive list of covered medical devices, surgical procedures, or diagnostic services or those that are excluded from coverage, the law generally provides for broad coverage of categories of services and excludes only those items or services that are "not reasonable and necessary" for the diagnosis and treatment of illness or injury for Medicare beneficiaries.

In most instances, new medical technologies are integrated seamlessly into existing Medicare payment systems as soon as the technologies are approved by the Food and Drug Administration and available in the marketplace. Most new technologies are similar to existing technologies, or are considered integral to existing procedures and, therefore, do not require new coverage decisions or new coding mechanisms for payment. Providers use already established codes to bill for the item or, under Medicare's prospective payment systems, the cost of the technology is simply accounted for in the bundled payment amount made to the provider. Bundling of services provides flexibility to practitioners and other providers in choosing the most appropriate technology based on the patient's needs within the payment amount. And it encourages practitioners and providers to use the most efficient technology available when the available clinical options might similarly benefit the patient.

For a small number of new technologies, the item or service may be a "breakthrough technology" and be clinically different from existing treatment options. There are certain limited instances when these breakthrough technologies are sub-

ject to our coverage, coding, and payment determination processes. Generally, this more thorough review occurs when there are clinical questions about these technologies that are of particular significance to the Medicare population, and warrant a more careful evaluation. However, these questions are usually raised only if there is a need for a new code for the technology or there is a question as to whether the cost of the new technology exceeds the payment provided under the existing coding structure.

BALANCING INTERESTS AND ENSURING ACCESS

We face a difficult challenge as we strive to assure high quality health care for our beneficiaries. We must balance multiple, and sometimes competing, interests as we work towards this goal. We must act as a prudent purchaser on behalf of our beneficiaries and hundreds of millions of taxpayers. We must pay providers adequately and fairly under the law while protecting the Medicare trust funds and ensuring quality care for Medicare beneficiaries. We also must consider and incorporate the views and interests of many stakeholders, including beneficiaries, providers, manufacturers, private health plans, taxpayers, Congress, and others.

At the same time, we must carefully assess the potential impact of coverage decisions. For example, we must ensure that decisions do not discourage the use of valuable new technology or, on the other hand, encourage the use of technologies that are unproven, ineffective, or harmful. Furthermore, we must be careful to ensure that decisions do not create unique advantages or financial incentives that encourage the use of a particular technology simply because it is new.

INCORPORATING NEW TECHNOLOGY

To the extent that the incorporation of a new technology or service requires a coverage decision under Medicare, the vast majority of these decisions regarding coverage are made locally by our contractors—the private companies that, by law, process and pay Medicare claims. New technologies flow easily into the Medicare system through the flexibility the coverage process affords to the local contractor medical directors. In the absence of a national coverage determination, these local medical directors have the discretion to make local coverage decisions about particular technologies. Local coverage policies are developed and set by the contractor's medical directors with the support and input of provider and supplier representatives. They may result in approval of individual claims for new technologies or the establishment of a local coverage policy. In November 2000, we issued instructions to our contractors standardizing the process for making local coverage policies and ensuring that the process is open and includes input from the public.

We also have the authority to set national Medicare coverage policies, but the actual number of these decisions is quite small. National coverage decisions can be conclusive and cover or not cover medical items or services. Alternatively, they can leave coverage decisions for medical items or services to local contractors. Finally, they also can put evidence-based limits on coverage, for example, limiting coverage to particular clinical conditions or situations. When a national decision is issued, it is binding on all Medicare contractors, Medicare+Choice plans, peer review organizations, and Administrative Law Judges. Importantly, the locally based decision-making process allows payment for new technologies to continue at the local level, while decisions are being considered or implemented for a particular technology or service at the national level.

ENSURING APPROPRIATE CODING SYSTEMS

The vast majority of new technologies are incorporated into Medicare's existing coding structure. However, in some instances, either as a result of a national or local coverage policy for a new technology or because the cost of a covered new technology is not adequately captured in the existing codes, the creation of new codes is necessary. We recognize the desire of manufacturers to receive more rapid assignment of codes for emerging technologies, but it is equally important to recognize that many other stakeholders are involved in assigning national codes and computing national payments.

The need for more rapid assignment of permanent codes must be carefully balanced with the interests of our provider partners, particularly hospitals and physicians offices, which seek stability in coding and payment. Frequent changes and updates to codes can disrupt claims processing systems, raise potential compliance issues for providers and claims processors, increase costs to physician offices and hospitals for re-training and system maintenance, and create general uncertainty in overall payment levels. In addition, we must ensure that coding systems used by providers are clinically coherent and appropriate. We also must be certain that the

private and public insurers, who have historically relied on shared systems for coding and payment, have an appropriate level of stability in coding and payment.

These multiple interests prevent us from unilaterally assigning permanent codes for new technologies and require that we work cooperatively with the many stakeholders as coding changes are made. Moreover, the Health Insurance Portability and Accountability Act will, in the near future, require greater standardization and consultation across the health care industry. Therefore, we must be careful to develop processes that meet these future requirements, as well as the ongoing needs of our beneficiaries and health care partners.

IMPROVING THE COVERAGE PROCESS

We firmly believe that Medicare's coverage processes must be transparent and understandable to beneficiaries, providers, manufacturers, and the public. We have taken a number of positive steps, over the last several years, in achieving this shared goal. And we are making solid progress, including:

- *Creating a Clear and Open Process.* In April 1999, we established new administrative procedures that allow any member of the public to request a national coverage policy decision. Action is taken on most requests for a national coverage determination within 90 days of the request and the public is kept informed of progress in making determinations through our coverage website. In November 2000, we instructed our contractors to institute a similarly open process for developing local coverage policies. A list of the 23 national coverage decisions we have made under this new process is attached to my testimony.
- *Establishing the Medicare Coverage Advisory Committee (MCAC).* The committee, established in June 1999, is made up of over 100 members, including nationally recognized experts in a broad range of medical, scientific, and professional disciplines, as well as consumer and industry representatives, who serve a vital role in making the coverage process more open and accountable. Through open meetings, information sharing, and dialogue, the committee helps facilitate public input, as well as scientific and medical expertise, into national coverage policy determinations on particularly complex issues.
- *Creating an Internet Website.* Our new coverage website (www.hcfa.gov/coverage) gives all members of the public, including beneficiaries, providers, and manufacturers, ready access to up-to-date information on the status of any pending national coverage decision, including information such as when a determination is expected, as well as the rationale behind each coverage decision. The website also provides detailed records of the issues considered for each coverage decision, including all of the evidence and the major steps taken in the review process.
- *Developing New Coverage Criteria.* Working with the public, we are developing new criteria that will serve as a framework for health care sector-specific guidance on Medicare coverage policy. These criteria will help providers and our contractors more easily determine whether a given treatment or service is "reasonable and necessary" and, therefore, covered under Medicare. In May 2000, we published a Notice of Intent regarding a proposed regulation on the new criteria. And, in September 2000, we held a Town Hall meeting for providers to share opinions, information, and advice with us. Taking the valuable suggestions we have received, we are continuing to work on a proposed regulation, on which we will again invite public comment, before we issue the final criteria.

RECENT LEGISLATIVE CHANGES

The recently enacted BIPA, includes important changes to the Medicare coverage process for beneficiaries, manufacturers and providers. For example, it enhances the fee-for-service appeals process for beneficiaries and provides an avenue to appeal both local and national coverage decisions. In addition, BIPA modifies the outpatient prospective payment system pass-through mechanism for devices, a mechanism that was created in the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA). BIPA changes the "device-specific" pass-through, as called for in BBRA, to one based on "categories" of devices. We are currently consulting with the device industry and providers on drafting the initial list of device categories, and we expect to meet the April 1 deadline for finalizing this list. We are aware of Congress' concerns regarding the operational difficulties of the pass-through and look forward to working with you to address any needed changes.

CONCLUSION

We recognize that there is considerable concern regarding the way in which HCFA and its contractors oversee the coverage process. Many of these concerns are well founded. However, we hope that our new processes and provisions of the new BIPA legislation will improve our administration of this critical part of the Medicare program. And of course, as we begin the process of modernizing Medicare, we are going to carefully examine ways to make the program more responsive to advances in technology and medical practice, to ensure beneficiaries get the highest quality care.

A clear, understandable, and predictable Medicare coverage process for beneficiaries, providers, manufacturers, Congress, and the public is critically important. We continue to make important progress towards this goal and we look forward to continuing to work cooperatively with all of you on this critical issue. We thank you for holding this hearing, and we are happy to answer your questions.

Mr. GREENWOOD. Dr. Kang, thank you for your testimony.

Dr. Goodman, please.

TESTIMONY OF CLIFFORD GOODMAN

Mr. GOODMAN. My name is Cliff Goodman, and I am with the Lewin Group, a health care policy and management consulting firm, based on Falls Church, Virginia.

The Medicare program exerts significant influence on patient access to new medical technologies. Contrary to common perception, approval of a new technology by the FDA does not guarantee that it will be available to Medicare beneficiaries. By controlling coverage—that is whether or not payment will be made—and reimbursement, which is the level of payment, Medicare can facilitate or impede patient access to new technology.

Figure 1, seen to your right, only hints at the complexity of the process. Gaining market approval for these technologies from the FDA requires meeting that agency's generally stringent criteria for safety and efficacy. Now, the FDA may be the toughest regulatory agency around, but there is only one FDA. In contrast, new technologies face many government and private sector payers who make largely independent payment decisions.

Now, Medicare is not a single entity. In fact, most coverage decisions are made by local Medicare contractors including about 36 Part A Fiscal Intermediaries and about 42 Medicare Part B Carriers.

HCFA makes certain national coverage decisions that supersede any local coverage decisions. HCFA may elect to make a national coverage decision when a technology is costly and/or has a large impact on the Medicare program, or when there is significant variation in local Medicare coverage policies.

As shown in Figure 2, to your right, the pathway to market can be time consuming as well. For the premarket approval, or PMA, devices which typically include the more advanced ones, the time from product to concept to FDA market approval can take several years or more. Following that, securing Medicare payment involves really three types of steps: coverage, coding, and reimbursement.

Now, for many devices that resemble existing ones, for which appropriate codes do exist that are adequately reimbursed, these steps can be perfunctory. But it is just those more advanced technologies that offer greater benefits and that don't fit existing molds that are more likely to encounter the higher hurdles to patient access and adequate payment.

With Medicare, the systems for making decisions about coverage, coding and reimbursement are separate and really largely uncoordinated, and as a result, yes, it can take 15 months to 5 years, and in some cases longer to add new technologies to Medicare.

It is important to note that some of the coding systems used in Medicare that you have heard about today are managed fully or in part by organizations outside of HCFA, for example, the CPT codes for medical procedures that are developed by the American Medical Association. Coding matters. It is a dry subject, but it matters.

Assigning an effective technology to a code whose payment is less than the cost of providing the technology in the first place can discourage the use of the technology and discourage further innovation. When this arises for a technology, for instance, in the inpatient prospective payment system, we call it a DRG loser.

There are reasons why, and there are truly reasons why FDA approval is not necessarily accepted as sufficient for payment by Medicare or other payers. For example, the technology may not fall under a covered benefit such as when screen technologies in general aren't covered by quite a few payers, or the beneficiary population, for example, the elderly and Medicare in this case, may not have been adequate represented in existing clinical studies on the technology. Also, any health benefit of a new technology might not be worth its additional cost in the view of the payer.

Now, here are four overarching observations of the current Medicare process:

(1) The Medicare process for coverage, coding and payment for many medical technologies can be inefficient and unnecessarily time consuming, particularly for the novel or more breakthrough technologies.

(2) HCFA's redesigned national coverage process does offer some important and welcomed improvements in transparency and responsiveness, and the gentleman to my left, Dr. Kang, has had much to do with these improvements. However, the process including the function and reporting of the Medicare Coverage Advisory Committee, or the MCAC, is really still under construction and remains unpredictable.

(3) Medicare evidence requirements and coverage criteria are increasing in general and remain unpredictable or ambiguous in certain important ways. Now, evidence-based coverage policy is—is—absolutely necessary, but the current ground rules, including as provided by HCFA in the notice of intent issued last May, are insufficient.

(4) While its transparency and openness could be improved, the local coverage process by the Part A Fiscal Intermediaries and the Part B carriers that I mentioned still remains a critical avenue for obtaining coverage, particularly given the uncertainty about the national coverage process as it now stands.

Let us be clear about it. Evidence-based decisionmaking for medical technology can be complex. You cannot make responsible coverage policy overnight for, say, use of PET scans for diagnosing multiple types of cancer, at different potential levels of severity, in diverse patient populations, and for which the existing clinical evidence may be, in fact, weak or inconclusive.

Nevertheless, it remains incumbent upon payers, including Medicare, to establish evidence requirements and related coverage criteria that are appropriate for different types of technology, and transparent, and implemented consistently in a timely manner. Now that is a tall order. But it is your order if you are responsible for health care coverage for nearly 40 million people at nearly $260 billion a year. It is also our responsibility.

There are in place—this is the good news—certain building blocks or models for a smoother, more predictable transition of new technology from investigational to covered status.

One is the 1995 Interagency Agreement between FDA and HCFA that makes certain Category B investigational devices eligible for Medicare payment during clinical trials. Good move.

A recently implemented executive order provides Medicare payment for the routine patient care costs of beneficiaries enrolled in clinical trials of new technologies.

Third, the BBRA of 1999 established temporary pass-through payments for certain new technologies under the outpatient prospective payment system.

And four, the Benefits Improvement and Protection Act, or BIPA, 2000 requires HCFA to establish a mechanism to adopt new medical services and technologies under the inpatient prospective payment system.

What do these have in common? They all provide conditional or temporary payment for promising health care technologies while evidence can be collected to support well-founded coverage coding and reimbursement policies.

In closing, here are five ways to buildupon ongoing efforts to improve the Medicare coverage process in the way it deserves.

First, FDA and HCFA should work closely on better alignment of the evidence requirements for market approval by the FDA and payment by Medicare. This greater alignment can reduce costs and the time line for making new technologies available to patients.

Two, HCFA and its MCAC should work with industry and others to develop evidence requirements and coverage criteria that are appropriate for different types of technologies.

Three, HCFA and the MCAC, and this is very important, should move promptly to establish clear and accountable lines of authority and review tracks.

Four, the process for assigning and updating codes should be made more frequent and adaptive to the diversity and costs of new technologies. Remember, HCFA cannot do this alone.

And five, HCFA should devote sufficient resources and expertise to technology assessment for the big job of assembling and interpreting evidence in support of Medicare coverage decisions.

Well, the Health Care Financing Administration is the world's single largest payer for health care—the world's. Recent improvements notwithstanding, this most influential gatekeeper for new technology must strengthen and streamline its process on behalf of its beneficiaries and the nation. Thank you.

[The prepared statement of Clifford Goodman follows:]

PREPARED STATEMENT OF CLIFFORD GOODMAN, THE LEWIN GROUP

Good afternoon, Chairmen Bilirakis and Greenwood, Ranking Members Brown and Deutsch, and other Members of the Committee. My name is Cliff Goodman, and I'm a senior scientist at The Lewin Group, a health care policy and management consulting firm based in Falls Church, Virginia.

Complex and Time-Consuming Pathway to Patient Access

As the nation's largest health care payer, the Medicare program exerts significant influence on patient access to new medical technologies. Contrary to common perception, approval of a new technology by the Food and Drug Administration (FDA) does not guarantee that it will be available to Medicare beneficiaries. By controlling coverage (whether or not payment will be made) and reimbursement (the level of payment), Medicare can facilitate or impede patient access to new technology.

Continued growth in demand for health care and for cutting-edge technologies in particular are focusing national attention on the pathway to patient access. Figure 1, attached, only hints at the complexity of this process. Gaining market approval for these technologies from the FDA requires meeting that agency's generally stringent criteria for safety and efficacy. The FDA is one of the toughest regulatory agencies around, but there is only one FDA. After overcoming that regulatory hurdle, new technologies face not one, but many government and private sector payers who make largely independent coverage and reimbursement decisions affecting access.

Of course, Medicare is not a single entity. In fact, most coverage decisions are made by local Medicare contractors, including about 36 Part A Fiscal Intermediaries (FIs) and about 42 Part B Carriers, including four Durable Medical Equipment Regional Carriers (DMERCs).

National coverage decisions are made by HCFA and must be observed by all Medicare Carriers and FIs. National coverage decisions supersede any local coverage decisions. HCFA may elect to make a national coverage decision when a given technology is costly and has a significant impact on the Medicare program, or when there is significant variation in local Medicare coverage policies.

As shown in Figure 2, the pathway to market can be time consuming. For Premarket Approval (PMA) devices, which typically include the more advanced ones, the time from product concept to FDA market approval can take several years or more. Following that, securing Medicare payment involves three types of actions: coverage, coding, and reimbursement. For a new device that resembles an existing one for which an appropriate code exists that is adequately reimbursed, these actions can be perfunctory. But it is those more advanced technologies that offer greater benefits and don't fit existing molds that are more likely to encounter higher hurdles to patient access and adequate payment. Within Medicare, the systems for making decisions about coverage, coding, and reimbursement are separate and largely uncoordinated. As a result, it can take 15 months to 5 years, and in some cases longer, to add new technologies to Medicare.

A complicating twist here is that some of the coding systems used in Medicare are managed fully or in part by organizations outside of HCFA, for example, the Common Procedure Terminology (CPT) codes for medical procedures that are developed and maintained by the American Medical Association.

Whether it be CPT codes for physician services, diagnosis related groups (DRGs) for the inpatient Prospective Payment System (PPS), or ambulatory payment classification groups (APCs) for the outpatient PPS, coding matters. Assigning an effective technology to an inappropriate code, or to a code whose payment is less than the cost of providing the technology, can discourage use of the technology, limit patient access, and discourage further innovation. In fact, when this arises for a technology in the inpatient PPS, we call that technology a "DRG loser."

FDA Approval Not Sufficient for Payment

To be sure, there are reasons why FDA approval is not accepted as sufficient for payment by Medicare or other payers. These may include the following.

- The technology may not fall under a covered benefit (e.g., screening procedures may not be covered).
- Payers care not just about efficacy ("Can it work under ideal circumstances?") but about effectiveness ("Does it work in actual clinical settings?").
- The beneficiary population may not have been adequately represented in existing clinical studies.
- Clinical studies done for FDA approval may have compared the new technology to placebo (or no intervention), instead of to the existing standard of care.
- Follow-up times may not have been sufficient to capture natural disease episodes and potential adverse events.

- Any additional health benefit of a technology might not be worth its additional cost.
- Even if covered, a technology might not be medically necessary for particular patients.

Overarching Observations of the Medicare Coverage Process

Based in part on a study that we conducted recently at the request of AdvaMed, here are five overarching observations of the Medicare coverage process.[1]

1. The Medicare process for coverage, coding, and payment for many medical technologies can be inefficient and time-consuming, particularly for novel or "breakthrough" technologies.
2. HCFA's redesigned national coverage process offers some important and welcomed improvements in transparency and responsiveness. However, the process, including the function and reporting of the Medicare Coverage Advisory Committee (MCAC), is still under construction and remains unpredictable and time-consuming.
3. Medicare evidence requirements and coverage criteria are increasing in general, and remain unpredictable or ambiguous in certain important ways. Evidence-based coverage policy is absolutely necessary, but the ground rules, including as provided by HCFA in the Notice of Intent issued in May 2000, are unclear and insufficient for the diversity of new technology.
4. While its transparency and openness could be improved, the local coverage process by Part A FIs and Part B Carriers remains a critical avenue for obtaining coverage, particularly given uncertainty about the national coverage process.
5. Problems inherent in the Medicare coverage, coding, and payment systems can influence provider behavior, impede patient access to health care technology, and affect the course of innovation.

Let's be clear about it; evidence-based decision making for medical technology can be complex. Even setting the matter of cost aside, you don't make responsible coverage policy overnight for, say, the use of PET scans for diagnosing multiple possible types of cancer, at different sites in the body, at different potential levels of severity, in diverse patient populations, and for which the existing clinical evidence may be weak or inconclusive. Then consider that many of the PET scans will generate the need for more invasive tests, and that treatments for these cancers may have limited effectiveness and severe side effects.

Nevertheless, it remains incumbent upon payers to establish evidence requirements and related coverage criteria that are appropriate for different types of technology, transparent, and implemented consistently in a timely manner. That is a tall order. But if you're responsible for health care coverage for nearly 40 million people at $257 billion per year, it's yours. And ours.

Build Upon Encouraging Developments

Historically, the coverage of new technologies has been, at least officially, characterized by a great binary divide: coverage or non-coverage. The Catch-22 has been that payers would not cover a new technology until there was enough patient data on which to base an informed coverage policy; however, it is difficult to accumulate such data unless a payer is covering the technology. The good news is that there are now in place certain building blocks or models for a smoother, more predictable transition for new technologies across that binary divide.

- The 1995 Interagency Agreement of FDA and HCFA makes certain "Category B" investigational devices eligible for Medicare payment during clinical trials being conducted toward FDA approval.
- There are selected instances of conditional coverage, in which research organizations and payers coordinate and pay for clinical trials of new technology, such as the National Emphysema Treatment Trial involving the National Heart, Lung and Blood Institute, HCFA, and the Agency for Healthcare Research and Quality (AHRQ).
- The recently implemented Executive Order for HCFA provides for Medicare to pay for routine patient care costs of beneficiaries enrolled in clinical trials of new technologies.
- The Balanced Budget Refinement Act of 1999 (BBRA) established temporary pass-through payments for certain new technologies under the outpatient PPS.
- The Benefits Improvement and Protection Act of 2000 (BIPA) requires HCFA to establish a mechanism to adopt new medical services and technologies under the inpatient PPS.

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[1] The Lewin Group. Outlook for Medical Technology Innovation. The Medicare Payment Process and Patient Access to Technology. Washington, DC: AdvaMed, 2000.

All of these have one thing in common: they provide conditional or temporary payment for promising health care technologies, while evidence can be collected to support well-founded coverage, coding, and reimbursement policies.

It should be noted that conditional coverage at a national level that allows payment only to specified providers can override local coverage that provided access to some patients. As these arrangements evolve, policy makers and industry should closely monitor their implications for access.

Avenues for Improvement

Building upon ongoing efforts, HCFA and Congress should consider the full process, leading up to and including coverage, coding, and reimbursement. Here are some approaches.

1. FDA and HCFA should work closely on better alignment of evidence requirements for market approval and payment for new technology. Without compromising the respective missions of these agencies, greater alignment will reduce the costs and timeline for making new technologies available to patients.

2. HCFA and its MCAC should work with industry and others to develop evidence requirements and coverage criteria that are appropriate for different types of technology. It is impractical and inefficient to apply the same types of evidence requirements to technologies used in prevention, screening, diagnosis, and treatment.

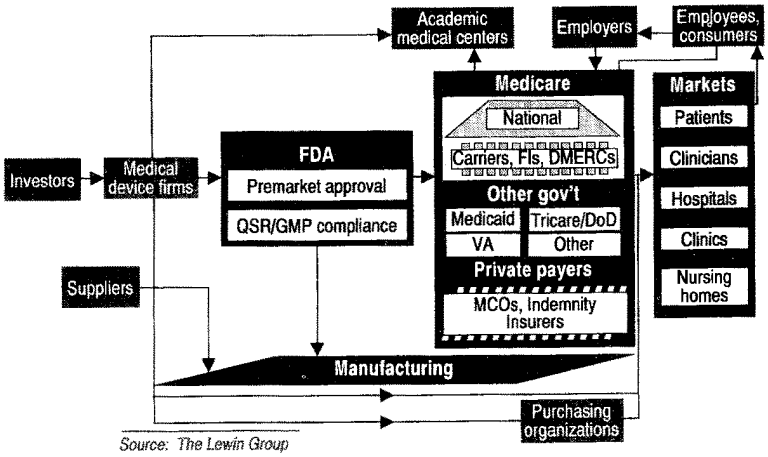
3. HCFA and the MCAC should move promptly to establish clear and accountable review tracks and lines of authority involving HCFA, MCAC and its components, and any outside review groups.

4. The processes for assigning and updating codes should be made more frequent and adaptive to the diversity and costs of new technologies. HCFA cannot do this alone; it must work with the organizations that manage these systems.

5. HCFA should devote sufficient resources, expertise, and organizational cooperation to technology assessment for assembling and interpreting evidence in support of Medicare coverage decisions. Aside from continuing to strengthen its capacity from within, HCFA should establish efficient, timely relationships with AHRQ, other federal agencies, and qualified technology assessment organizations in the private sector.

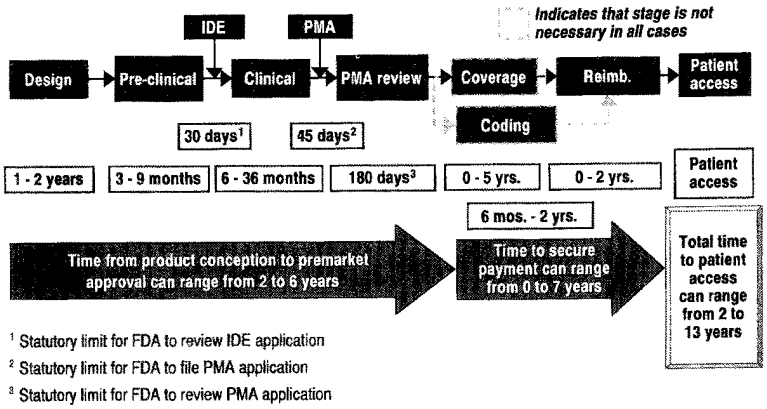
The Health Care Financing Administration is the world's single largest payer for health care. Recent improvements notwithstanding, this most influential gatekeeper for new technology must strengthen and streamline its process on behalf of its beneficiaries and the nation.

Fig. 1: New Technology Pathway to Markets



Source: The Lewin Group

Fig. 2: Time to Patient Access, PMA Devices



[1] Statutory limit for FDA to review IDE application
[2] Statutory limit for FDA to file PMA application
[3] Statutory limit for FDA to review PMA application

Source: The Lewin Group

Mr. GREENWOOD. Thank you, Dr. Goodman, for your statement. Dr. Ross, your statement, please.

TESTIMONY OF MURRAY N. ROSS

Mr. ROSS. Good afternoon, Chairman Greenwood, Chairman Bilirakis, Mr. Brown, Mr. Deutsch, members of the subcommittees. I am Murray Ross, Executive Director of the Medicare Payment Advisory Commission, and I am pleased to be here at this joint hearing, to discuss access to new technology and the role of Medicare payment policy. My written testimony draws heavily on a chapter from MedPAC's newly released March 2001 report to the Congress.

Medicare handles new technology in two broad steps. The first step, of course, is deciding what to cover and we have heard a lot about that this morning. The second step is seeing to it that Medicare's payment policies provide sufficient resources for health care providers to adopt new technologies without spending more than necessary and without introducing unnecessary complexity into the program.

The second step is the focus of my testimony. Medicare now pays prospectively for most services provided in hospitals. This raises questions about whether the program recognizes the introduction of new technologies quickly enough to ensure needed access for beneficiaries and whether the payment systems account adequately for new technologies.

In looking at both the inpatient and the outpatient prospective payment systems, MedPAC has concluded that the Secretary should develop formal procedures for assigning codes, updating relative weights and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies.

To avoid unnecessary spending and complexity in these payment systems, additional or pass-through payments should be both budget neutral and limited to technologies that are new or substantially improved and that it adds significantly to the cost of care.

Prospective payment was adopted by Medicare to promote efficiency in the provision of services and thus protect beneficiaries and taxpayers from unnecessary treatments and spending.

By setting payment rates in advance, Medicare gives hospitals a fixed payment that ideally reflects an efficient provider's costs. Hospitals are placed at financial risks for the costs above the payment amount and rewarded if they keep their costs below it.

By its nature, prospective payment provides financial incentives to adopt new technologies that lower costs. However, the payment system should also provide mechanisms to account for the cost of new technologies that enhance quality even if they increase costs. The payment system should maintain neutrality regarding clinical decisionmaking including adoption of new technology.

It should not favor the use of one procedure or technology over clinically appropriate substitutes, but pay the cost of an efficient provider for all options, leaving clinicians to make decisions given individual circumstances. A balancing process is needed to ensure that payments are sufficient to maintain access to needed services, but without spending more than necessary.

Further, payment mechanisms should be administratively feasible from both the perspective of HCFA and hospitals using the most reliable data sources available.

The outpatient system pays for new technology in two ways: by defining new technology, ambulatory payment classification, or APC groups, and by making pass-through payments to provide additional funds for specific drugs, biologicals and medical devices. The new APC groups aim to ensure timely payment for technologies that represent new services distinct from the existing groups.

HCFA established 15 new groups with cost ranges from zero to $50 to between $5,000 and $6,000; payment rates for these groups will be at the midpoint within each group. This approach is most applicable to a system with a narrow unit of payment and limited bundling, as is the case in the outpatient payment system.

One difficulty with this approach, however, is that it uses a temporary payment rate, the new technology APC group rate, while data on costs are being collected to set a permanent rate. Data derived in this way are not easily verified and may not represent hospitals' operational costs.

The pass-through payments seem to ensure adequate payment for new technology is used as inputs to an outpatient service rather than as distinct services themselves. Pass-throughs for certain drugs, biologicals and medical devices were authorized under the Balanced Budget Refinement Act in response to concerns that the 1996 data used to calculate base payment rates did not adequately reflect costs in 2000.

However, the Benefit Improvement and Protection Act of 2000 removed the criterion that technologies be underrepresented in the 1996 data. All medical devices described by A Category will receive pass-through payments regardless of when they were first used in the outpatient setting.

By paying hospitals' incremental costs for new devices at the claim level, these pass-through payments encourage their adoption and diffusion. However, they also dilute the ability of the outpatient payment system to provide incentives for efficiency and cost control. In effect, this provision will result in unbundling payments and providing cost-based pass-through payments for most medical devices.

Introducing cost-based pass-through payments gives manufacturers and hospitals an incentive to increase prices for them. Pass-through payments for drugs and biologicals will be based on average wholesale prices with similar incentives for manufacturers to increase prices. These inflationary trends will also increase future payments as the pass-through costs are incorporated into the base.

MedPAC recommends that in the outpatient payment system pass-through payments for specific technologies be made only when technologies are new and substantially improved to avoid double counting those costs that are already in the base, and only when they add substantially to the cost of care in an ambulatory payment classification group to avoid introducing unnecessary complexity to the payment system.

We recommend that pass-through payments be made on a budget-neutral basis, but that the aggregate costs of new or substan-

tially improved technologies be factored into the update to the outpatient conversion factor. This gives policymakers control over how much to increase payments.

I would like to touch briefly, even though in it is in a different jurisdiction, on inpatient. Prospective payment for inpatient services has been in effect since 1984. BIPA changed Medicare's payment approach to new technology by formalizing methods that HCFA already had in place and requiring additional payments for the cost of new technologies.

We support having HCFA formalize its procedures and offer some guidelines for implementing these additional payments.

The additional payments for new technologies on the inpatient side are essentially pass-throughs, but several reasons make them less appropriate there than they are in the outpatient setting. First, new drugs, devices or services make up a much smaller share of cost for a discharge than for an outpatient service.

Second, neither patients' classification nor recalibration of payment weights depends on assigning new codes.

Third, we lack reliable data on which to base payments.

Fourth, we face difficulty in predicting how often new technology will be used, and thus the reduction in the base payment rates needed to make the pass-through funding budget neutral.

And, finally, the adjustments will introduce administrative complexity, again for HCFA and for hospitals alike.

Our recommendations on the inpatient side combine aspects of the previous system and the provisions of the Benefit Improvement and Protection Act. First, the Secretary should develop formal procedures for expeditiously assigning codes, updating relative payment weights, and exploring the need for changes in patient classification.

Second, additional payments should be limited to new or substantially improved technologies that add significantly to the cost of care in a diagnosis-related group and should be made on a budget neutral basis. And again, we would recommend accounting for the aggregate impact of new technologies through the update.

That concludes my testimony and I will be happy to answer any questions.

[The prepared statement of Murray N. Ross follows:]

PREPARED STATEMENT OF MURRAY N. ROSS, EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION

Chairman Bilirakis, Chairman Greenwood, Members of the Subcommittees. I am Murray Ross, executive director of the Medicare Payment Advisory Commission. I am pleased to be here this morning to discuss Medicare beneficiaries' access to new technology and how Medicare payment policy can help to continue ensuring access. My testimony draws heavily on a chapter from MedPAC's March 2001 report to the Congress.

Medicare needs to take two steps in ensuring beneficiaries' access to new technology. The first step is determining what to cover. The second step is seeing to it that Medicare's payment policies provide both incentives for health care providers to adopt new technologies and sufficient resources for them to do so. This second step is the focus of this testimony.

Most services provided in hospitals are now paid for prospectively. Recently, concerns have arisen regarding the treatment of new technology under prospective payment. Does Medicare recognize the introduction of new technologies quickly enough to ensure access for beneficiaries? Do payment rates adequately reflect the costs of new technologies? The Balanced Budget Refinement Act (BBRA) of 1999 addressed this issue for the outpatient prospective payment system (PPS) by establishing pass-

through payments for certain types of new technology. The recently enacted Benefits Improvement and Protection Act (BIPA) of 2000 requires HCFA to develop new mechanisms to pay for technological advances under the inpatient PPS.

We conclude that under both the inpatient and the outpatient prospective payment systems, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies. Also, to avoid unnecessary spending and complexity in these payment systems, additional or pass-through payments should be both budget-neutral and limited to technologies that are new or substantially improved and that add significantly to the cost of care.

In support of these conclusions, this testimony considers how new technology should be defined, what payment principles should apply to the treatment of it, and how prospective payment systems for hospital services should account for new technologies.

DEFINING NEW TECHNOLOGY

In the most basic sense, technology is the practical application of knowledge. In the health sector, this may include: drugs; devices, equipment, and supplies; medical and surgical procedures; support systems; and organizational and managerial systems. Some of these technologies, such as drugs or surgical procedures, affect identifiable services and individual patients. Others, such as new diagnostic equipment, may be used for an array of services and multiple patients. Still others, such as information systems or improved management techniques, affect all services provided in a hospital.

When defining new technologies, both new types of technology and substantial improvements to older technologies may be considered. Within a payment system, a technological advancement might be application of an existing technology to new clinical situations, such the broadening use of PET scans. Although the overall effect of technology has been to increase costs, specific new technologies may increase or decrease costs.

The mechanisms used to account for the costs of new technology in a payment system depend, in part, on the kind of technology considered. Recognition of the costs of a device used in a particular procedure, such as coronary stents used in angioplasty, may be reflected in the relative weight assigned that procedure or through an additional payment. The costs of broader technologies, such as capital equipment or information systems, however, are more easily treated through updates to the base payment rate. In some cases, such as the inpatient PPS, changes in relative weights are made in a budget-neutral fashion. In that case, the payment system still needs to account for the cost-increasing nature of technology through the update process.

PROSPECTIVE PAYMENT AND THE TREATMENT OF NEW TECHNOLOGY

Prospective payment was adopted by Medicare to promote efficiency in the provision of services and thus protect taxpayers and beneficiaries from unnecessary treatments and spending. By setting payment rates in advance, Medicare gives hospitals a fixed payment that ideally reflects an efficient provider's costs. Hospitals paid prospectively are placed at financial risk for costs above the payment amount and rewarded if they keep their costs below it.

By its nature, prospective payment provides financial incentives to adopt new technologies that lower costs. However, the payment system should also provide mechanisms to account for the costs of new technologies that are enhance quality, even if they increase costs.

A PPS should maintain neutrality regarding clinical decisionmaking, including adoption of new technology. The payment system should not favor the use of one procedure or technology over clinically appropriate substitutes, but pay the costs of an efficient provider for all options, leaving medical personnel to choose what is clinically optimal given individual circumstances. Payment rates are set for a given output, but the number and mix of inputs used to create the output is left to the clinical judgment of the provider.

A balancing process is needed to ensure that payments are sufficient to maintain access to needed services without spending more than necessary. The calculation of adequate payment rates must be administratively feasible, using the most reliable data sources available. Limited data and predictable variations in costs across providers also imply that payment adequacy be determined at a broad level, with payment adjustments such as those given to teaching hospitals used to account for predictable variations in costs among types of providers.

COMPONENTS OF PROSPECTIVE PAYMENT SYSTEMS

PPSs have certain common elements, including a patient or service classification system and a unit of payment. They also have a process for updating both the relative payment weights and base payment amounts. The way these elements are treated has implications for the treatment of new technology under a given PPS.

Classification system

The classification system, which groups services for payment, may influence how technology is defined and how new technology is treated. A narrow payment system—such as the outpatient PPS which groups services based on a single service or small bundle of services—may target a specific device or drug by using additional payments or other mechanisms. Basing the classification system on diagnosis—as is done in the inpatient PPS—can make it more difficult to tie a specific technology to a given case.

Unit of payment

The unit of payment determines which services are bundled for payment purposes. The outpatient PPS relies on a limited bundle: payment is for the inputs required for a narrowly defined procedure, such as a diagnostic test, an outpatient surgical procedure, or a clinic visit. In contrast, the inpatient PPS encompasses a broad bundle: all services provided during a hospital stay. In general, the broader the bundle, the more room for efficiency enhancements at the provider level, but the greater the opportunity for withholding services.

The unit of payment influences how a payment system captures the costs of new technologies. If the unit of payment incorporates a large bundle, increased costs in one area, such as a new-generation medical device, may decrease costs in another area, such as length of stay, causing total payment for the bundle to stay the same or decline. For a narrow bundle, however, there is less scope for offsetting efficiencies, and the costs of new technologies may need to be taken into account more explicitly.

Updating relative payment weights

Updating codes and payment weights (which account for differences in the resources needed to furnish care) provides another way to account for the costs of new technology. Introducing new codes can help account for the cost of innovative procedures. Recalibrating payment weights for services takes into account how new technologies, increased productivity, and other factors change the costs of services in relation to one another. The frequency with which codes and weights are revised affects the length of time before appropriate payments are made for new technologies. However, multiple priorities must be balanced, including the integrity of the coding and payment systems, disruption to providers from revising their billing processes to reflect new codes and new weights, data availability, and administrative requirements.

Payment updates

Finally, updates to base payment rates, which account for changes over time in the efficient costs of providing care, may also reflect the cost impacts of new technology. Some updating approaches—such as the update framework MedPAC developed for updates for the inpatient PPS and other fee-for-service settings—explicitly consider the effect of quality-enhancing but cost-increasing technologies on costs, and increase payments accordingly. Of course, when new technologies increase efficiency and decrease costs, payment updates should also reflect those trends. For the inpatient PPS, the Congress legislates the update annually, with guidance from MedPAC and Secretary of Health and Human Services. For the outpatient PPS, the Congress has set the update to the conversion factor through 2002. The updating process for future years has not been fully developed by the Health Care Financing Administration (HCFA). For the present, no explicit mechanism accounts for the cost impacts of new technology in updating the outpatient conversion factor.

TREATMENT OF NEW TECHNOLOGY IN THE OUTPATIENT PAYMENT SYSTEM

The implementation of the outpatient PPS on August 1, 2000, marked a move away from primarily cost-based payment for services provided in hospital outpatient departments. This section describes the outpatient PPS and MedPAC's recommendations for improving how the system pays for new technology.

Structure of the outpatient payment system

The outpatient PPS classifies services based on their HCFA Common Procedure Coding System (HCPCS) code into ambulatory payment classification (APC) groups.

The unit of payment for the outpatient PPS is the individual service. Payment for a service in an APC group includes limited bundling of ancillary services and supplies considered incident to the primary service. The most extensive bundling occurs for outpatient surgery. Payment for outpatient surgery covers the hospital's costs for the operating and recovery rooms, anesthesia, most drugs, and most surgical supplies used during the surgery.

Responding to technology costs

The outpatient PPS pays for new technologies in two ways: by defining new technology APC groups and by making pass-through payments that provide additional reimbursement for specific drugs, biologicals, and medical devices. The new technology APC groups aim to ensure timely payment for technologies that represent new services, distinct from the existing groups. The pass-through payments aim to ensure adequate payment for new technologies that are inputs to an outpatient service, rather than a distinct service. A pass-through payment is a cost-based payment that supplements the standard APC payment when a specific technology is used.

Coding and classification issues

Industry has expressed concern that delays in the coding and classification processes hamper the diffusion of new technologies, although there is no clear evidence of access problems. In the outpatient PPS, the process for handling new technologies includes assigning codes to new services and procedures, updating the classification (APC) weights, and investigating the need for new or restructured service classification groups. MedPAC recommends that the Secretary develop formalized procedures to expedite this process.

Timely development of payment codes is especially important in the outpatient sector, where payment bundles are small and most procedures require a code for hospitals to be reimbursed. New outpatient codes are assigned by HCFA and/or the CPT Editorial Panel. In addition, to implement the outpatient technology provisions of the BBRA, HCFA has developed a system for assigning codes for pass-through payments, including setting aside a block of temporary codes to be assigned quickly.

In addition to assigning codes, HCFA must also review the outpatient payment weights on an annual basis and restructure the APCs as needed, although the process for doing so has not been fully detailed beyond establishing an external advisory committee.

New technology ambulatory payment classification groups

In developing the outpatient PPS, HCFA created separate APC groups to classify new technology services that do not qualify for pass-through payments. These groups contain services that are similar in cost, but are not necessarily clinically similar. The agency established 15 new technology groups, with cost ranges from $0-$50 to $5,000-$6,000. The payment rate for all the services or items within a particular group will be the midpoint of the group's cost range.

To qualify for classification within a new technology APC, a service must be covered by Medicare, be underrepresented in the 1996 data used to set payment rates, have a HCPCS code, and be deemed reasonable and necessary for treating an illness or improving an impaired function. HCFA will group qualifying new technologies or services within new technology APC groups for at least two but no more than three years before assigning the services to an existing or new standard APC group. This mechanism will allow HCFA to pay for new technologies shortly after they become available and qualify for Medicare payments. It also allows the agency to collect clinical and cost data to refine and update the APC classification system.

This approach to accounting for new technology is most applicable to a PPS with a narrow unit of payment and limited bundling, as is the case in the outpatient PPS. One of the difficulties with this approach, however, is that it uses a temporary payment rate—the new technology APC group rate—while data on hospital costs are being collected to set a permanent rate. HCFA uses an application process to gather cost data to place services within the new technology APC groups, but data derived in this way are not easily verified and may not be representative of hospitals' operational costs.

Pass-through payments

Pass-through payments for certain drugs, biologicals, and medical devices were authorized under the BBRA to ensure that payments under the outpatient PPS adequately accounted for the costs of new technologies. The policy responded to concerns that the 1996 data used to calculate base payment rates did not adequately reflect the costs of certain new technologies. However, BIPA removed the criterion that technologies be under-represented in the 1996 data. All medical devices de-

scribed by a category will now receive pass-through payments, regardless of when they were first used in the outpatient setting. In effect, this provision will result in unbundling payments and providing cost-based pass-through payments for most medical devices.

By paying hospitals' incremental costs for new devices at the claim level, pass-through payments encourage their adoption and diffusion. For drugs and biologicals, additional payments are set at 95 percent of average wholesale price. For medical devices, pass-through payments are based on each hospital's costs (as determined by adjusting charges using a cost-to-charge ratio). For example, when a pacemaker is implanted, a hospital receives a base payment for costs associated with performing the procedure and a pass-through payment based on the costs of the device. In principle, the amount of the pass-through payment will be offset by subtracting the estimated cost of the device it replaces from the base payment rate. However, HCFA has not yet been able to identify the cost of most devices in the underlying payment rates.

Pass-through payments will be paid for two to three years until standard payment rates can be modified to incorporate the costs of new devices. Data collected during the transition will be used to modify the standard payment rates. Total payments under the pass-through provision are limited to 2.5 percent of total program payments through 2003, and 2 percent thereafter. If this limit is exceeded, all pass-through payments are to be reduced. Additionally, total payments must remain budget neutral, meaning that the conversion factor will be reduced to account for the cost of the pass-through payments. In effect, the provision redistributes payments among services.

In our June 2000 report, MedPAC noted that although transitional pass-through payments may help to ensure access to new and innovative technologies, they may also dilute the ability of the outpatient PPS to provide incentives for efficiency and cost control. Introducing cost-based pass-through payments gives manufacturers and hospitals an incentive to increase prices for these items. Pass-through payments for drugs and biologicals will be based on average wholesale prices, which are also subject to manipulation. Inflationary trends in the pass-through payments will also increase future standard payment rates as the pass-through costs are incorporated into the base.

The cap on total payments—2.5 percent of total program payments through 2003 and 2 percent thereafter—and proportional reductions of all pass-through payments if the cap is exceeded is meant to prevent increases in overall spending due to the pass-through payments. However, the cap will not be applied in 2000 and 2001, and program spending will increase despite the cap. Whether or not the limit will be exceeded in the future depends, in large measure, on the definition of what qualifies for pass-through payments. HCFA has expanded its definition numerous times since releasing the final rule—more than 1,000 items were eligible on January 1, 2001—and BIPA will lead to further expansions.

In considering pass-through payments, two principles should be kept in mind: minimizing interference with in clinical decision-making, and ensuring that mechanisms are in place to limit the program's exposure to cost-based payment. Balancing these potentially conflicting notions requires consideration of the eligibility criteria for pass-through payments. MedPAC recommends that in the outpatient payment system, pass-through payments for specific technologies should be made only when a technology is new or substantially improved and adds substantially to the cost of care in an ambulatory payment classification group. We also recommend that pass-through payments be made on a budget-neutral basis and the costs of new or substantially improved technologies should be factored into the update to the outpatient conversion factor.

Limiting pass-through payments to new and substantially improved technologies protects the program and beneficiaries against unnecessary exposure to cost-based payments. It also eliminates the potential to pay for technologies twice: once in setting the initial payment rates (which include older technologies) and again through a pass-through payment. For this reason, the definition of "new" should not include items whose costs were reflected in the 1996 data used to set payment rates. Limiting pass-through payments to those new or substantially improved technologies that add substantially to the cost of care limits the program's exposure to the administrative burden of special payment provisions and the introduction of cost-based payment for technologies that compose a small part of overall payment.

Budget neutrality—when implemented—will protect against the inflationary pressures of cost-based pass-through payments. This mechanism will reimburse hospitals for the increased costs of specific technologies when they are used, but will not account for the overall cost-increasing nature of new and substantially improved technologies. Therefore, in a manner similar to the inpatient PPS, the costs of these

new technologies should be brought into the system through the update to the conversion factor. However, any increase to the update for new technology should not include the costs of technologies in use prior to 1997 because their costs are already accounted for in the base. Similarly, the update should not factor in the costs of new procedures that are part of the new technology APC groups. The costs of these services are covered directly as each unit is paid for, leading to increases in total spending.

TREATMENT OF NEW TECHNOLOGY IN THE INPATIENT PAYMENT SYSTEM

Medicare's PPS for acute inpatient services has been in effect since 1984. The process for annually changing its payment rates already includes a set of largely informal procedures for responding to the costs of new technology. BIPA enacted a method to account directly for the costs of new services and technology, patterned somewhat after the outpatient technology pass-through provision discussed above.

Structure of the inpatient payment system

The unit of payment in the hospital inpatient payment system is the case, or inpatient discharge, as classified by diagnosis related group (DRG). This unit of payment is broader than that of the outpatient APC system, encompassing all routine nursing, support service, and ancillary costs incurred in patients' stays. The payment system comprises:

- operating and capital base payment rates, which reflect the national average costliness of Medicare cases, adjusted for the relative input prices of the hospital's local area;
- case weights, which account for the relative costliness of each DRG compared with the national average Medicare case; and
- special adjustments, such as outlier payments for unusually costly cases.

Responding to technology costs

The BIPA changed Medicare's approach to new technology in the inpatient PPS by formalizing some methods already in use by HCFA and mandating new payment adjustments for inpatient care. We support having HCFA formalize its procedures for responding to new and substantially improved technologies and offer guidelines for implementing the technology pass through mandated by BIPA.

Previous methods

Technology has been addressed in Medicare's inpatient PPS in four ways. The first component of HCFA's system is a technical advisory panel that assigns ICD-9-CM codes to new technologies and deletes codes for outdated procedures.[1] The process of assigning codes has no fixed timetable, but generally takes at least a year.

Second, HCFA staff analyze variation in the costliness of cases within DRGs, primarily in response to suggestions by industry representatives that the costs of certain types of cases are systematically higher than the applicable DRG average. Based on these analyses, HCFA periodically reassigns certain types of cases to a different DRG or splits DRGs into two or more new groupings and modifies the case weights accordingly.

The third way in which HCFA responds to new technology is by recalibrating the DRG case weights. Recalibration is done annually and reflects the relative costliness of cases in the most recent year's claims file. Although annual recalibration plays an important role in maintaining accurate payment relatives, it can only reflect the current degree of dissemination. If only a few hospitals are using a new technology, their charges will have only a small effect on the DRG rate and they may continue to be underpaid pending the next recalibration.

The final mechanism for responding to technology changes is the annual update to the base payment rates. Since the early years of the inpatient PPS, Congress has legislated updates for operating payments, while HCFA has set the updates for capital payments through an annual rulemaking process. Congress rarely indicates the factors it has taken into account in making an update decision, but both MedPAC and HCFA develop recommendations on the basis of an update framework. MedPAC's framework specifically addresses technology costs through a scientific and technological advancement factor, which is intended to account for the impact of quality-enhancing but cost-increasing new technologies and is offset at least partially by a negative productivity adjustment, which captures the effects of cost-decreasing new technologies.

[1] The ICD-9-CM acronym stands for International Classification of Diseases, 9th Revision, for Clinical Management.

Provisions of the Benefits Improvement and Protection Act of 2000

BIPA mandated that HCFA develop a process to incorporate new medical services and technologies expeditiously into the clinical coding system for inpatient hospital services; collect data on the costs of new technologies for a period of 2 to 3 years and assign cases using the technologies into new or existing DRGs that have case weights derived from the new data; and provide for additional payment to cover the costs of each new technology during the study period. This payment could be in the form of new technology groups or it could be an add-on or adjustment to the normal DRG payment for cases where the technology is used.

The first two provisions serve to formalize, and perhaps expedite, procedures that HCFA already uses. The third provision, implementing what amounts to an interim payment for specific new technologies, represents a sharp departure from current policy. Like the outpatient technology pass through, the Secretary is expected to implement the provision on a budget-neutral basis. This means the effect of the additional payments for specific new technologies would be entirely distributional; the provision would not affect the need to account for the cost-increasing impact of new technology in annual payment updates.

The additional payments for new technologies are pass-throughs in the sense that HCFA must establish rates that cover the estimated cost of each technology. However, the inpatient pass-through provision differs from the outpatient one in that it is based the average cost of a technology rather than each hospital's costs. Thus, hospitals will benefit financially if they can negotiate a purchase price that is beneath the national average, and vice versa.

The reason for a technology pass-through for acute inpatient care is ensuring that inadequate payment for specific DRGs or cases within DRGs does not provide a significant disincentive for hospitals to adopt new services and technologies. However, two reasons make this advantage less compelling for inpatient care than for outpatient services. First is the broader construct of DRGs, such that a new drug, device, or service is likely to make up a much smaller portion of overall costs. The second reason is that, unlike in the outpatient PPS, neither patients' DRG classification nor the process for recalibrating the DRG weights is dependent on HCFA assigning codes to new services or procedures. New codes serve only to facilitate analyses that might lead HCFA to restructure DRGs.

Several other problems cited above for the outpatient technology pass through will also likely apply to an inpatient pass through. These include a lack of reliable data on which HCFA can base an appropriate interim payment adjustment for a technology before hospitals have much experience in providing it, the difficulty of predicting how frequently new technology will be used and thus the reduction in base payment rates needed to make pass-through funding budget-neutral, and the administrative complexity of the process for HCFA and hospitals alike.

Our recommendations envision taking the best aspects of the previous system and the provisions of BIPA to develop a system that accounts for the costs of new technology for inpatient hospital services. First, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for patient classification changes to recognize the costs of new and substantially improved technologies. Second, additional payments should be limited to new or substantially improved technologies that add significantly to the cost of care in a diagnosis related group and should made on a budget-neutral basis.

Although annual recalibration of inpatient payments has an established track record, the other two processes—code assignment and patient classification changes—are somewhat informal and perhaps not completed as quickly as they could be. For example, the ICD-9-CM Coordination and Maintenance Committee only meets twice per year to consider potential code changes. In addition, there are no established procedures for affected parties to request DRG restructuring, and no fixed process or timetable for HCFA staff to respond to such requests.

With these changes to formalize the system for assigning codes to new services and procedures and investigating the need for DRG changes, we believe that the inpatient payment system would have responded adequately to the costs of new technology. In contrast to the procedure-based system for outpatient payment—which makes it difficult to respond to the introduction of new technologies without using pass-through payments—the inpatient PPS makes it easier to ensure an appropriate distribution of payments while accommodating technological advances.

BIPA, however, requires that a payment adjustment be made. The "substantial impact" provision would provide a temporary boost in payments when the impact of a new technology on its early users is the most severe, while minimizing interference with clinical decisionmaking at the local level. Budget neutrality would limit the pass through to influencing the distribution of payments, leaving decisions regarding changes in the overall level of payments to the annual updating process.

Mr. GREENWOOD. Thank you, Dr. Ross, for your very thorough testimony.

The Chair recognizes himself for 5 minutes for questioning and would direct a question to Mr. Kang for starters. Mr. Kang, today is, I believe, March 1, and my understanding of the practices at HCFA are that if today HCFA decided to approve a particular technology or device for coverage, that pursuant to its procedures the reimbursement would not be available until 180 days following the next quarter. That would take us to July 1 plus 6 months so the end of the year. So you could decide today that PET imaging technology should be covered. It wouldn't be reimbursed for 9 months till the beginning of next year.

No. 1, in fact, have I accurately described your process? If no, please correct me. If so, please explain why such an arbitrary system is utilized.

Mr. KANG. Mr. Chairman, what you are actually asking me is when my office has already made the coverage decision, and then about assigning the coding and payment, and that is actually Dr. Miller's area so I will let him respond to that.

Mr. GREENWOOD. Very well.

Mr. MILLER. Is this one on?

Mr. GREENWOOD. Yes.

Mr. MILLER. There are a couple of things going on there that explain the 180 days. The first thing that comes into play here is that HCFA makes system changes, and these are legislative changes, coding changes, and any changes in policy that it makes, go into its computer system on a quarterly basis. These are large quarterly updates of any changes, that is how they get into the system, and there are sort of four major changes in the system.

Mr. GREENWOOD. Let me interrupt you there. I am not a computer expert. What I am trying to understand is if you made—what you are telling me is if you have made a coverage decision today on March 1, that would be entered in on July 1, and if made a coverage decision on June 30, that would also be entered on July 1?

Mr. MILLER. No. It is 180 days from when the decision is made and what is happening is that you have quarterly updates and you are trying to catch the next quarter update or the next quarterly update after that. We set the 180 days as a goal. Now, generally we make that. Sometimes we make it sooner. Sometimes it is a little bit after that.

But what is happening, so that you understand why it cannot happen instantaneously, is that a code needs to be created and a payment needs to be created. Then that needs to be communicated to the carrier so that they can do the programming. Then you need to educate the providers, "here is how you change your payment,"—I mean, "here is how you submit bills under the new form," and then the system goes into effect in the computer system so that people can bill for it. I also am not a computer expert.

The other thing I will say about this is when a national coverage decision is made, at the local carrier level, decisions can be made to say in the interim I will give you a temporary code and a payment during this period if the carrier medical director so chooses.

But the direct answer to your question is fundamentally there are four periods where we try and make all the system updates on an orderly basis, and that is why the 180 days.

Mr. GREENWOOD. Okay. But I am trying to understand why it is not done on a constant rolling basis as opposed to these quarterly demarcations?

Mr. MILLER. That is a fair question, and I think there are fundamentally two answers to that question. The first answer is that, as I said, it is not just there is one code, let us make this change. What is happening, for example, what is happening in the agency right now is the provisions that were passed as part of the Benefits Improvement and Protection Act, the BBRA, the BBA, those provisions are all being programmed and put into the system, so there is all kinds of changes that occur, and it is a fairly complex problem to define the policy, define the computer code. And so on a quarterly basis, that is how we try and do it to make sure that the systems don't just come down around us.

The second reason is I think if you made these changes on, let us say, a daily basis every time a new technology, a new code—and let us say we could move that fast—I think you also have to be conscious of the burden on providers. Every time we change a code, hospitals, physicians' offices, suppliers have to change their computer systems, have to change their billing practices, have to educate their coders and billers, and that, you know, we try and have some regimen to that so that we change the code and educate people in an orderly fashion.

Mr. GREENWOOD. Dr. Kang, you wanted to comment?

Mr. KANG. Mr. Chairman, just one other observation. Actually when I was up in Boston, I was the medical director of a couple of managed care organizations or insurance organizations, and this issue of periodic updates of the system's changes and the time it takes to do this is actually reasonably consistent with what happens in the rest of the insurance industry. It takes time to get all this done.

Mr. GREENWOOD. If I may, of course, it takes time, and no one is arguing that. What we are trying to find out if there is something that arbitrarily adds to the timeframe, and, for instance, just from the top of my head, if I were a hospital administrator, and I had to upgrade my computer, it would seem to me I would have—if, in fact, I was getting daily data from HCFA instead of quarterly data, I could make a decision. I could choose to do that on a quarterly basis. I could let it mount and then do it on a quarterly basis, or I could do it on a daily basis at my option rather than have only the one choice. But if you want to quickly respond, Dr. Miller, you may, but my time has expired.

Mr. MILLER. No, that is fine.

Mr. GREENWOOD. And with that, the Chair recognizes and turns the Chair over to Mr. Bilirakis.

Mr. BILIRAKIS. Thank you. And the Chair now recognizes Mr. Brown to inquire.

Mr. BROWN. Thank the chairman. Dr. Goodman, we have heard different people talk about making sure that HCFA has adequate resources to do its job. How does HCFA compare to other industri-

alized countries in terms of resources available for payment and coverage functions for making some of these decisions?

Mr. GOODMAN. Yes, let me think for a moment. I guess the answer is a bit surprising. If you look at United Kingdom, for instance, United Kingdom, on the coverage question, this coverage function, has a special agency just devoted to it. It is called the National Institute for Clinical Excellence, interestingly enough the NICE. They just upped their budget this year to the equivalent of about maybe $16 or $18 million. That is for the UK. It is a smaller country than ours, and I believe the Coverage and Analysis Group, which has the similar function at HCFA, may be $3 million. I will say $3 million. Is that about right? Or I would say at the outside maybe $4 million, but it is a few million dollars.

And then I am familiar with in the country of Sweden, Sweden has got 9 million people. They devote almost as much as Dr. Kang does to coverage questions and related technology assessment as HCFA. So much smaller country spends about what we do, what Medicare does.

And finally, if you look in the United States, the big payers, some of the big Blue Cross/Blue Shield plans, United Health, some of the other bigger payers, they spend $4 or $5 million or more on this function. So, again, as I said before, if you are responsible for 40 million beneficiaries and, you know, $270 billion a year, you might want to spend more than $3 million on the coverage function.

Mr. BROWN. So the question that my friend from New Mexico asked of the first panel, why does the private sector do it so much more quickly, implying that they always do—I don't think they do—but why they would do it more quickly than HCFA might be that the private sector spends more money in carrying out these functions; correct?

Mr. GOODMAN. Yes, sir. In part, it is because they have just as much or more money. It is also in part because when you are making a coverage decision in the private sector, you don't have to do everything in public and you don't have to have a committee of 120 people kind of trying to manage things with you. So they have that advantage.

The other thing is that sometimes private sector payers can cover something, say that we will pay for a certain procedure, but they have more utilization review at the time a procedure is offered for a given patient, and so it is at that later step that they might be able to deny coverage. Even if they cover it in general, they might not think that the patient's indications meet the situation for that person.

Mr. BROWN. I am just intrigued by your answer because I have been on this subcommittee for 8 years, and I have heard members of this, and we have had a significant number of hearings, particularly in the last 6 years, critical of HCFA, and we blame HCFA for all, not all, many of the problems that Medicare faces as some strive to privatize Medicare, and then we don't appropriate HCFA enough money to do its job when Congress is ultimately responsible, and I am just sort of intrigued by that.

Dr. Kang, Medicare decides what to cover. Insurance companies privately decide. Private insurers decide what to cover. When a new drug or device is approved by FDA, do either insurance compa-

nies or Medicare automatically approve them? I mean is that sort of an automatic kind of thing?

Mr. KANG. The answer is no. The quick answer is no.

Mr. BROWN. When would it not be? Give me some examples of when they would not automatically cover something. This morning in the earlier panel, obviously there is something that those are pretty useful medical devices and medical procedures, but when would they not?

Mr. KANG. There are several places. One very good example actually is when, in fact, it is not a benefit. So, for example, in the Medicare program, oral drugs are not a benefit. It has been approved by the FDA, but Medicare has no authority to cover that.

The second would be many times the FDA approval is based on what we call efficacy. The lab test, for example, tells you what the selenium level is. What we have to ask as an insurer is, "is that clinically useful information? Do we care? Does that help the beneficiary's health outcome?"

It may be nice to know the test measures the selenium level, and I am just making this up, you know, but the question really for us as an insurer is that useful information and does that improve the patient's care?

And then the third major area really is the FDA does not look at what is called comparative effectiveness; so they compare versus placebo. What we are very interested in is, "is the new technology better than what we are currently covering?" So there may be a new technology, but, let us say, for example, it is inferior to what we are currently covering, I would imagine as a prudent purchaser, I am not sure why we would want to cover that. So those would be three quick reasons. And there are many others.

Mr. MILLER. Could I also respond to that? The one other aspect of this that I just think we should focus on—I think what Jeff is referring to—is breakthrough technology. I believe that the overwhelming majority of technology when it is approved gets into the payment systems. They are prospective payment systems. It is a covered benefit. Payment is there for it. It moves right in. HCFA is not involved in the decisionmaking process at all.

The clinicians on the ground, in the hospital or whatever the provider settings are make the decision to use it or not. I think what we are talking about here is when this is something brand new, not covered, no code, or something like that.

Mr. BILIRAKIS. What happened to the gentleman from North Carolina, the vice chairman of the committee? Well, he is not here. Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. Dr. Goodman, as you may know, Congress twice has urged HCFA to consider outside data in making DRG reclassifications, first in the BBA 1997 report language, second in the fiscal year 1999 Senate Labor HHS Approps Report.

My question is can you relate your understanding of HCFA's use of non-MedPAR data in the adoption and adequate payment of new drugs and technologies in the hospital inpatient system?

Mr. GOODMAN. That was for me? Yes. I am not the world's expert on MedPAR, but what I do know is this: for many new technologies the evidence is somewhat limited and it is often difficult to conduct

strong clinical trials to get data, and I think that it is probably a mistake to be very narrow in the sorts of data selected to help support a DRG decision. I think we need to look outside to experience among other payers elsewhere in the country, similar populations, in order to pull together as much data as we can on some of these new technologies so that we will have a strong enough evidence base upon which to base a DRG update decision. Being too narrowly focused on any particular data base may be shortsighted.

Mr. PITTS. Anyone else like to add to that? Dr. Kang, do you agree?

Mr. KANG. I think this would actually be more Dr. Miller's area.

Mr. MILLER. I don't have a lot to add to it. My understanding is that since the Congress has encouraged us to consider outside data, we have not had many instances where people have asked us to consider it, and the kinds of things beyond using additional data are, you know, sample sizes to assure that it actually represents something that is happening in the population, and whether the population it is being drawn from is representative of the population that would actually end up using the service. But I don't necessarily have anything to add to his comment.

Mr. PITTS. All right. In its proposed fiscal year 2000 Inpatient PPS Rule, HCFA outlined criteria for the submission and use of third-party data to allow for quicker access of new technologies for Medicare patients. To your knowledge, is this criteria reasonable, especially for smaller companies?

And second, have you had any knowledge that third-party data has been successfully submitted to HCFA, then actually used by the agency to recalibrate the DRG payments?

Mr. MILLER. I think I would like to answer your question for the record because I don't think I have the specific answer to whether, how data has been collected and used in that instance. I believe we have only received a couple of submissions from outside data. And they have generally—I believe they have not been used to make the decision, and that is either because the sample size wasn't large enough or some characteristic of the data. But I would rather answer your question for the record because I think I don't necessarily have this in detail in front of me.

[The following was received for the record:]

I believe the criteria for the submission and use of third-party data are reasonable for small and all other sizes of companies. As indicated in the FY 2000 Inpatient PPS rule, we remain open to considering third-party data in the diagnosis-related group (DRG) reclassification and recalibration process as long as the data are reliable and validated.

We also established and published a timetable for submitting data. We request at least a representative sample of data by the August, and a complete database by the December prior to the publication of the proposed Inpatient PPS rule in the spring. The Medicare Payment Advisory Commission agreed that this timetable is "a valid basis for assessing the feasibility and appropriateness of using outside data." Additionally, we are open to receiving data in various formats, as long as we are able to verify and validate the data, consistent with the language of the Conference Report that accompanied the Balanced Budget Act of 1997.

This past summer, we met with individuals representing four different new drugs or technologies, and discussed issues pertaining to inpatient payment, including the submission of outside data. We received data from one of the four representatives this past December. Although we reviewed the data, they were not submitted in time for us to verify the Medicare discharges prior to the upcoming publication of the FY 2002 proposed Inpatient PPS rule.

We remain open to working with representatives of the medical device and pharmaceutical manufacturing community to receive and analyze third-party data. We are committed to expediting the introduction of new technology, while continuing to uphold our obligation to pay appropriately for all DRGs.

Mr. PITTS. Dr. Goodman.

Mr. GOODMAN. Yes. Adding to what Dr. Miller said, one of the aspects of medical devices in some populations is that a device that can be very, very effective may only be useful in small numbers of people, small populations, and it makes it that much more difficult to gain, as Dr. Miller said, a big enough sample size upon which to draw conclusive findings, but my point is this: that the sorts of criteria used to evaluate technologies and to make these kinds of decisions or updates need to be adapted to the technology at hand and the population at hand.

It is not enough to say, well, the population is so small, we can't get good data. We need a better answer than that, which is we need to adapt and be flexible with these criteria to get the best data we can and make the most informed decision that we can.

Mr. PITTS. All right. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. The vice chairman of the full committee, Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. Let me just direct this to HCFA and Dr. Goodman and Dr. Ross. I will give you a scenario and just tell me whether this is possible to happen under the current system of approval.

This is from a doctor at New Hanover Hospital, a cardiovascular surgeon. He said there is new vascular stent technology. He used it in radiology and trauma cases. The first 38 cases, he lost $14,000 per case because of inadequate reimbursements. The only factor that changed was the device he used. Medicare reimburses the vascular stent with the regular stent payment. Trauma cases left the hospital with this new stent within 24 hours with the vascular stent. Without the vascular stent, they spent 3 to 5 days. He has since stopped using the stent because he can't afford what he is losing in the procedure.

Dr. Kang, can that be an accurate statement of a new technology?

Mr. MILLER. I think I will take this one.

Mr. BURR. Dr. Miller.

Mr. MILLER. Payment.

Mr. BURR. Sorry you missed Monday.

Mr. MILLER. Yes, I heard you were there. I was getting ready for this.

To answer your question, and I was listening also when you were asking your other questions because I think this kind of cuts into the cost issue, prospective payment systems are designed to put a dollar amount out, let the clinicians decide how to mix the services that they provide to help the patient, whether it is technology, numbers of days in the hospital, nursing, whatever the case may be.

That issue that you have raised and the issue that Dr. Popma was talking about is the issue that when something is new and introduced, the actual DRG, you can get reimbursed for it, but the

incremental difference may not fully cover the cost of the new device, in this instance, the stent.

The other part of your point I think is relevant here because what is also happening in that case, if I followed your point, is that a length of stay was being reduced as a result of that. In the DRG system, both of those behaviors should be reflected, the bump up for the technology and the collapsing in the length of stay. And as we collect cost data, that is precisely what happens to the calibration of the DRG. It does get adjusted. It does take time and that is your point.

Mr. BURR. Yes, how much data are you going to be able to collect given that he did 38 and stopped? I mean there is a point where in his surroundings, a decision was made I can't lose money anymore. Now, to the next developer of the next generation of stents that may make the procedure easier, faster, more effective, what incentive have we given the person who is going to lay on the line the capital that it takes to develop that that it is worthwhile, that there is some point where they will be rewarded for their investment?

Mr. MILLER. And your point is taken. The philosophy behind the prospective payment systems are that those decisions are not only case specific, but what we are doing is paying for all admissions on an average basis. On some, they get money. On some they lose money, and the ideal situation is they make those economic decisions across a series of admissions. But that is not—your point is still taken. There is a specific case and on a specific case basis, it may be that the DRG has not caught up.

If I could just make one other point on this, there is—the system contemplates situations where, when the cost exceeds by a large margin the amount that the DRG pays, it does fall and begins to get outlier payments where additional payments can be made. But I fully acknowledge that there is a threshold there and sometimes cases don't make it up to it.

Mr. KANG. Mr. Burr, if I may, just because maybe I am not sure I am understanding the example, but if we are paying a hospital a DRG, and this device actually saves 2 or 3 days on the admission, in fact, the saved cost on the hospital side more than usually offsets the actual technology or device. And that is actually what the——

Mr. BURR. That is certainly the assumption that HCFA works under. I am not certain that that is the reality of the real world. But I think that is what we are here to uncover, and before Dr. Goodman and Dr. Ross have an opportunity to respond to this, in the culture of this model that we have got that we go through to determine reimbursements, you make numerous references that if it is like a previous product, we just put it into that category. We put it into that code. Forget the fact that it may be substantially different in the cost of that particular product for its usage.

So the system that we have does not evaluate it necessarily based upon the technology that has gone into it. I question whether it evaluates it based upon the long-term savings per incident, as well, but we tend to hide under the DRG. That it is for a broad sense and if you go outside on this side or if you stay under it on this side, you make a little bit here, you lose a little bit over here.

As we head into the age of where technology is going to play in devices and pharmaceuticals, when you go outside of the umbrella, you are losing a lot.

The net result is that people stop using it, that the quality of care goes down, but more importantly, and this is the point I want to make, the cost to us for health care continues to go up. We don't reap the benefits of any of the technological breakthroughs. We can't reverse this and ultimately find——

Mr. BILIRAKIS. The gentleman's time has long expired.

Mr. BURR. Can I allow Dr. Goodman to——

Mr. BILIRAKIS. Only if you have a very few words' in response to that.

Mr. ROSS. Yes, I would like to respond actually very quickly, if I could.

Mr. BILIRAKIS. Quickly.

Mr. ROSS. Not to the larger question of technology in the future. The first is it is hard to respond to any specific instance or any specific DRG, but if we want to be assured that we always pay for everything, we had a system that did that. It was called cost-based reimbursement. It had unsustainable spending growth and we very deliberately chose to move to prospective payment, and that gets us to a fundamental tradeoff between trying to accommodate quality-enhancing, cost-increasing new technology while at the same time making sure that they are fiscally prudent.

We typically as a commission recommend putting funds into the base with each coming year to try and adapt for technologies we see coming down the pike. I would also add that Medicare as a program makes a number of payments over and above what it costs for basic patient, the so-called indirect medical education adjustment for inpatient care, pumps a fair amount of money to recognize the higher cost in teaching hospitals where a lot of the investigational work is done and where a lot of the new technology is being adopted and diffused.

It is not showing up at the basic DRG rate, but it is definitely showing up in their payments for discharges.

Mr. BILIRAKIS. Mr. Whitfield to inquire.

Mr. WHITFIELD. Mr. Chairman, thank you. In the question and answer series with Mr. Brown, there was some discussion that in Great Britain and in Sweden, the amount of money available for coverage determination is much larger than in the U.S. per person, but it is my understanding, and you all correct me if I am wrong, that HCFA like Blue Cross/Blue Shield and a lot of other private companies used the same, in fact, used the Technology Evaluation Center under contract to make the coverage determination. Is that correct or is that not correct?

Mr. GOODMAN. Yes, sir. HCFA as well as payers in other countries do look to outside sources and organizations for support and technology assessment. But even if you add all that up, I believe we would find that the resources available to HCFA to do the work internally as well as externally would fall short of those other countries.

Mr. WHITFIELD. Okay. Because I was sort of under the impression that you all were making the argument that the coverage determination was being delayed because of lack of funds, but I guess

what really is happening is making the coverage effective is what is being delayed.

Mr. GOODMAN. Well, yes, sir, I believe, as Ms. Eshoo said before earlier today, the first thing to do is get the thing streamlined, get the coding situation straightened out, get the relationship with the MCAC straight with the reporting relationship and so forth. If you don't do that, additional funds aren't going to help at all.

However, and this concerns me, the new technology pipeline is as busy and as full as it has ever been in history and it is going to get more so. Whether it is HCFA, for that matter, or the FDA, we need the expertise and resources to accommodate the new technology pipeline. Without those resources and expertise, we just will not be able to process these technologies fast enough, and just in answering Mr. Brown's question, it is interesting that other countries who are industrialized spend more than we do. It is just an interesting point of resource allocation.

Mr. WHITFIELD. But the private companies in the U.S. would just have more resources and expertise than what is available at HCFA?

Mr. GOODMAN. Interesting point. The outside organizations can provide analyses in support of a coverage decision. It is still the payer's responsibility, whether it is HCFA or another payer, to look at that information and say how does that apply to my Medicare beneficiary population? You still have to make the policy, interpret the data, and make the policy, even when you get good support from outside sources.

Mr. WHITFIELD. Because I was given an example that in the transplantation procedure relating to liver, that the year that it was approved by Blue Cross/Blue Shield Technology Evaluation Center was 1986. It was approved by Blue Cross/Blue Shield the same as the coverage determination was made by the Technology Center, and yet it was first covered by Medicare in 1992, 6 years later. And that would be because of?

Mr. GOODMAN. Well, I am sure the information was available to all parties. There may be multiple reasons why HCFA took longer. One may have been that HCFA had to understand how the available information about liver transplantation applied not just to anybody, but to elderly people, and it may not have been as good a match, and perhaps HCFA may have been wanting to wait for data to support that, because there is a downside to providing technologies for people in whom they have not been adequately tested to date. I would hope not in this situation, and it wasn't borne out that way, but that is a caution that a prudent purchaser of health care has to consider.

Mr. WHITFIELD. Right. Now, it is my understanding that someone testified that Part A had 36 contractors nationwide and Part B 42?

Mr. GOODMAN. Yes, sir.

Mr. WHITFIELD. And if HCFA makes a national determination for coverage, then every contractor is subject to that decision. They must honor that decision?

Mr. GOODMAN. Yes, sir.

Mr. WHITFIELD. Okay. And then there is a statement in here that says that in the absence of a national coverage determination,

local medical directors, I guess of the contractors, have the discretion to make local coverage or not; is that correct?

Mr. GOODMAN. Yes, sir.

Mr. WHITFIELD. So if you have not made a national coverage determination, any local contractor can approve it on their own?

Mr. GOODMAN. That often happens, and there is an advantage to that for technology diffusion.

Mr. WHITFIELD. Okay.

Mr. BILIRAKIS. The gentleman's time has expired. Very quickly, Ed, go ahead.

Mr. WHITFIELD. One other question. I mean that creates a lot of disparity around the country, though; right?

Mr. GOODMAN. It does, but, sir, it may be helpful because in the absence of a national coverage decision, technology can be used in certain regions of the country by choice of those medical directors, which is well-founded, and we accumulate data and evidence that may be used subsequently to put in place a national coverage decision. That is an important avenue for technology evaluation and diffusion.

Mr. WHITFIELD. Thank you.

Mr. BILIRAKIS. Thank you. The Chair now will inquire and yield 30 seconds of his time to Mr. Burr.

Mr. BURR. I thank the chairman for that generous opportunity. Dr. Kang, I just wanted to clarify one thing that you said in your opening statement that I couldn't find in your written testimony. You were referring to assessing new technologies and you went on to say that you had to make sure that they weren't unproven, ineffective or harmful. Did I understand that correctly?

Mr. KANG. That is correct.

Mr. BURR. Is that not the process that the FDA goes through when they approve a device or pharmaceutical for their approval process?

Mr. KANG. In some situations, yes. In some situations, no.

Mr. BURR. There are some situations where the FDA does not approve the safety and efficacy of a device or pharmaceutical?

Mr. KANG. That is correct.

Mr. BURR. Can you give an example of that?

Mr. KANG. Frequently in the 510(k) process for devices, what they are really looking at is whether it is similar to a predicate device or not. That would be the first example. The other example is——

Mr. BURR. And under a 510(k), you feel that they have not given a stamp of approval to safety and efficacy?

Mr. KANG. Actually, though under the B, IDE devices, we are okay with those, and we end up covering those. It would be the A's.

Mr. MILLER. Category A.

Mr. KANG. It is Category A's.

Mr. MILLER. Which are the more novel technologies.

Mr. KANG. Which are the more novel ones. The other place is many times the FDA approval is for specific indication. What they are asking for is what in the parlance would be called an off-label indication, and they have not then looked at that issue.

Mr. BURR. I thank the chairman.

Mr. BILIRAKIS. Well, I appreciate the gentleman raising that point. I have always felt that is the particular function of FDA, and once it reaches your point, the efficacy and the safety has already been decided. With the exception, I suppose, of applying those particular devices or drugs to seniors, I can see where there might be a little bit of a difference there.

You know, we visited Baltimore the other day, and Dr. Miller and others were very kind and helpful. We emphasized then, and we try to emphasize today, that we are not trying to demonize HCFA. We are trying to help, and I can't imagine that Dr. Miller or any of the good civil servants at HCFA who have been there for years and have been faced with problems of turnover at the top, I can't imagine that they are happy with taking 3½ years longer than Blue Cross/Blue Shield for new transplant procedures, 5 years or more in some instances.

So we have to talk here. I have heard all kinds of reasons why these problems exist and why the delays take place. But let us see if we can reduce the delays. Let us see if we can improve the process. That is the idea. It is not to demonize. It is trying to improve the process. And what we asked of you all the other day up there is to help us help you, so that we can help the people that really count, the patients.

And Mr. Brown has made a lot out of the funding. I don't know that I can recall many, if any, instances over the years that HCFA has come here and testified and said, we need more money, and if you assure us that we will receive more money, we are going to do a better job, speed up the process, and speed up the coding.

So, let's get back to the point that Dr. Shreve was making in the first panel, the women's health uses, the use of the PET scan. In some cases the PET scan is covered, the reimbursement is covered for some diseases and for women, and some diseases it is not, in spite of the fact that there is coverage for those using the PET scan for those diseases by private plans. What is the reason for something like that? Can you tell us? I can't imagine.

One of you all made the comment earlier—certainly you are right—HCFA is kind of looked upon as the leader by the private sector in terms of coverage. Ordinarily that is the way it takes place, and yet here we have cases where private plans cover and HCFA does not. Explanation?

Mr. KANG. I actually think that——

Mr. BILIRAKIS. I say explanation and I hope we are not talking about rationale.

Mr. KANG. I think that we appreciate being here because there does need to be improvements and I would like to point to the improvements that we have made in the last 2 years that you heard in my testimony that were very welcomed.

Some of the other things that we are working on, and in part precipitated by the PET issue, for example, we have published recently a guidance document on criteria and standards for diagnostic imaging and that I think is something that was definitely needed. That will help in the future for future innovators to really understand what sort of information we are looking for for diagnostic imaging.

The other thing that we are doing with NCI and the FDA is a special bio-imaging panel which really is trying to look at frontloading all of the questions that we are asking for at the initial design of trials. So, for example, let us see——

Mr. BILIRAKIS. So they could be taken care during that process before they——

Mr. KANG. That is right.

Mr. BILIRAKIS. Okay.

Mr. KANG. Instead of answering the NIH question first, then the FDA question, then the HCFA coverage or other insurers'—quite frankly, this is the same as other insurers—question third, we actually say can we design a trial that answers those questions for all three parties? And we are doing this with the industry. It is the National Electronic Manufacturers Association, FDA, NCI and HCFA. And it has been very welcomed. And these are the kinds of processes that I heard referred to this morning that we need to work on.

Mr. BILIRAKIS. You know much of the problems that we have here legislating, besides a lack of bipartisanship and things of that nature, is these turf fights over jurisdiction. Do you run into that also, vis-a-vis FDA, for instance?

Mr. KANG. I don't want to—it is human nature.

Mr. BILIRAKIS. You are under oath, I guess.

Mr. KANG. I mean I think I don't want to point fingers, but this is human nature.

Mr. BILIRAKIS. Yes, it is.

Mr. KANG. But I think that over the last 2 years, we have made significant inroads, all three of our agencies, and in large part because we really want to serve the beneficiaries and improve their care and make sure the technology diffuses. So there have been significant inroads.

Mr. BILIRAKIS. Okay. Well, one of the things that we are going to certainly concentrate on is trying to improve the coordination and the relationship. I appreciate your having told me what you just did, because I feel that in the process, the FDA process, much of the testing, the analysis that you all do, has got to be pretty duplicative, and can be done during that particular FDA process.

My time has really expired. Dr. Goodman, you look like you want to say something, but please keep it brief.

Mr. GOODMAN. I would prefer to emphasize the building blocks that we have in place rather than the divisive ones. The FDA-HCFA Interagency Agreement of 1995 is a great example of the alignment we need. The current relationship between the National Heart, Lung and Blood Institute and HCFA on funding a clinical trial of a highly advanced left ventricular cyst device—it is called the rematch trial—is a great example of interagency collaboration that will speed up getting information about technology that will make a more definitive coverage decision. We can build on things that we know already work.

Mr. BILIRAKIS. All right. Well, let us hope so. The hearing is now over. I do want to ask you if you would be willing to respond to written questions? You know we usually have some after the hearing concerned is over. We are trying to work together, and you

have given us a lot of ideas. There are plenty more I am sure you can give us.

To our HCFA witnesses, we have constantly over the years asked your agency for help, help us to help you to make your job easier. Some things you can do to improve the process, you have the authority to do it. Some things you don't have the authority and you need some legislation. We have asked for those ideas, and frankly we have not been receiving them.

Thank you very much. Thank you, Mr. Brown.

[Whereupon, at 1:20 p.m., the subcommittees were adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

AdvaMed is the largest medical technology trade association in the world, representing more than 800 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $68 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $159 billion purchased annually around the world.

AdvaMed strongly believes that Medicare should be encouraged to capitalize on advanced technologies, which have revolutionized the U.S. economy and driven productivity to new heights and new possibilities in many other sectors. Significant advances in health care technologies—from health information systems that monitor patient treatment data to innovative diagnostics tests that detect diseases early and lifesaving implantable devices—improve the productivity level of the health care delivery system itself and vastly improve the quality of the health care delivered. New technologies can reduce medical errors, make the system more efficient and effective by catching diseases earlier—when they are easier and less expensive to treat, allowing procedures to be done in less expensive settings, and reducing hospital lengths of stays and rehabilitation times.

AdvaMed applauds Congress for the steps it took in the Balanced Budget Refinement Act of 1999 (BBRA) and the Benefits Improvement and Protection Act (BIPA) of 2000 to begin to make the Medicare coverage, coding and payment systems more effective and efficient. In addition, the Health Care Financing Administration (HCFA) has recently made some changes to modernize its coverage and payment systems.

Despite these efforts, however, current policies still fail to keep up with the pace of new medical technology. Serious delays continue to plague the amount of time it takes Medicare to make new medical technologies and procedures available to beneficiaries in all treatment settings.

As Cliff Goodman from the Lewin Group will explain today, Medicare delays can total from 15 months to five years or more because of the program's complex, bureaucratic procedures for adopting new technologies. Keep in mind that all this is after the two to six years it takes to develop a product and the year or more it takes to go through the Food and Drug Administration (FDA) review. In addition, these delays are even more pronounced when you consider that the average life span of a new technology can be 18 months.

The impact on patients has been dramatic. As witnesses today will explain, cancer patients have had to fight for years to get Medicare to cover positron emission tomography, a potentially lifesaving scanning technology that has been broadly available to people under private health insurance for a decade. Tens of thousands of seniors and people with disabilities have not been able to receive advanced technologies like coronary stents (which reopen blocked arteries), cochlear implants (which restore hearing) and heart assist devices (which keep patients alive while waiting for a heat transplant).

These delays stem from the fact that for a new technology to become fully available to Medicare patients, it must go through three separate review processes to obtain coverage, receive a billing code and have a payment level set. Serious delays in all three of these areas create significant barriers to patient access.

While HCFA has improved the transparency for making national coverage decisions and attempted to instill timeframes within the process, timeliness is still a major problem. Under the current national coverage process framework, HCFA has 90 days to determine whether it will make a coverage decision or refer the request to either the Medicare Coverage Advisory Committee (MCAC) or an outside health technology assessment (HTA) group—or sometimes even to both. These outside as-

sessments take between 3 and 12 months each. HCFA then has 60 days to review the recommendations of the MCAC or HTA, and should a positive coverage determination be made, it takes 180 days from the first day of the next calendar quarter to issue a code and set a payment level.

The coverage process should be streamlined and made more accountable, timely and transparent. Steps should be taken to reduce redundancies in the MCAC panel and HTA reviews. In addition, the focus of the MCAC panels should be directed toward gaining practical clinical advice from the medical experts on its panels.

After coverage is approved, there are three separate coding processes that determine how a device or procedure is identified and to which payment bundle it is assigned. Each of these coding systems have significant time-lags in assigning and updating codes. Under the new hospital outpatient perspective payment system (PPS), HCFA now assigns and updates codes on a quarterly basis. To reduce coding delays of 15-27 months, HCFA should use the outpatient PPS system as a model for applying similar systems to other settings, such as the inpatient hospital setting and doctors' offices.

Coverage and codes mean very little, however, if the associated payment level is inadequate. HCFA's procedures for updating relative payment weights and reassigning technologies and procedures are informal and infrequent. For example, it took HCFA 5 years to ultimately decide that the applicable diagnosis related group (DRG) should be split into two DRGs for angioplasty with and without stent. During those 5 years, hospitals took significant losses on each stent procedure and the diffusion of this cost-saving technology was hampered.

As required by BIPA, HCFA should develop formalized procedures for expeditiously assigning codes, updating relative weights and reassigning technologies to recognize the value of new and substantially improved technologies. HCFA should also fully implement the BIPA requirement to provide a transitional payment mechanism for new technologies where the DRG payment is inadequate.

Again, AdvaMed applauds Congress for recognizing the value of technology in improving the quality and efficiency of the health care system, and taking steps to reduce the barriers patients face to accessing these innovations. Recent reforms continue to improve the system and AdvaMed encourages additional changes to make coverage, coding and payment decisions more predictable, transparent and timely.

PREPARED STATEMENT OF THE CENTER FOR PATIENT ADVOCACY

The Center for Patient Advocacy is pleased to submit written testimony to the House Energy and Commerce Subcommittee on Health and the Subcommittee on Oversight and Investigations as you seek to improve seniors' access to quality health care in this country. We commend the subcommittees for conducting this hearing and for demonstrating an early commitment in the 107th Congress to ensure that our nation's seniors continue to have access to top quality health care.

Founded in 1995, the Center for Patient Advocacy is a private, non-profit, grassroots organization representing the interests of patients nationwide and dedicated to ensuring that patients have timely access to state of the art, quality health care. With a grassroots coalition of thousands of "citizen lobbyists" across the nation, the Center has brought the patient's perspective to a number of critical issues that Congress has considered in recent years, including managed care reform, biomaterials reform, and FDA modernization. In all of our endeavors, our goal has been and continues to be to ensure that health care policymakers recognize and address patients' needs and concerns.

Too often, economic, administrative, or other concerns dominate health care policy discussions, and patients, many times, become an afterthought. We must constantly remind ourselves that all health care begins and ends at a single point—the patient. To a sick patient and his family, access to life-saving and life-enhancing therapies is all that matters. The title of your investigation—"Patients First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage"—demonstrates that you understand the real challenge of health care reform—insuring patient access to high-quality care. By keeping the focus on patients, this committee has great potential to achieve their goals. You are off to a great start by considering ways in which the Federal Government can improve access to new treatments and technologies for Medicare beneficiaries.

Since its enactment as part of the Social Security Amendments of 1965, the Federal Government has provided health care coverage for senior citizens and the disabled through the Medicare program. The program is administered by the Health Care Financing Administration (HCFA), which is also responsible for administering the federal portion of Medicaid and the State Children's Health Insurance Program

(SCHIP). Currently, Medicare serves approximately 40 million beneficiaries at a cost to the taxpayer of about $300 billion each year.

In spite of the best efforts of Congress and HCFA, it has become increasingly clear to patients and patient advocates that the Medicare system and the HCFA infrastructure on which it relies for administration have lost step with the dramatic pace of medical discovery and treatment options now available to patients. Though many of HCFA's current guidelines represent good faith efforts by the agency to meet the needs of Medicare patients, to follow the law, and to reflect accurately congressional intent, the unfortunate end result for many Medicare patients is the denial of needed care.

A telling example of Medicare's problems with which many of the committee members are already familiar relates to the establishment of the prospective payment system (PPS) for Medicare outpatient care. One way that Congress has sought to keep down Medicare costs is by reimbursing providers a predetermined amount for all patients having a particular diagnosis or treatment regimen rather than reimbursing providers according to their costs. While the PPS appears to be a reasonable approach to controlling costs and has succeeded to some degree in the inpatient setting, the outpatient PPS has failed to meet its first responsibility—providing Medicare patients with timely access to top quality care.

The bureaucratic outpatient PPS processes established by HCFA as a result of the Balanced Budget Act of 1997 exemplify the way HCFA's policies and procedures have delayed access to treatment and hurt patients. Under the original PPS rule, after an outpatient therapy was approved by the FDA, HCFA would then determine if it would be included in the Medicare coverage portfolio. Sometimes this process was conducted quickly at the local level, resulting in unequal coverage across the country (some jurisdictions providing coverage while others did not). Alternatively, sometimes a national determination was required, and these coverage decisions could take as long as 3 years. Next, the therapy would be assigned a procedure code for providers to use in billing Medicare. This would often take another year or more. Finally, HCFA would determine how much it would pay for the procedure by placing into an ambulatory payment classification (APC), a system by which similar procedures with similar costs are categorized. A single price is set for each category, rather than for each specific procedure. All told, however, the lag time between the FDA approving a therapy and Medicare providing access to it was sometimes as long as 3-5 years. Unfortunately, Medicare patients do not have 3-5 years to wait for an effective treatment.

Recognizing the difficulties and delays caused by the outpatient PPS, Congress went back to the drawing board and created a transitional, cost-based, "pass-through" payment system for newer therapies. Under the pass-through system, newer therapies (mostly those approved after 1996) are reimbursed at 95% of the average wholesale price (AWP). This system was put in place to guarantee Medicare patients access to new therapies while HCFA completed the coding and payment processes. Full pass-through payments were initially to continue through 2001. HCFA, however, moved late last year to reduce pass-though payments by 50%, again threatening Medicare patients' access to care. Such a reduction would render it financially infeasible for providers to continue to provide new therapies to their patients, as the costs of providing treatment would far exceed reimbursement levels. Thankfully, with the help of Congress and the pressure of thousands of citizen lobbyists from around the country, HCFA finally agreed to maintain pass-through payments through 2001, allowing both Congress and the Bush Administration time to reconsider the problem in hopes of developing a more workable payment methodology for emerging therapies.

Medicare patients with cancer have been particularly vulnerable to flaws in the outpatient PPS, as many cancer therapies are now frequently provided in outpatient facilities rather than in hospitals. Now that new and more effective cancer therapies are receiving quicker approvals from the FDA (thanks to the previous work of the Commerce Committee and the Congress), we must make every effort to streamline the processes by which these therapies are made available to Medicare patients with cancer. Furthermore, we must insure that once a therapy is added to the Medicare coverage portfolio, reimbursement levels are sufficient to allow providers to use it and, therefore, allow patients to access it. Recognizing that cancer patients are often have the most difficulty accessing the treatments they need, in 1999 the Center for Patient Advocacy launched a new division of the Center, the Access to Cancer Care Alliance (ACCA), which is actively addressing access and quality care issues for cancer patients.

Finally, it is vital that Congress and HCFA approach this new reform effort with an eye to simplifying the Medicare system. Doctors now must contend with over 130,000 pages of Medicare and Medicaid regulations. That is about 6 times the size

of the confusing and unwieldy Internal Revenue Code that Congress is now trying to simplify. Not only does compliance with these regulations cost physicians valuable time and money, but it also costs Medicare patients access to care as doctors choose no longer to participate in the Medicare system. And when physicians or their staffs make honest mistakes in complying with Medicare coding or claims, they are suddenly treated as criminals. It's time for Congress and HCFA to remove these dangerous disincentives to providing care to Medicare patients.

Thank you again for the opportunity to provide testimony today. The Center for Patient Advocacy looks forward to continuing to work with Members of Congress, the administration, and the members of the healthcare community to ensure that our nations Medicare program is responsive to the patients it serves, and that it provides patients with timely, state-of-the art care that they need and deserve. Advancements such as the mapping of the human genome promise to accelerate scientific research even further, and it is imperative that Congress act now to insure Medicare patients full access to state-of-the-art care.

PREPARED STATEMENT OF BRUCE STEINWALD, MEMBER, COMMITTEE ON MEDICARE PAYMENT METHODOLOGY FOR CLINICAL LABORATORY SERVICES, INSTITUTE OF MEDICINE/NATIONAL ACADEMY OF SCIENCES AND INDEPENDENT CONSULTANT IN HEALTH ECONOMICS

Good morning, Chairman Greenwood, Chairman Bilirakis and members of the Subcommittees. My name is Bruce Steinwald and I am an independent consultant in health economics in Washington, DC. I served as a member of the Institute of Medicine (IOM) Committee on Medicare Payment Methodology for Clinical Laboratory Services. The IOM is an arm of the National Academy of Sciences, chartered by Congress in 1863 to advise the government on matters of science and technology.

Background:

Recognizing that Medicare's payment system for clinical laboratory services may have to be modernized, Congress mandated in the Balanced Budget Act of 1997 that the Secretary of the Department of Health and Human Services arrange for the IOM to review the current Medicare payment methodology for outpatient clinical laboratory services and make recommendations to improve the system. The Department's Health Care Financing Administration (HCFA) contracted with the Institute of Medicine in 1999 to conduct the study. To meet this charge, the IOM put together a 12-member panel of experts composed of laboratorians, physicians, economists, and health care policy and management experts. We met five times between January and August 2000 to gather information, deliberate over findings, and formulate recommendations. As a result of the study, the IOM released our report, *Medicare Laboratory Payment Policy: Now and in the Future,* in December 2000.

The focus of the IOM study was different from the current hearing. We examined a wide range of issues related to the Medicare payment methodology in addition to new technology, but our focus was limited to the Medicare Part B fee schedule for outpatient clinical laboratory services only and did not include other types of services or providers. When examining any health services payment methodology, however, one must consider how it incorporates new technology, since that is a crucial factor that affects the adaptability of the payment methodology for the future. In this statement I will briefly put Medicare clinical laboratory payments in context and summarize the key findings and recommendations of the Committee's report, particularly as they relate to new technology. In addition, I will include a copy of the full report and a short summary of it.

Background:

Clinical laboratory tests are a key component of modern health care. Laboratory tests represent a small share of total health care spending, but play a complementary and an integral role in good medical care by helping physicians to diagnose and treat patients. Technological changes in laboratory testing, both those in the pipeline and those anticipated in the near future, offer the prospect of new opportunities for diagnostic, monitoring, and screening improvements.

Medicare is the largest payer of clinical laboratory services. It pays 29 percent of the nation's laboratory bill of $30 to $35 billion for inpatient and outpatient laboratory services. The Medicare Part B fee schedule for outpatient clinical laboratory services, the subject of our study, accounts for approximately one-third of what Medicare spent for laboratory services, or 1.6 percent of its total annual budget, in 1998. While this is a small proportion of overall Medicare spending, maintaining beneficiary access to laboratory services is essential. In addition, there is evidence

that Medicare payment policy influences other payers' policies for laboratory services.

The incentive for manufacturers to develop new laboratory technologies and the ability of Medicare beneficiaries to have access to them are affected by Medicare's payment policy. Medicare's current system of payment for laboratory services in outpatient settings was designed in the early 1980s. Although specific payment rates have changed over the past 20 years, the basic payment methodology has not. The introduction of new technologies and changes in regulations and the laboratory marketplace have had a significant impact on the structure of the laboratory industry during the past 20 years. Even in the face of these changes, the committee did not find a lack of interest in or adoption of innovation, up to this point in time. It did conclude, however, that current Medicare payment policy for outpatient clinical laboratory services seems not only outdated, but also irrational. Unless it is changed, the committee was concerned that the current payment system could eventually inhibit innovation and reduce beneficiary access to care. Inadequate payment rates could slow the industry's ability to develop and disseminate new technology and laboratories' willingness to adopt valuable but more expensive technologies.

Technology Trends:

The laboratory environment has been characterized by ongoing rapid and dramatic innovation since the 1980s. There has been remarkable growth in the range and complexity of available tests and services, which is expected to continue. Laboratory technology is often at the forefront of medical advances. In some cases, testing techniques to diagnose or screen for a particular condition are available before effective treatment. Innovation in laboratory technology, which includes both new tests and advances in equipment and testing techniques, has made testing more efficient and automated. Information technology has revolutionized the transfer of data by decreasing the time it takes to order and receive test results and by creating opportunities for research on large datasets. New technology is positively associated with increased efficiency, reduction in errors, and improved quality in the delivery of health care services.

While efforts to automate central laboratories are likely to continue, trends appear to indicate that much routine testing in the future could be delivered through point-of-care testing at the patient's bedside and home-based testing. Centralized laboratories are likely to concentrate more on rare and complex tests. The mapping of the human genome and other scientific advances lead laboratory experts to expect major advances in clinical tests and methodologies in the near future, particularly in the areas of genetic testing, surface markers to identify specific types of cancers, pharmacogenomics to individualize drug treatments, and molecular-level tests. Whether new technologies are implemented may depend on their impact on laboratory costs and, if they are more costly, on payers' willingness to pay for them.

Current Medicare payment system:

Medicare currently pays for outpatient clinical laboratory tests using a prospective payment system established in 1984. Payments for 1,100 tests are set separately in fee schedules for each of 56 geographic jurisdictions, limited by national fee caps called National Limitation Amounts. Payments are based on what laboratories charged in 1983, updated periodically for inflation. For each test, the median of the 56 fees is taken and reduced by 26 percent to calculate the National Limitation Amount. Most fees currently are constrained by the National Limitation Amount. Laboratories accept Medicare fees as full payment; there is no beneficiary cost sharing. The Health Care Financing Administration, which administers the Medicare program, and its private contractors, known as carriers and fiscal intermediaries, make and interpret policy, set prices, and process claims.

Many tests resulting from new technological developments have been added to the fee schedule since 1983. Decisions about how much to pay for new tests are made both by the carriers and by HCFA. There are two different procedures to set the fees for new tests called *cross-walking* and *gap-filling.* Cross-walking is designed for new tests that are similar to existing tests, and gap-filling is designed for breakthrough technology. The choice of which procedure to follow is made by HCFA, based largely on how the new technology is handled by the American Medical Association's panel that assigns Current Procedural Terminology codes for new tests.

When a new technology is similar to an existing test, it is assigned an existing identifying code and the payment amount that is attached to that code will apply to the new technology. Alternatively, if HCFA determines that the new technology is similar to "old" technologies described under two or more existing codes, it may average the existing payment amounts for those codes and apply it to the new test.

The determination of which new tests can be cross-walked to which existing codes is made internally by HCFA, based on AMA advice about CPT codes. There are no published criteria guiding this process, no public description of the process, and generally no participation by the public or stakeholders other than medical organizations. There is no official process for stakeholders to challenge these decisions.

When a testing product is so radically new that there is little relevant experience upon which to base payment, the payment amount for the test is determined through gap-filling. There is no standard data source to provide comparison prices when creating the base fee for such new tests. HCFA relies on the carriers to set their own fees for the first year after the new test has been approved for coverage. HCFA specifies which new CPT codes are to be gap-filled by the carrier (usually more than a dozen new codes) with the issuance of the new annual fee schedule, but it does not tell the carriers how to calculate the payment amount. There is much flexibility in the way each carrier collects information and sets its fees. All 56 carriers go through the gap-fill exercise separately in order to develop their area-specific fee for the test.

There are two distinct problems with gap-filling that can sometimes lead to setting inappropriate payment levels. First, carriers set their fees based on historical experience, current cost data, and analysis, but unless they inflate the fees before the National Limitation Amount is applied, the cap could create payments that are substantially below costs. This occurs because of the nature of the mandated payment formula, which sets the level of the national cap at 74 percent of the median of the carriers' fees. We understand that legislation passed after our report was released, the Benefits Improvement and Protection Act of 2000, eliminates this reduction of the median for setting the National Limitation Amount for new tests and services. The second problem is that there is no mechanism for reassessing the appropriateness of the new fees and cap once they have been set. Even if the cost of the new test drops significantly after it comes into common use and may become easier to conduct, or even if the gap-fill fee is so low it could limit beneficiary access, there is no routine and practical method for changing it. Hence, neither HCFA nor the carriers regularly look back at fees to see if they are still reasonable.

Assessment of the current Medicare payment system:

The committee defined goals that we believe should guide payment policy. Then we conducted an extensive examination of the current Medicare payment system for outpatient clinical laboratory services and assessed the methodology according to those goals. We examined:

Beneficiary access—The committee found no evidence that beneficiaries currently have difficulty obtaining outpatient clinical laboratory services, including STAT tests.

Flexibility—The committee concluded that existing mechanisms for keeping payments up to date are inadequate. The existing methodology does not provide adjustments to accommodate changes needed in payment levels for specific, individual tests. The process for integrating new technologies into the payment system, including determinations of coverage, assignment of CPT billing codes, and development of appropriate prices, is slow, administratively inefficient, and closed to stakeholder participation. These problems are likely to become increasingly important with the anticipated changes in laboratory technology and medical practice.

Transparency—We concluded that the current payment system lacks "openness" and adequate procedures for stakeholder involvement. Clear and consistent information on how the system works and opportunities for the public and stakeholders to have input into decision processes are limited.

Value—The committee found it had little data with which to judge whether Medicare spending in aggregate is too high or low, whether Medicare is paying reasonable amounts for individual tests and services, or whether physicians are ordering tests appropriately.

Administrative simplicity and efficiency—We concluded that the system, with 56 separate fee schedules and 56 separate processes for coverage determination, is unnecessarily complex and inefficient, particularly in the way the system incorporates new technologies and determines whether or not a laboratory's claim should be paid.

Recommendations:

Based on our analysis of the current payment method and alternative approaches, the committee reached consensus on 12 recommendations for improving Medicare's payment system for outpatient clinical laboratory services. Our choices were guided by the previously stated goals. Because many of the changes could require new legislation, implementation of the committee's recommendations will entail congres-

sional action. The committee recommended that HCFA, the administration, and the Congress work together to develop the necessary enabling authority and support.

The committee's first six recommendations are interrelated, focus specifically on payment methodology, and broadly define the preferred payment system and specific elements of the system and its implementation. The final six recommendations focus on problems in the current system and can be implemented independently or concurrently with the first six. I will not go into detail here on all the recommendations, since they are included in the committee's report that I have submitted along with this statement, but I will call attention to the key ones relating to new technology.

The committee's key recommendation was that Medicare payments for outpatient clinical laboratory services should be based on a single, rational, national fee schedule. In effect, there is already a national fee schedule, since most services are paid at the National Limitation Amounts rather than by carrier-specific fees. A national fee schedule means a single set of payments (instead of 56 fees), with adjustments for differences in local labor costs, prices for goods and services the laboratory purchases, and other relevant factors. The long-term goal of a national fee schedule is to establish relative payment amounts that accurately reflect the relative resource requirements of providing services, minimizing the financial incentives to overuse or underuse services. The committee considered this important for promoting the clinically appropriate use of all laboratory services, both new and old technologies, and ensuring that beneficiaries continue to have access to services.

We recommended that, on an interim basis, relative payments for Medicare outpatient clinical laboratory services should be based on the current National Limitation Amounts. This is an appropriate starting point for the national fee schedule because it formalizes current, de facto Medicare payments and should minimize dislocations and disruptions for laboratories, beneficiaries, and contractors. Nevertheless, HCFA should move quickly to refine the fees, based on a data-driven consensus process. The fee schedule should be updated periodically. HCFA should explore alternative methods for gathering data to be used in the process.

We recommended that, to incorporate new tests into the Medicare laboratory fee schedule, there should be an open, timely, and accessible process that is subject to challenge. The process and fees produced should not impede clinical decision making that is essential to providing appropriate care. The committee concluded that a consistent, public process for developing interim values for new laboratory services is essential for an effective payment system. HCFA should create a committee of laboratorians, pathologists, other physicians and scientific experts, health care policymakers, and economists to advise on setting interim relative values or national fees for new technologies. After interim relative values or fees for new services have been established, Medicare should allow time for diffusion of the new technology and stabilization of costs. The interim relative values for these new services should be reviewed and revised as necessary. Once they are "official," these services would be included in the periodic review of relative values for the full fee schedule.

The committee recommended that HCFA should review alternatives to the current system for coding outpatient clinical laboratory services for claims processing. More accurate, open, and timely coding processes for new technologies as well as tests and services should be sought. The committee heard testimony form several sources that the application process for a new Current Procedural Terminology (CPT) code often adds to the time required to incorporate new technologies into the Medicare laboratory payment system. There are also problems with the inadequate specificity of the codes. Coding, the Medicare coverage process, and payment determinations are closely intertwined; tend to lack transparency; and can add considerably to the time required to incorporate a new test, new equipment, or a new testing methodology. The rapid development of anticipated new technologies will exacerbate this problem. HCFA should examine how to reduce coding delays within the current system and should explore alternative coding systems.

As we seek to reform payment policy for clinical laboratory services, it is important to assess the impact these changes have, particularly on both beneficiary access and the diffusion of new technologies. The committee, therefore, also recommended that HCFA collect data to monitor and assess the impact of new policies as they are implemented.

Conclusion:

We believe Congress and HCFA have the opportunity to fix the current payment system for clinical laboratory services, averting the possibility of a crisis in the future. Payments for some individual tests likely do not reflect the cost of providing services and anticipated advances in laboratory technology will exacerbate the flaws in the current system. Problems with the outdated payment system could threaten

beneficiary access to care and the use of enhanced testing methodologies in the future, however, the committee found no evidence of this now. Although radical changes are not called for at this time, implementing the committee's recommendations will likely improve the efficiency of the system and ensure that Medicare beneficiaries continue to have access to high-quality laboratory services.

Thank you for the opportunity to testify and I would be glad to answer any questions you might have.

PATIENTS FIRST: A 21ST CENTURY PROMISE TO ENSURE QUALITY AND AFFORDABLE HEALTH COVERAGE

WEDNESDAY, APRIL 4, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH, JOINT WITH THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman, Subcommittee on Health) presiding.

Members present, Subcommittee on Health: Representatives Bilirakis, Greenwood, Deal, Burr, Norwood, Wilson, Shadegg, Bryant, Ehrlich, Brown, Strickland, Barrett, Capps, Deutsch, Stupak, and Green.

Members present, Subcommittee on Oversight and Investigations: Representatives Greenwood, Bilirakis, Stearns, Burr, Bass, Deutsch, Stupak, Strickland, and DeGette.

Staff present: Tom Giles, majority counsel; Joe Greenman, majority professional staff; Kristi Gillis, legislative clerk; Chris Knauer, minority professional staff; and Bridget Taylor, minority professional staff.

Mr. BILIRAKIS. We are going to start. Generally, I don't like to do it unless we have a member of the minority in the room, but we are already running late, and we have a vote coming up in just a few minutes on the floor, I am advised. So, hopefully we can get two or three opening statements in before then.

Today, I am pleased to convene this second hearing in our ongoing Patients First initiative. Along with Chairman Greenwood, of the Oversight and Investigations Subcommittee, I am pleased to continue our review of the Health Care Financing Administration and administrative issues surrounding the Medicare, Medicaid, and SCHIP programs.

Today's hearing will focus on how HCFA interacts with providers regarding the rules and regulations that guide the Medicare program. Our Patients First initiative builds on a hearing and subsequent roundtable discussion held last year by the then Health and Environment Subcommittee. And as I said last year, this project, and I quote myself, "is especially significant, because any effort to reform Medicare must include a careful review of the agency that administers the program."

"I don't intend to bash HCFA;" we have made that point, I think, many times so far this year. "But rather we want to conduct a thorough examination of the Health Care Financing Administration, its regulations, policies, and interactions with stakeholders, as well as the impact of congressional mandates."

So it is important that all Medicare providers understand the rules of the road within the Medicare system. I have heard often and forcefully from constituents that honest, law-abiding providers have a difficult time understanding the rules, let alone following them. I know other members have heard similar views from providers in their districts.

Today's hearing provides an opportunity for us all to better understand the nature and source of these concerns. At the same time, I want to emphasize that this committee supports the efforts underway to curtail fraud and abuse in government health care programs. Providers who knowingly attempt to defraud the Federal Government through the Medicare Program should be identified and punished. However, there are many instances of honest providers trying to make a living practicing medicine who don't fully understand the coding process or specific rules and regulations that govern the Medicare Program. Sometimes these honest mistakes cause undue suffering and hardship. The intent of this hearing is to find out how the information flow occurs and how it can be improved.

I am pleased that Dr. David Becker, a gastroenterologist from Clearwater, Florida, is able to join us today. As I said, I have heard often from providers in the 9th Congressional District of Florida, most notably from the Pinellas County Medical Society, which is represented today by Dr. Becker, and the Pinellas County Osteopathic Medical Society, under the leadership of Dr. Ken Webster.

As we will hear from Dr. Becker, providers want a system that they can understand, as well as clear explanations and training for coding and documentation. I have heard from providers back home who feel strongly that communication and education will do more to improve the system than regulation and retribution. And I hope that this hearing and the testimony of Dr. Becker and the others will help us to understand the flow of information and how to improve the administration of the Medicare Program.

I do want to thank all of our witnesses for their time and effort in joining us today. I am hopeful, as I think all of us are, that this hearing will lead to improvements in operations of the Medicare Program and ultimately to improvements in the quality of care for Medicare beneficiaries. That should be our focus and I would like to think our shared objective.

The Chair now yields to Mr. Brown.

Mr. BROWN. I thank the chairman. I apologize for being late. For some reason, I had 2218 as the room, and I don't know why that would be, but anyway, I apologize.

Mr. BILIRAKIS. There must be some Greek in your genes, because Greeks are known to always be late.

Mr. BROWN. You can always have an excuse.

Thank you. I thank the chairman, and thank the witnesses for joining us this morning.

I am pleased we are focusing our attention today on provider concerns and recommendations that can help us improve the traditional Medicare Program. I read the testimony of the witnesses last night, and there clearly are issues that we in Congress have a responsibility to address.

There is a number of fundamental issues, I think, we in this room can all agree on. Communications among HCFA, its contractors, providers, and beneficiaries can and must be improved. Providers and administrators should receive fair notice about new policies and procedures, along with clear instructions on how to implement them. And providers should not have to wait for months before mistakes made by a contractor or by HCFA are resolved. And they certainly should not have to struggle just to find out whom they are to talk to about it.

I hope it hits home that the time providers and their staffs spend on administration is not a throw-away commodity. It is valuable. Every effort should be made to eliminate extraneous, time-consuming paperwork.

Mr. Chairman, I have several goals for this hearing. First, we need to listen carefully to providers' concerns and uncover where the breakdown in communication and education is occurring. Second, we need to figure out how to fix the problems that we identify. Is the problem an administrative issue? Is it a legislative issue? Is it a resource issue? Or is it some combination of the three? And most important, third, is that we do what it takes to make sure that traditional Medicare remains a viable and important program that both providers and seniors can depend on.

One thing that we will hear today is that this is, in part, a resource issue. I want to submit two documents for the record, Mr. Chairman. The first is a letter that Chairman Dingell, Mr. Waxman, and Mr. Stark and I sent to Chairman Regula and Ranking Member Obey, advocating a substantial increase in HCFA's administrative budget.

Mr. BILIRAKIS. Without objection.

Mr. BROWN. Thank you. The second is an open letter to Congress written by a bipartisan group of health care experts.

Mr. BILIRAKIS. Without objection.

Mr. BROWN. In that letter they, too, make the case for a significant increase in HCFA funding. Congress just can't be focusing, as we have in the last 2 or 3 years, on increases to HMOs. We have to pay attention to the needs of the fee-for-service side of the program too.

HCFA and its contractors have experienced a dramatic increase in workload over the last 4 years. The BBA in 1997 alone added 350 new Medicare and Medicaid policies, many of which were complex, and many of which required a significant effort to implement in a short time period, like the hospital outpatient department prospective payment system, home health prospective payment system, and skilled nursing facility prospective payment system, just to name three of the many. Yet over the last decade, increases in HCFA's administrative budget have been essentially flat during this period of significant work growth. With just over 4,400 employees, HCFA's workforce is smaller today than it was 20 years ago. Contractors, too, must meet these increased demands, and they,

too, have seen their budgets remain essentially constant over this period of time.

There are many consequences of this underfunding. The agency has not been able to finance vitally needed customer service and provider and beneficiary education improvements; survey and certification of providers has lagged; and timely responses to patient and family complaints have been compromised. Lack of investments and information systems due to resource constraints has prevented increased efficiency in service improvements and constraints on funding for new staff erode morale and make the agency less competitive in a tight labor market. No insurer, whether it is HCFA, whether it is a HCFA contractor or whether it is employer-sponsored health plan can run on fumes.

HCFA's administrative budget is roughly 1.8 percent of benefits. Compare this to Blue Cross Blue Shield plans that have administrative costs, on average, of 12 percent of benefits, or other commercial providers that have administrative costs upwards of 25 percent. With such a limited budget, the agency must make choices about how to allocate resources. HCFA cannot make the choice to insure fewer beneficiaries, to process fewer claims or to inspect fewer nursing facilities. When funding is limited or reduced, the agency and its contractors must make tough choices about where to devote resources. If we believe that the concerns we raise here today are serious and merit our attention, if we want to listen to providers and make the traditional Medicare Program work better for them and for seniors, then one of the things that we need to is put our money where our mouth is, and give HCFA and the contractors the resources they need to manage the program effectively.

Earlier this year, at a public forum on the future of HCFA, two former HCFA administrators—two Democrats and two Republicans—were unanimous in a call for significant increases in the agency's budget. I am working with the chairman to bring these administrators before the subcommittee to further underscore that point.

Again, I thank Chairman Bilirakis for holding today's timely hearing. I look forward to working with the providers, the agencies, and my colleagues across the aisle to find ways to address the issues we will hear about today and improve Medicare for beneficiaries and especially for the providers and especially the beneficiaries.

[The information follows:]

Congress of the United States
House of Representatives
Washington, DC 20515
April 3, 2001

The Honorable Ralph Regula
Chairman
Subcommittee on Labor, Health & Human
Services, Education and Related Agencies
Committee on Appropriations
2358 Rayburn House Office Building
Washington, D.C. 20515-6024

The Honorable David Obey
Ranking Member
Subcommittee on Labor, Health & Human
Services, Education and Related Agencies
Committee on Appropriations
1016 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Regula and Ranking Member Obey:

We are writing to express our strong support for a substantial increase in the administrative budget of the Health Care Financing Administration (HCFA) as you begin consideration of appropriations for fiscal year 2002.

This Agency, with responsibility for administering Medicare, Medicaid, and the State Child Health Insurance Program (S-CHIP) and other health-related provisions of the Health Insurance Portability and Accountability Act (HIPAA), has experienced a dramatic increase in workload over the past four years. The Balanced Budget Act (BBA) of 1997 alone added nearly 350 new Medicare and Medicaid policies, many of which were complex and required a significant effort to implement in a short period of time. The S-CHIP program, also authorized by the BBA, involved establishing new policies and guidance for the States and operating a review process to consider S-CHIP plans from all the States and Territories. In addition, the 1996 HIPAA law conferred on HCFA the responsibility for overseeing, and in some cases enforcing, the insurance reforms that provides protection for consumers in the individual and group insurance markets.

HCFA also faces a need to make a significant investment in information technology to modernize its claims processing operations and to strengthen its efforts to prevent program fraud, abuse, and waste. This challenge requires both human and capital investments over a period of years. Without such an investment, HCFA cannot experience the productivity gains and improvements in service that today's technology offers.

Finally, HCFA has broad responsibilities in the area of quality of care and provider performance. These activities encompass the enforcement of hospital, nursing facility, home health agency, and hospice standards as well as the evaluation of new medical services, drugs, and devices

for coverage under Medicare. These vital patient protections are increasingly at risk as available resources are not sufficient to ensure appropriate oversight or timely review of advancements in care.

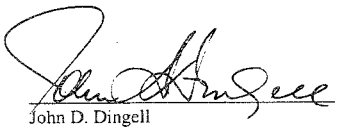
In the wake of this unprecedented increase in the responsibilities and tasks assigned to this Agency, most of which results from decisions made by Congress, we have an obligation to provide the resources to get the job done. Regrettably, we have failed to support HCFA's expanding workload with an adequate administrative budget.

Over the last eight years, increases in HCFA's administrative budget have just barely kept pace with inflation or, to put it another way, it has been essentially flat during this period of significant workload growth. With just over 4,400 employees, HCFA's workforce is smaller today than it was in the early 1980s. There are many consequences of this underfunding. The Agency has not been able to finance vitally needed customer service and provider education improvements. Survey and certification of providers has lagged and timely responses to patient and family complaints have been compromised. Lack of investments in information systems prevents efficiency and service improvements. And, constraints on funding for new staff erode morale, and make the Agency less competitive in a tight labor market.

Earlier this year at a public forum on the future of HCFA, four former HCFA Administrators -- two Democrats and two Republicans -- were unanimous in a call for significant increases in the Agency's budget. We strongly agree with this recommendation and urge your Subcommittee to consider a substantial increase in the FY 2002 appropriations bill.

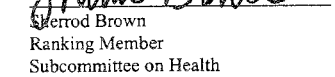
All Americans have a vital stake in the health and vitality of the Medicare and Medicaid programs. Over 74 million Americans have access to needed care through the programs managed by HCFA. We cannot sustain the promise of these programs to current or future beneficiaries unless we are willing to meet our responsibility to provide resources that match the scope of HCFA's responsibilities.

Sincerely,

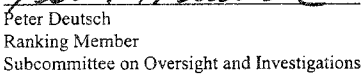


John D. Dingell
Ranking Member
Committee on Energy and Commerce

Henry A. Waxman
Ranking Member
Committee on Government Reform



Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce



Peter Deutsch
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

cc: The Honorable W. J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce

The Honorable Dan Burton, Chairman
Committee on Government Reform

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health
Committee on Energy and Commerce

The Honorable James C. Greenwood, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Crisis Facing HCFA & Millions Of Americans

THE SIGNATORIES TO THIS STATEMENT believe that many of the difficulties that threaten to cripple the Health Care Financing Administration (HCFA) stem from an unwillingness of both Congress and the Clinton administration to provide the agency the resources and administrative flexibility necessary to carry out its mammoth assignment. This is not a partisan issue, because both Democrats and Republicans are culpable for the failure to equip HCFA with the human and financial resources it needs to address what threatens to become a management crisis for the agency and thus for millions of Americans who rely on it. This is also not an endorsement of the present or past administrative activities of the agency. Congress and the administration should insist on an agency that operates efficiently and in the public interest.

Over the past decade Congress has directed the agency to implement, administer, and regulate an increasing number of programs that derive from highly complex legislation. While vast new responsibilities have been added to its heavy workload, some of its most capable administrative talent has departed or retired; other employees have been reassigned as a consequence of reductions in force. At the same time, neither Democratic nor Republican administrations have requested administrative budgets of a size that were in any way commensurate with HCFA's growing challenge.

The latest report of the Medicare trustees points out that HCFA's administrative expenses represented only 1 percent of the outlays of the Hospital Insurance trust fund and less than 2 percent of the Supplementary Medical Insurance trust fund. In part, these low percentages reflect the rapid growth of the denominator—Medicare expenditures. But, even accounting for Medicare's growth, no private health insurer, after subtracting its marketing costs and profit, would ever attempt to manage such large and complex insurance programs with so small an administrative budget. Without prompt attention to these issues, HCFA will fall further behind in its implementation of the many significant reforms mandated by the Balanced Budget Act (BBA) of 1997. In the future the agency also has to cope with a demographic revolution that it is ill equipped to accommodate and with changes in medical

technology that will increase fiscal pressures on the programs it administers.

As the Bipartisan Commission on the Future of Medicare grapples with the problem of reshaping the Medicare program for the next millennium, it would do well to consider two important reforms concerning HCFA's administration. First, the commission should recommend that Congress and the Clinton administration endow the agency with an administrative capacity that is similar to that found in the private sector. Second, the commission should consider ways in which the micromanagement of the agency by Congress and the Office of Management and Budget could be reduced. Congress and the public would be better served by measuring the agency's efficiency in terms of its administrative outcomes (such as accuracy and speed of reimbursement of various providers), rather than by tightly controlling its administrative processes. Only if HCFA has more administrative resources and greater management flexibility will it be able to cope with the challenges that lie ahead.

The mismatch between the agency's administrative capacity and its political mandate has grown enormously over the 1990s. As the number of beneficiaries, claims, and participating provider organizations, quality and utilization review, and oversight responsibilities have increased geometrically, HCFA has been downsized. When HCFA was created in 1977, Medicare spending totaled $21.5 billion, the number of beneficiaries served was twenty-six million, and the agency had a staff of about 4,000 full-time-equivalent workers. By 1997 Medicare spending had increased almost tenfold to $207 billion, the number of beneficiaries served had grown to thirty-nine million, but the agency's workforce was actually smaller than it had been two decades earlier. The sheer technical complexity of its new policy directives is mind-boggling and requires a new generation of employees with the requisite skills.

HCFA's ability to provide assistance to beneficiaries, monitor the quality of provider services, and protect against fraud and abuse has been increasingly compromised by the failure to provide the agency with adequate administrative resources. Even with the addition of $154 million to its administrative budget that Congress included in its latest budget bill, the likelihood that HCFA can effectively implement all of its varied assignments is remote. The Health Insurance Portability and Accountability Act of 1996 assigns many new regulatory responsibilities to HCFA, but a far

larger task is implementing the BBA of 1997 The BBA has more than 300 provisions affecting HCFA programs, including the Medicare+ Choice option, which will require complex institutional changes and ambitious efforts to educate beneficiaries

Medicare spending accounts for more than 11 percent of the U S budget Workable, effective administration has to be a primary consideration in any restructuring proposal Whether Medicare reform centers on improving the current system, designing a system that relies on market forces to promote efficiency through competition, or moving toward an even more individualized approach to paying for health insurance, Congress and the administration must reexamine the organization, funding, management, and oversight of the Medicare program Doing anything less is short-changing the public and leaving HCFA in a state of disrepair

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Mr. BILIRAKIS. I thank the gentleman. The Chair now recognizes the co-chairman of this hearing and the chairman of the Oversight and Investigations Subcommittee, Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman. Chairman Bilirakis, I am pleased to co-Chair this very important joint hearing of the Health and Oversight and Investigations Subcommittees with you today. Like many of my colleagues on both sides of the aisle, I am concerned about ensuring that Medicare providers are receiving clear and concise guidelines and information on how to properly submit claims to Medicare.

Medicare is an essential program to the millions of seniors and disabled who are served by it. It provides its beneficiaries with the medical services and treatments necessary for ensuring quality of life. The Medicare Program relies on thousands of our country's highly trained and extremely qualified medical providers to administer these medical services and treatments. We are grateful to them for participating, and we should do everything in our power, as Members of Congress, to make serving Medicare beneficiaries an opportunity for health care providers to spend with patients on this important task of improving the quality of their lives.

Medicare's rules and guidelines should provide clear directives to its contractors and providers on how to provide an efficient health care delivery system. Clear and understandable rules and guidelines are an absolute necessity for guaranteeing accountability within the system. The better that providers understand Medicare's rules and the better they are crafted so that providers can consistently follow them, the more accountability will be brought into their transactions with the program.

Increased clarity will turn fears of being investigated into clearer understandings of what is and what is not allowable under Medicare rules and regulations. Today, we will evaluate areas where Medicare is unclear or not easily understandable for its providers and explore ways to improve this process.

With these goals in mind, we should be mindful of the progress that has been made over the last 5 years in curtailing improper Medicare payments. The Department of Health and Human Services Office of Inspector General has estimated that the amount of improper Medicare payments has fallen from $23.2 billion in fiscal year 1996, down to $11.9 billion in fiscal year 2000. To put it another way, the estimated amount in improper Medicare payments has been cut by almost half.

This is a direct benefit to the current and future Medicare beneficiaries. We have seen the estimated insolvency date of the Medicare Trust Fund as recently reported by Medicare trustees, pushed back another 4 years. The trustees cited continuing efforts to combat fraud, waste, and abuse in the Medicare Program as one of the main components that has slowed Medicare spending.

It is my opinion that decreasing improper billing of the Medicare Program and effective outreach to Medicare's providers must go hand in hand. As I have already stated, increased vigilance in monitoring fraud, waste, and abuse has had a significant impact in reducing the rate of improper payments made by Medicare. It may very well be the case that we are also need to increase our diligence with regard to reaching out to providers in an effort to allevi-

ate areas of confusion or misunderstanding regarding everyday compliance with Medicare regulations. To that end, we are holding this hearing today.

In recent months, physicians have been voicing their concerns regarding the complexity of dealing with the Medicare Program. In a general sense, they are expressing their frustration with a lack of clear and consistence guidance from the Health Care Financing Administration and its contractors. In many cases, this frustration has led to a fear on the part of many providers that they could be unfairly penalized for innocent mistakes in billing Medicare claims.

The Health Care Financing Administration is the Government agency charged with administering the payment of Medicare claims. In this capacity, it contracts with fiscal intermediaries who process Part A claims and carriers who process Part B claims. Providers get much of their information on Medicare's guidelines and regulations from HCFA's contractors.

Today, we will be examining how HCFA promulgates information and guidelines from its headquarters in Baltimore, Maryland to its regional offices, down through its contractors and ultimately to Medicare providers. In the process, we will get perspectives from various stakeholders on Medicare's provider outreach process.

I would also like to thank Ranking Members Brown and Deutsch for working with us on this issue in a bipartisan way. I look forward to working with you and Chairman Bilirakis to address the concerns of Medicare providers, find the inefficiencies within the system, as it now exists, and work with HCFA and others to fashion the solutions. And I thank in advance all of the witnesses for their testimony today.

Mr. BILIRAKIS. The Chair thanks the gentleman. We are going to try to go through here without having to take a break. The Chair now recognizes Mr. Deutsch for an opening statement, and then hopefully Mr. Norwood or Mr. Greenwood or I will be back before—after we cast a vote. Maybe we can continue on. Otherwise, we will have to recess. Mr. Deutsch.

Mr. DEUTSCH. Thank you, Mr. Chairman. And, again, I appreciate the fact this is the second hearing designated to focus on HCFA reform, and I am committed to working with you on this project.

We ask that we make sure, though, that we get very precise and specific information which details how management of the Medicare Program is failing and then what must be done to correct whatever is uncovered.

Mr. Chairman, it is critical that we proceed with this and other related hearings, that we determine exactly what, if anything, is broken at either HCFA, the carriers or the providers themselves. We must get specifics. Mr. Chairman, we also need to determine what specifically Congress can do to address whatever shortcomings are identified by the witnesses that are testifying today. Whatever we determine is broken, is it fixable through legislation or is it a problem with resources? Is it a combination of the two? I hope our respective subcommittees intend to dig deep enough to determine the answer to that question.

Is it not necessarily clear, however, that the problem which will be voiced today by our witnesses can necessarily be addressed

through legislation alone. If these hearings are going to be productive, then I believe it is critical that we, as a committee, be responsive. That means we must not only verify whether the problems do exist, as claimed by some, but we must also analyze the root cause of these problems so we can determine where corrective action is needed.

Then, provided that we agree that certain problems are in fact evident, we must determine what we need to do to address them. I am looking forward to the witnesses' testimony to hear if they have specific ideas about what changes they will suggest that HCFA make administratively or we make legislatively. Thank you, and I yield back.

Mr. BILIRAKIS. I thank the gentleman. Ms. Capps, for an opening statement.

Ms. CAPPS. Thank you. Thank you, Mr. Chairman, for holding this important hearing today to discuss the relationship between HCFA and the providers and carriers of Medicare.

Medicare is a sacred program to many of today's seniors. They count on this program for their health care and should be able to do so in the future. Managing Medicare is an enormous challenge, and HCFA must engage in a delicate balancing act. While we don't want to compromise patient care with excessive regulation, we also need to make sure that the agency preserves a high level of program integrity and works to prevent fraud, waste, and abuse. If we don't do this, we won't be able to guarantee Medicare's continued solvency.

That being said, I believe there are many areas that need improvement when it comes to Medicare's management. I am afraid the Congress has occasionally made this task harder, and so I look forward to hearing specific ways we can help fix this system. I know from my own district some of the difficulties that have arisen.

Last December, I was contacted by a doctor in San Luis Obispo, California who was having difficulty getting reimbursed by the Medicare carrier for southern California. He had gone for a month without receiving any payment or any acknowledgement of his effort to be paid. This posed a serious threat to his ability to treat patients and to health care access for my constituents.

Dr. Palchek, the doctor in question, is the only medical oncologist in the southern part of San Luis Obispo County. Because of this failure on the part of the carrier, he was unable to purchase chemotherapy, hormonaltherapy or immunotherapy for his patients and was forced to send them to the local community hospital. I soon discovered this problem was not limited to Dr. Palchek and that many other providers in my district were experiencing similar difficulties. Some of the doctors offices that were affected were even forced to seek bank loans to stay open and to stay in business.

I am pleased to say that after I intervened with the carrier and with HCFA, this carrier has worked diligently to resolve these problems. And since that time, the system has been working better.

But the reason I raise this example is not to point a finger at any particular person or entity but to illustrate the consequences of the problems that can and do arise and to remind us of what is at stake. Constituents, mine or anyone else's, should never have

to deal with this, and we on this committee need to see that they and people like them across this country do not have to face this kind of situation in the future.

I am looking forward to hearing from witnesses today about the particular difficulties they see in the way Medicare is managed and the ways that we can work together to address them. I hope we, as a committee, will take the time to really listen to dig into what they have to say, to discover what we need to do to improve on the current situation.

I suspect that we are going to discover that some of the problems we see are due to HCFA's limited resources and that some are due to the operation of carriers and that some are even due to provider practices. When we have determined the specific difficulties in our system that it faces, we can then have a reasonable and bipartisan effort to correct the situation without emasculating the Medicare Program or disrupting the services it provides so well.

I believe in Medicare. I think we must commit ourselves to the improvement of administering this program. We need to work with HCFA to help them in their task of preserving program integrity while ensuring adequate care. And so I look forward to working with you, Mr. Chairman, with our colleagues on this committee to do this in a very fair and sound way.

I yield back the balance of my time.

Mr. BILIRAKIS. Well said, and the Chair thanks the gentlelady. We have run out of members of the subcommittee, so I guess we are going to have to recess. Possibly we can ask the witnesses to sort of take their positions while we are gone. And as soon as either Mr. Greenwood or Norwood returns, we will get started again. Thank you.

[Brief recess.]

Mr. GREENWOOD. We will reconvene, and the Chair recognizes, for 3 minutes, for the purposes of making an opening statement, the gentleman from North Carolina, Mr. Burr.

Mr. BURR. I thank the chairman. I thank my colleagues, and I welcome our panel of witnesses. Mr. Chairman, I will try to be brief. I want to take this opportunity to show the bipartisan spirit I have always tried to approach O&I investigations as well as Health Subcommittee investigations.

And to say that, as I prepared for this hearing yesterday, there was only one testimony that we didn't have. That was the testimony of HCFA. It came in after six last night. They have had 10 days notice for this hearing. When there was a different administration in, I was very quick on this committee to note late testimony. We have changed administrations. I want to continue to note late testimony, testimony that does not allow us to prepare, testimony that is a great example of what many of the people in this panel will explain as less than the best from an agency that claims to have changed.

Let me read, if I could, Mr. Chairman, some of Mr. Miller's testimony. "We are continuing to pursue an open process as we implement these new programs and policy changes seeking insight and recommendations from physicians and providers, their associations and other members of the public. This is far different from the way many private insurers conduct their business and greatly benefits

everyone as we incorporate stakeholder recommendations into our new policies and regulations."

Mr. Chairman, I won't be here for the whole hearing, but let me highlight some of the testimony of three of our witnesses. First is David Becker, County Medical Society, and he says in his testimony, "We need a system everyone can understand. We need training from our HCFA carriers for correct coding documentation. Communication and education, as opposed to regulation and retribution will greatly improve today's Medicare Program."

Jyl Bradley, "Not only did this communication breakdown between HCFA, the carriers, and ultimately the providers result in physician practices around the country having to submit thousands of denied claims billed from October 30, 2000 to February 8, 2001, it undermined the trust and credibility necessary to preserve a good working relationship between practices and carriers."

Mr. Wood from the Mayo Foundation, "The work of the staff has been very gratifying, and it is clear from this example that staff can make changes that are helpful not only to physicians but beneficiaries. Field testing or simplified ABN found better beneficiary response to new, simpler forms. However, it is difficult for me to understand why it has taken a decade to resolve an issue that required only a year of development and testing. We should be able to make faster progress than solving one problem every 10 years."

"Unfortunately, HCFA staff members have informed PPAC members that at least two of the issues important to physicians and included on the PRIT physicians' issues list are nearly impossible to resolve, notably, claims, resubmissions, and the requirement for prior hospitalization for skilled nursing facility placement."

I am going to miss a lot of the testimony, so I wanted to make sure that everybody here heard the quotes that you made that I think fly in the face of some of the statements that HCFA will make throughout this testimony about the transformation they have gone through of openness, communication, listening, reality. It is right in the opening part of it: "Our goal is to ensure that beneficiaries get the care they need without imposing unnecessary burdens on beneficiaries, physicians, and providers." That is their goal. Clearly, that is not happening today. The purpose of this meeting is to get us on the road to where we determine whether statutorily they can do it or legislatively we have to do it.

Mr. Chairman, let me just share for the members, I hold in front of me the list of forms required to be filled out on the first home care visit. Let me restate that: This is the entire packet of forms that must be filled out on the first home care visit. I think this is a great place for us to start to figure out how we reduce some of the burden that we have placed on providers, and then we can start on dealing with the other realities that we know, which may lead us to 130,000 pages of regulations that we, in fact, deserve some credit for creating. And I hope, in fact, we will deserve some credit for solving.

I thank the chairman. I yield back.

Mr. GREENWOOD. Chair recognizes the gentleman from Georgia, Mr. Norwood, for 3 minutes, for an opening statement.

Mr. NORWOOD. Thank you, Mr. Chairman. In the interest of getting to our witnesses, I will be brief, but I am going to be to the point.

There is something very, very wrong with a system that is so bureaucratic that it takes 130,000 pages of rules and forces the doctor to spend more time and effort working for HCFA in fear of going to jail than working for their patients. Now, if you can't manage a system with less rules and regulations than that, we are going down the wrong road with training, because training is not the solution until we reduce the amount of paperwork, as Mr. Burr just showed, and the amount of rules these people have to deal with. That is if you want well patients. There isn't a doctor in this country that deals with Medicare that doesn't have some form of horror story about the complexities of this process. These stories are very painful to the providers and to the patients.

Now, I have not yet read the GAO report that praises the work of the Department of Justice in implementing the False Claims Act for Medicare, but it is strange credibility to say that it is making things any easier for the providers of the patients so that the patient may get well. Some may argue that efforts to stop improper payments have saved the Government money. And someone earlier pointed out how much money. But it has also increased the level of anxiety amongst the Medicare providers to the point that many either want to retire as quick as they can or they want to stop seeing Medicare patients.

The question is, is the money that the Justice Department says it is saving really, really from improper payments? With 130,000 pages of rules and regulations governing Medicare, my suspicion is, and I am pretty sure it is more than just a suspicion, that the providers are downcoding to save themselves from ever hearing from the Justice Department or the Inspector General.

Providers are forced to charge themselves less for fear of the IRS, the FBI, and OSHA. There is something wrong with that system, particularly in a system that pays fees typically at cost and in some cases below cost, and the provider is forced to downcode in order to keep them off their back.

Now, I didn't come here today to lay blame or point fingers for the problems that providers face in dealing with Medicare. Is it HCFA? Is it the carriers? Is it the providers themselves? Have we constructed a Medicare system that necessarily breeds this type of adversarial arrangement on purpose? I don't know the answer today, but I do know this committee is going to find the answer. Mr. Chairman, I believe we are going to make changes in the way this system works so that these horror stories are rare instead of regular, every day.

I thank you, Mr. Chairman, for having this hearing, and I yield back the balance of my time.

Mr. GREENWOOD. Chair thanks the gentleman and recognizes the gentlelady from Colorado for 3 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. Provider education and training are key components of a strong, efficient, and financially sound Medicare Program. If providers and beneficiaries are properly educated, fewer mistakes will be made, precious resources will

be appropriately allocated, and beneficiaries will be well-served. I think that that is a basis we can all agree on.

What is more difficult to find agreement on, I think, is the extent to which providers are not adequately educated, what types of problems exist with regard to inadequate education and training, who is to blame, and what could and should be done to address those issues? For example, according to the testimony we will hear from the Office of Inspector General this morning, 93 percent of all payments to providers were error-free. This suggests, as the IG concludes, in part, that providers are fairly well-educated about Medicare's rules.

However, many of the providers' representatives testifying here today do not concur with that conclusion. Providers will report that the current system does not offer the level of education required to properly navigate the Medicare coverage and billing maze, that they are frequently and consistently left in the dark by HCFA and the contractors, and as a result, fear criminal prosecution if they make honest mistakes. Undoubtedly, there is disagreement about these matters, because Medicare's rules are complex, and its administration is complicated. There are a variety of reasons for the complexities, including the fact that our Nation's health care system is complex.

With regard to the Medicare Program, I don't think we can underestimate the role that Congress has played in increasing the program's complexity. Over the past few years, from the passage of the Balanced Budget Act to changes in the law in 1999 and 2000, Congress has enacted hundreds of provisions dealing with Medicare which in turn require the promulgation of hundreds of regulatory rules. While much of what we did strengthened the program's benefits and its financial health, quite often we provided very little time to implement and test the changes. This, I think, also contributes to confusion and uncertainty around the laws and regulations. In addition, HCFA's interpretation and its surrogates' application of the laws and providers' willingness and ability to understand the rules are factors in the equation.

It is my hope that in this and future hearings, we will be able to identify specific problems and solutions to further our understanding of the Medicare administration process and that we examine the experience of the participants and the issues before we rush to legislative solutions.

And I yield back the balance of my time.

Mr. GREENWOOD. Chair thanks the gentlelady and recognizes, for purposes of an opening statement, the gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank the chairman for yielding me time and for holding this hearing. Recently, I was back in my district and visited the University of Tennessee Medical School in Memphis and one of the departments there, the School of Allied Sciences, had a briefing that included the information that many of their problems there are caused by a shortage of students willing to go into these areas of study. Many of these areas, including the laboratory technicians, are short. And one of the reasons, I am told, is that the pay has gone down so much or has not kept pace with other profes-

sions, largely due to the low reimbursement rates that are available through the Medicare Program.

Yesterday, I had a doctor in my office, also from the laboratory side of medicine, and he provided me with a payment policy and several recommendations that his association would like to make to HCFA.

As Mr. Burr said, many of us are in and out today because of different commitments and different hearings and so forth. I want to ensure that I can provide these recommendations to Dr. Miller on behalf of HCFA. And I will have this copied and given to him, and I would like to make it a part of the record, if I could, also. It is four pages, and it contains some 12 recommendations from that particular laboratory association of doctors and so forth on how they view improvement could be made to HCFA in the way business is conducted. I would like to ask Dr. Miller, if you could, as a late filed exhibit to your testimony today, if you could respond to these 12 recommendations and discuss those for me.

And with that, I would yield back the balance of my time. Thank you.

[The material follows:]

HCFA FACT SHEET

MARCH 2001

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OUTREACH TO PHYSICIANS AND HEALTH CARE PROVIDERS

Overview: Physicians and other health care providers play a critical role in providing quality care and services to nearly 40 million senior citizens and disabled Americans who rely on Medicare for their health coverage. The Health Care Financing Administration (HCFA), which runs the Medicare program, strives to simplify Medicare for health care professionals while ensuring the program pays appropriately for covered services as required by Medicare law and regulations. HCFA solicits and incorporates input from practicing physicians and other providers as it implements and updates the payment systems and rates required by law. HCFA also sponsors an aggressive outreach effort to help doctors and other providers understand Medicare's benefits and payment policies and to simplify those procedures while continuing to protect beneficiaries and taxpayers from improper payments.

Each year, HCFA pays more than $210 billion in benefits for the nearly 40 million Medicare beneficiaries, involving nearly 1 billion claims from more than 1 million physicians, hospitals and other health care providers. In 2000, Medicare paid $37 billion for physician services alone. HCFA oversees the work of 50 private insurance companies that, by law, process and pay these claims. HCFA also contracts with private managed-care companies that serve about 5.6 million beneficiaries.

The laws enacted by Congress specify the framework for Medicare's coverage policies, payment systems and payment rates. Congress has limited Medicare coverage to services that are medically necessary for the diagnosis and treatment of injury, disease or impairment, as well as certain specified preventive benefits. As Medicare's administrator, HCFA must ensure Medicare pays only for the services allowed by law and regulation while making it as easy as possible for qualified physicians and other health care providers to treat Medicare beneficiaries. To achieve these goals, HCFA works to help doctors and other providers understand and follow Medicare's requirements so that they receive accurate, timely payment. HCFA is also taking steps to make Medicare more understandable to both beneficiaries and physicians.

PHYSICIAN LEADERSHIP AT HCFA

Since beginning a comprehensive reorganization in 1997, HCFA has recruited physicians and others with private-sector experience in health care for key policy positions. As a result, HCFA has doubled the number of physicians in leadership positions. A geriatrician now heads the Office of Clinical Standards and Quality, which oversees Medicare coverage policies and quality standards. A physician who once worked as a Medicare contractor medical director now oversees Medicare's claims-processing contractors. An emergency-room physician serves as the deputy director for HCFA's program integrity group. Other physicians are involved in developing Medicare coding and payment systems.

HCFA also relies on physicians in an organized way to guide decisions affecting Medicare beneficiaries. Through internal working groups, formal advisory panels and other efforts, HCFA incorporates the practicing physician's viewpoints into policy decisions. These efforts include

The Physicians' Regulatory Issues Team (PRIT). In 1998, HCFA created the PRIT to improve the agency's responsiveness to the daily concerns of practicing physicians as the agency reviews and creates Medicare requirements. The team, which includes physicians working throughout HCFA, seeks to make Medicare simpler and more supportive of the doctor-patient relationship. Major on-going initiatives include consulting physicians about proposed program changes, developing an easy-to-use handbook to guide physicians through relevant Medicare laws and regulations, and investigating physician concerns to find ways to simplify or eliminate unnecessary Medicare requirements. Last year, the work of team members led to changes to allow physicians to fax their orders for patients to receive wheelchairs and other needed equipment, and to allow physicians to receive separate payments for their work determining patients' eligibility for the Medicare home health benefit.

The Practicing Physicians Advisory Council (PPAC). The council, established by Congress in 1990, advises HCFA on proposed changes in Medicare regulations and manual instructions related to physician services. A HCFA physician leads the PPAC, and all 15 members are practicing physicians who bill Medicare, representing a wide variety of specialties and both urban and rural areas. The PPAC provides HCFA with guidance on Medicare issues. More information about PPAC is available at www.hcfa.gov/medicare/ppacpage.htm

IMPROVING OUTREACH TO PHYSICIANS

As part of its overall mission, HCFA strives to meet the needs of the doctors who care for Medicare beneficiaries. These efforts include.

Ensuring accurate, timely payment. Medicare requires contractors to pay most clean claims no more than 30 days after they are submitted - as fast or faster than many private insurers. HCFA also has launched a new customer service initiative aimed at improving contractors' responsiveness to the concerns of physicians and other providers. HCFA now evaluates contractors' customer service efforts and will survey providers on the issue this year.

Establishing toll-free information lines. As part of its increased commitment to customer service, HCFA in 2000 required Medicare claims-processing contractors to establish toll-free lines for doctors and other health care providers. Each Medicare contractor offers the toll-free service to answer billing and claims questions from physicians, hospitals, home health agencies, and other providers. The numbers are listed at www.hcfa.gov/medlearn/tollfree.htm. Each contractor also maintains a Web site and electronic bulletin boards. Beneficiaries can call 1-800-MEDICARE (1-800-633-4227) for information about Medicare.

Simplifying evaluation and management guidelines. In June 2000, HCFA held a town hall meeting with doctors to discuss a new proposal to simplify the documentation guidelines for physician office visits under Medicare. Since the town hall meeting, HCFA has sought and obtained broad input from practicing physicians, including the PPAC, and is continuing to refine the guideline and prepare to pilot test them in 2001. The goal is to develop guidelines that intuitively make sense to physicians while ensuring accurate payment for their services.

Improving the enrollment process. HCFA is issuing revised procedures to better ensure that the relatively few unqualified providers cannot bill Medicare while reducing the burden of the Medicare enrollment process on the large number of qualified health care providers. The new process will reflect extensive input from doctors and other providers.

Conducting monthly conference calls with physicians. Each month, HCFA holds conference calls with physician organizations across the country to provide information and obtain feedback. The calls are open to representatives of more than 100 national, state and specialty associations. Participating associations often share information from these calls with their physician members. HCFA staff, including physicians, also attend national, state and local medical society meetings to meet with physicians, to hear their concerns and to explain Medicare policies.

THE MEDICARE LEARNING NETWORK

To help doctors and other health care providers, HCFA has free information, educational courses, and other services available at the Medicare Learning Network at www.hcfa.gov/medlearn. The network provides timely, accurate and relevant information about Medicare coverage and payment policies. The online network includes:

Free computer-based training courses. Doctors, members of their office staff, and other interested individuals can access a growing number of informational courses designed to improve their understanding of Medicare. Some courses focus on important administrative and coding issues, such as how to check in new Medicare patients or to correctly complete Medicare claims forms, while others explain Medicare's coverage for home health care, women's health services and other benefits.

Relevant e-mail updates. To share information as quickly as possible, HCFA is e-mailing updates about Medicare payment systems to interested providers, trade associations and others. As of February 2001, about 10,000 subscribers received timely updates about topics such as two new prospective payment systems implemented in 2000 for outpatient hospital services and for home health services.

***Medicare & You* handbooks.** Responding to physician requests, HCFA sent copies of the *Medicare & You 2001* beneficiary handbook to more than 500,000 individual physicians and group practice offices. The handbook is updated and mailed to nearly 40 million Medicare beneficiaries as an easy-to-understand guide to explain Medicare's benefits and policies.

Satellite broadcasts. HCFA sponsors live national satellite broadcasts for physicians and health care providers about Medicare topics such as women's health, preventive benefits, and preventing fraud and abuse. The broadcasts can be viewed in hospitals, medical schools and virtually any other location across the country through satellite television.

JAMA articles. HCFA has highlighted news and issues of interest to practicing physicians in quarterly articles published in the *Journal of the American Medical Association*. Through these articles, HCFA has informed physicians around the country on such topics as Medicare's new preventive benefits and ensuring accurate claim filings to Medicare.

Mr. GREENWOOD. Chair thanks the gentleman and recognizes for 3 minutes the gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and I will submit my total opening statement. But following a lot of my colleagues, we know the frustration with providers, with HCFA, and sometimes with the slow payment schedule, and not only the amount of dollars but the slowness in responding. We have to keep in mind that HCFA covers 39 million beneficiaries, and they contract with 50 different intermediaries. And most of the contractors do a pretty good job.

But there are a number of concerns, and HCFA can and should provide more guidance to the contractors, improve the provider education and simply existing forms and procedures and streamline the communication. And I certainly heard from providers, like my colleagues have, in my district who have experienced difficulty with the system and feel they are spending more time filling out paperwork than treating their patients.

If there are problems in the current system, we need to address it. And like my colleague said before, there have been a great many additional burdens placed on—or responsibilities placed on the Health Care Financing Administration in the last few years, and it is amazing that in this time of surplus the HCFA's budget was $2.2 billion in fiscal year 1995, and yet in fiscal year 2000 it is actually $2.1 billion. So we need to provide the resources to HCFA to be able to do that. Hopefully have a speedy response to our providers.

And I yield back my time, Mr. Chairman.

[The prepared statement of Hon. Gene Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Chairman: Thank you for holding this second hearing on the Health Care Finance Administration and its relationship with providers and contractors.

HCFA has the unenviable task of administering the Medicare program to over 39 million beneficiaries.

It is responsible for educating tens of thousands of health care providers, processing claims, conducting audits for program integrity, and ensuring the health and well being of Medicare beneficiaries.

For the most part, HCFA contracts most of these responsibilities to fifty different fiscal intermediaries and carriers who are responsible for the day to day operation of the Medicare program.

While most of these contractors do a good job administering the Medicare program, there are a number of concerns that HCFA can and should do more to guide contractors, improve provider education, simplify existing forms and procedures, and streamline communication.

I have certainly heard from providers in my district who experience difficulty with the system, and feel they are spending more time filling out paperwork than they are treating patients.

If there are problems within the existing system, than we should address them.

But I'd like to point out what I think is a rather obvious problem.

Since 1996, the Congress has passed many laws changing Medicare payment policies.

This has resulted in a considerably larger workload for both HCFA and the private contractors.

But there has been no corresponding increase in resources for HCFA or its providers to execute those changes.

In FY 95, before passage of HIPAA, creation of the State Children's Health Insurance Plan, or passage of the Balanced Budget Act, HCFA's administrative budget was $2.2 billion.

In FY 2000, however, HCFA was appropriated even less money—only $2.1 billion.

Mr. Chairman, I am very concerned that providers are experiencing difficulty with HCFA.

But I fear that we in Congress are as much to blame about some of the problems that exist as the agency is.

I look forward to the testimony of the witnesses, and really hope that we are able to identify some problems within the agency, and reach consensus on how to resolve them.

Thank you and I yield back the balance of my time.

Mr. GREENWOOD. Chair thanks the gentleman, and recognizes for 3 minutes the gentleman from Florida, Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. I thank you and Chairman Bilirakis for convening this joint hearing. I think like in any bureaucracy, HCFA is so complex, and because of its complexity, a lot of people inside and outside are having trouble understanding all the regulations. And perhaps what we need here is new, clear, and consistent guidance from HCFA so that this perception can be cleared up. Because I think, like many members hearing from doctors and others, they feel they are unfairly penalized for innocent billing mistakes, and it is causing a lot of the providers, particularly in central Florida, to reconsider treating Medicare patients.

So I think this hearing is timely and hopefully we can receive a response from the witnesses into how we can make HCFA more effective and some of the subcontractors they use can be more in line with the customers' attitude and response. And so I think it is worthwhile to analyze HCFA.

I welcome this hearing, Mr. Chairman. I yield back the balance of my time.

Mr. GREENWOOD. Chair thanks the gentleman and recognizes for 3 minutes the gentleman from New Hampshire, Mr. Bass.

Mr. BASS. I thank the chairman, and I would like to associate my remarks with those individuals who preceded me about the importance of this hearing in providing a perspective of the various stakeholders and the issue of delivery of important health care services to Medicare recipients.

As a Member of Congress, I can't tell you how many issues that we have internally, within my district, from folks who have problems interacting with HCFA of one sort or another; everybody from the insurance providers through some of the folks who are testifying here today. And we have a pretty good relationship with the agency in trying to ferret through problems that occur. It is a very timely hearing, though, and it is important, as we face the whole issue of reform, of Medicare, preserving Medicare, that we address issues of delivery of important health care services.

I also want to take a second to recognize one of my constituents from Sullivan County, from Claremont, Jyl Bradley, who is here today representing the Medical Group Management Association. She has wonderful qualifications, not the least of which having gotten a Master's Degree at Dartmouth College, which is the finest college in the country. And I think that her testimony will be very interesting and helpful to the business of this committee.

And with, Mr. Chairman, I will yield back.

Mr. GREENWOOD. Chair thanks the gentleman and recognizes for 3 minutes the gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. I believe it is the duty of this subcommittee to monitor and take necessary action to im-

prove Medicare and ensure its viability well into the future. No one argues that the fact of the job of administering Medicare is a tedious, thankless one. The Health Care Financing Administration, HCFA, and its providers are responsible for ensuring that Medicare runs smoothly, and in an ideal world, Medicare would run smoothly. However, we are not in an ideal world. And so we have this hearing today to ask HCFA and private contractors to shed light on how to improve their interdependent system.

I am pleased that HCFA has taken steps in the past few years to improve their provider education, namely, installing a toll-free hotline for provider inquiries, issuing handbooks on the basics of Medicare for providers, satellite broadcasts of seminars, and a medical resident and training program. I believe that provider education is absolutely essential to preventing possible costly mistakes. And it is certainly true for provider education that an ounce of prevention is worth a pound of cure.

At the heart of providing the optimum level of provider education is the issue of resource allocation. In the interest of making HCFA and Medicare run ever more smoothly, Congress has heaped mandate after mandate upon HCFA, and at the same time asked it to respond in a meaningful way, while keeping their administrative budgets static. Although I do not necessarily think throwing money at a problem is always the cure, I do think that it is somewhat unreasonable to ask HCFA to operate with a 2 percent administrative budget. In 1995, prior to major program changes mandated by Congress and HIPAA, HCFA's administrative budget was $2.2 billion. In 2000, HCFA's administrative budget was only $2.1 billion.

I look forward to hearing from our distinguished panel of guests and hearing their input on how and where to find to address problems currently found within the Medicare system.

Mr. Chairman, thank you for holding this hearing. I yield back any time I may have left.

Mr. GREENWOOD. Chair thanks the gentleman, and recognizes for 3 minutes the gentleman from Maryland, Mr. Ehrlich.

Mr. EHRLICH. I will pass, Mr. Chairman.

Mr. GREENWOOD. Chair recognizes for 3 minutes the gentleman from Georgia, Mr. Deal, who also passes.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Chairman Bilirakis and Chairman Greenwood, thank you for holding this important hearing. This is the second in a series of hearings this Committee is holding on the reform and modernization of Federal health care programs.

At this morning's hearing, we will focus our attention on how the Health Care Financing Administration informs and educates health care providers about the regulations it promulgates. Specifically, I am most interested in hearing how HCFA currently provides educational materials to its regional offices, how that information is disseminated to contractors and eventually to providers—those on the front lines in providing care to patients. To the extent problems exist in that flow of information, we must identify the problem, and work to find a responsible solution, be it administrative or legislative.

For example, I have heard that an individual can call HCFA with a question, and that answer may vary depending upon who answers the phone. Is that possible? Is that what we want?

I have also heard that this is not a HCFA issue, but a contractor issue. That is something we need to explore. But if I contract with somebody to do work on my behalf, I am ultimately responsible. If Congress has tied the hands of HCFA in

terms of its ability to contract to do this work, then we need to see how we can improve that process. HCFA is ultimately responsible for ensuring that educational materials are disseminated to providers and that providers know the "rules of the road."

Education is critical. I would think that HCFA would consider it of utmost importance. Unfortunately, I must question HCFA's stated emphasis on education when I read in the October 31, 2000 Federal Register a notice entitled "Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During Fiscal Year 2000." That notice states that the carrier's "conduct of educational and outreach efforts" are functions that MAY be evaluated under the criterion. Why would we not want this to be a mandatory criterion for evaluation?

The need for guidance from HCFA to help providers understand the rules of the road was made clear to me after reading the February 19, 2001 USA Today article entitled "Rejections Rise for Medicare Patients. Crisis Feared as More Urban Doctors Refuse Insurance Plan." The article is about physician dissatisfaction with the Medicare program and points out that as a result, in part, of HCFA's burdensome and confusing regulations, physicians across the country are beginning to discontinue seeing Medicare Fee-For-Service Medicare patients. If true, this is a serious problem that needs to be remedied quickly.

In addition, Dr. Becker, a constituent of Chairman Bilirakis and a practicing physician before us today, stated in his testimony that "Some doctors are limiting or no longer seeing Medicare patients for fear of retribution in a system they don't understand. Doctors fear legal liability for errors as simple as a keystroke mistake on a computer that will miscode a charge or a diagnosis."

I am concerned when I hear that physicians' fear of prosecution and their inability to obtain adequate assistance from HCFA are causing them to reconsider their commitment to Medicare patients. I am glad to see the Office of Inspector General is here to clarify the type of cases they pursue. However, the Committee needs to explore ways to reduce the complexities of the Medicare program and identify ways to educate providers about complying with existing rules and regulations.

As is the case with all of the hearings we will have on this topic, I want to work to find solutions. I am not here to demonize any agency or any party. I stand ready to work with anyone interested in rolling up their sleeves and working hard to ensure that our Federal Health care programs are providing quality, affordable health care to patients. As I stated at the first hearing in this series, I pledge we will do this together, on a bipartisan basis—not to score points at one another's expense but to improve the lives of patients.

Chairman Bilirakis and Chairman Greenwood, thank you again for holding this hearing. I look forward to hearing from the witnesses.

PREPARED STATEMENT OF HON. ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Chairman Bilirakis, Chairman Greenwood, I appreciate your efforts in holding this hearing today. We are here to take a close look at HCFA and its administrative process. Since 1996 Congress has placed several mandates on HCFA to carry out changes and improvements and it is now our responsibility to make sure that the new provisions were implemented properly. Much of the focus during the last few years has been aimed at preventing fraud and abuse. The result has been a significant decrease in the number of improper claims paid. In fact, the number has been cut in half, saving taxpayers over $11 billion dollars. This is a significant achievement, but we now have to examine the effect these provisions have had on the delivery of care and the administration of HCFA.

We will hear many complaints today regarding the hoops that providers must jump through to get reimbursed for routine visits or procedures and the fear many have of the penalties associated with billing mistakes. However, much of the problem is caused by the fact that there is a lack of communication amongst HCFA, local carriers, and providers. These misunderstandings are leading to fear and frustration and many providers are fed-up with the administrative process and simply want out. Better communication and education about billing and coding and such can alleviate many of the concerns we hear about. However, HCFA is ill equipped to increase educational efforts because of budgetary constraints.

In fact, HCFA's budget has been static for the last 10 years. We have not invested in the agency and that is now being reflected in its administration. Mr. Chairmen, Congress asked HCFA to implement these changes and today we are saying shame on you for what you are doing to doctors and hospitals, and other providers. We need to examine the problems the agency is experiencing and fix them so that pro-

viders can be at ease and continue to render high quality care without feeling like every action is under scrutiny by HCFA. I look forward to the testimony from our panel, and I trust that we will use the information gathered today in a constructive manner. Mr. Chairmen, I hope to work with both of you and the other members of the committee to address these issues further.

Mr. GREENWOOD. Are there any other requests for opening statements? If not, the Chair calls the witnesses. They are Mark Miller—Dr. Mark Miller, acting director of the Center for Health Plans and Providers, from the Health Care Financing Administration. Mr. Michael Mangano, the Acting Inspector General, Department of Health and Human Services; Dr. David Becker, from Largo, Florida, on behalf of the Pinellas County Medical Society; Jyl Bradley, administrator, Dunning Street Ambulatory Care Center, Associates in Surgery and Gastroenterology of New Hampshire, on behalf of Medical Group Management Association; Douglas Wood—Dr. Douglas Wood, vice-chair, Department of Medicine of the Mayo Foundation in Rochester; Mr. Harvey Friedman, vice president, Medicare and Seniors Program, Blue Cross/Blue Shield Association of Chicago.

The witnesses, thank you for your patience. You are aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Do you have any objections to testifying under oath?

The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today? Seeing no affirmative responses, I would ask that you rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. Thank you. You may be seated. You are now under oath. You may give your written testimony. Ordinarily, we ask witnesses to confine their remarks to 5 minutes. We have one panel today. We have a great interest in your testimony. We are going to give you 10 minutes to provide your testimony. If you can do so in less than 10 minutes, you will get a gold star next to your name in the official record.

And we will begin with Dr. Miller.

STATEMENTS OF MARK MILLER, ACTING DIRECTOR, CENTER FOR HEALTH PLANS AND PROVIDERS, HEALTH CARE FINANCING ADMINISTRATION; MICHAEL MANGANO, ACTING INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DAVID BECKER, ON BEHALF OF THE PINELLAS COUNTY MEDICAL SOCIETY; JYL D. BRADLEY, ADMINISTRATOR, DUNNING STREET AMBULATORY CARE CENTER, ASSOCIATES IN SURGERY AND GASTROENTEROLOGY, ON BEHALF OF MEDICAL GROUP MANAGEMENT ASSOCIATION; DOUGLAS L. WOOD, VICE CHAIR, DEPARTMENT OF MEDICINE, MAYO FOUNDATION; AND HARVEY FRIEDMAN, VICE PRESIDENT, MEDICARE AND SENIORS PROGRAM, BLUE CROSS BLUE SHIELD ASSOCIATION

Mr. MILLER. Chairman Bilirakis, Chairman Greenwood, Congressman Brown, and Congressman Deutsch, distinguished subcommittee members, thank you for inviting me to discuss physician and provider education efforts here today. Medicare is a vitally im-

portant program to millions of Americans, elderly and disabled. Our partnership with physicians and other providers plays a critical role in providing quality care to beneficiaries, and our goal is to ensure that beneficiaries get the care they need without imposing unnecessary burdens on beneficiaries, physicians or providers.

We know that there is a lot of work that needs to be done. We feel that we are making progress, and that progress is outlined in detail in the written testimony that I submitted.

Medicare pays for the health care for 40 million beneficiaries. It processes a billion claims a year on behalf of 1 million physicians, hospitals, and other providers. Today alone, more than $500 million will be paid out in claims, and that happens every single day. This represents a tremendous volume of billing and payment. Moreover, the program has changed rapidly over the past 4 years.

As stewards of this program, we strive to ensure that Medicare pays only for services that are allowed by law, while making it as simple as possible for qualified health care providers to treat Medicare beneficiaries. We are careful to balance the impact of the laws and regulations on physicians, while at the same time meet our responsibility to account for more than the $210 billion that are paid out in Medicare payments every year. We are committed to finding the right balance between Medicare's rules, and we are committed to finding the right balance and simplifying Medicare's rules, reducing burden, and explaining requirements to physicians and providers.

Over the last few years, we have made great strides in reaching out to physicians and providers to help them bill us appropriately. Working with our contractors, we have taken a number of steps to ensure that information is consistent, clear, and unambiguous. We are making materials available in print, on the Internet, through toll-free telephone lines, via satellite broadcasts, and developing new materials and local and national education seminars. It is very critical that we listen. And there have been several efforts that we are going through to more clearly get the message from physicians and providers. I want to highlight two here.

It is critical that we listen both to understand what problems physicians and providers are encountering as well as to determine what kinds of communication best suit their needs. The two examples that I want to give here of how we are listening to physicians in particular are the Practicing Physician Advisory Council, that we work with at HHS on precisely the issues that are being discussed here as well as a team inside HCFA, which is the Physicians' Regulatory Issues Team. These two components are just examples of how we listen so that information we provide is sensible, reality based and supportive of the care that they give to beneficiaries.

To talk for just a moment about the Physicians' Regulatory Issues team, that is comprised of program staff and HCFA physicians. It is led by a practicing physician, Dr. Barbara Paul, who is here with me today. The purpose of the Physicians' Regulatory Issues Team is to amplify the physicians' voice in HCFA's decision-making processes as well as to pinpoint problem areas and develop suggestions to solve those problems. For example, through these two bodies, the Practicing Physician Advisory Committee and the

Physicians' Regulatory Issues Team, we have been working with the physician community on new guidelines for billing office visits, rewriting our manuals to clarify billing instructions and enhance education, and improving the enrollment process so it easier for physicians and providers to participate in the program.

We share a common mission with our physicians and providers, that is, ensuring high quality care for Medicare beneficiaries. Communicating clearly with physicians and other providers is an important aspect of administering the Medicare program. While the focus of our discussion today is likely to be physician issues, I also want to clarify that our education efforts extend to the full spectrum, physicians, suppliers, providers, institutions, and managed care plans.

Strong communication entails both delivering and receiving information. We recognize that there are concerns in the way that HCFA and its contractors interact with physicians and providers. While we believe that the vast majority of the 1 billion claims transactions that occur each year occur smoothly and positively, we are aware of delays and mistakes. I want to assure you that we take these problems seriously because we know that each transaction involves a physician or a provider, but most importantly each transaction involves a beneficiary.

We believe that our education efforts will improve the administration of the program and will improve our relationship with physicians and providers. I appreciate you asking me here today to talk about these issues, and I look forward to answering your questions.

[The prepared statement of Mark Miller follows:]

PREPARED STATEMENT OF MARK MILLER, ACTING DIRECTOR, CENTER FOR HEALTH PLANS & PROVIDERS, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Chairman Greenwood, Congressman Brown, Congressman Deutsch, distinguished Subcommittee members, thank you for inviting me to discuss our physician and provider education efforts with you. Medicare is vitally important to senior citizens and disabled Americans, and our partnership with physicians and other providers plays a critical role in providing quality care and services to beneficiaries. Our goal is to ensure that beneficiaries get the care they need without imposing unnecessary burdens on beneficiaries, physicians, and providers. The Administration is reviewing regulatory and legislative changes that may be needed to enable us to better focus our efforts on achieving this goal. It also is clear that we must reimburse physicians and other providers in a timely, efficient, and fair manner. We know we need to continue to improve in this area, and we are working to address this through the host of activities I will describe today.

Over the last few years we have made great efforts to improve our relationship with physicians and providers. Working with our contractors, we have taken a number of steps to ensure the information we share is consistent, clear, and unambiguous. We are making materials available in print and on the Internet, by toll free telephone request, and via satellite broadcasts, and we are developing new materials to provide updates and clarifications about Medicare. We are reaching out to physicians and providers with mailings and local and national educational seminars. And, we are listening to them, so that the information we convey is sensible, reality-based, and supportive of the care they give to Medicare beneficiaries.

While we have made substantial progress, we know we still have important work to do. We are looking to physicians and other providers for their input so that we can better focus our education efforts and make the rules required by Medicare more understandable. We have formed a special team that is helping us to pinpoint problem areas for physicians and develop suggestions to simplify Medicare requirements. For example, we have been working closely with the physician community to develop new guidelines for billing physician office visits under Medicare. We are rewriting our manuals to clarify billing instructions and enhance education. We also

are improving the physician and provider enrollment process so it will be easier to participate in the Medicare program.

We share a common mission with our physicians and providers—ensuring high quality medical care for Medicare beneficiaries. We look forward to our continued partnership with the physician and provider community, and Congress, to further improve the education, outreach, and streamlining efforts that we will discuss today.

BACKGROUND

Medicare pays for the health care of almost 40 million beneficiaries, involving nearly one billion claims from more than one million physicians, hospitals, and other health care providers. As the administrator of this program, the Health Care Financing Administration (HCFA) must strive to ensure that Medicare pays only for the services allowed by law while making it as simple as possible for qualified health care providers to treat Medicare beneficiaries. We have to carefully balance the impact of Medicare's laws and regulations on physicians and providers with our accountability for more than $210 billion in Medicare payments, and we are committed to finding the right balance.

The Health and Human Services Inspector General recently reported that Medicare pays virtually all claims correctly based on the information submitted; however, improper payments do occur for reasons such as insufficient documentation, lack of medical necessity, and improper coding. During the past five years, we have worked with physicians and providers to improve their understanding of the process. As a result, Medicare has reduced its payment error rate by half, from 14 percent in fiscal year 1996 to 6.8 percent in fiscal year 2000, meeting our 2000 Government Performance Review Act goal and keeping us on track for continued improvement. However, we realize that the volume of laws and regulations covering Medicare's responsibilities is substantial, so the need for balance has never been more compelling.

Over the last five years a number of new laws have dramatically altered the Medicare program and the health care arena, including the *Health Insurance Portability and Accountability Act of 1996 (HIPAA), Balanced Budget Act of 1997 (BBA), Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), and Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.* Combined, these laws contained hundreds of provisions that we have the responsibility for implementing, such as new prospective payment systems for numerous segments of the health care industry, including home health, skilled nursing facilities, and emergency departments; new preventive benefits; and new health plan choices for Medicare beneficiaries. The number and complexity of these changes were greater than any we had ever before experienced.

We are continuing to pursue an open process as we implement these new programs and policy changes, seeking insight and recommendations from physicians and providers, their associations, and other members of the public. This is far different from the way many private insurers conduct their business, and greatly benefits everyone as we incorporate stakeholders' recommendations into our new policies and regulations. But, as we implement these legislative and regulatory changes, we have had to undertake the most extensive education program in our history, including outreach to beneficiaries, physicians, and providers to help them understand how the changes affect them.

OUTREACH THROUGH OUR CONTRACTORS

We primarily rely on the private insurance companies, who by law process and pay Medicare claims, to communicate policy changes and other information to the physicians and providers they serve. We recognize that the decentralized nature of this system can result in inconsistent communications, and we have taken a number of steps to improve the educational process.

These efforts include:

- **Centralizing our focus for Medicare education.** We have centralized the majority of our educational efforts and their oversight in our Division of Provider Education and Training, whose sole purpose is educating and training our contractors and the physician and provider community regarding Medicare policies.
- **Providing consistency through contractor train-the-trainer sessions.** We are providing contractors with a standardized training manual and in-person instruction regarding their education of physicians and providers. These programs ensure that our providers speak with one voice on national issues. For example, coordinating with the Blue Cross/Blue Shield Association, we developed train-the-trainer sessions for the Home Health Prospective Payment System regulations. We then developed a satellite broadcast, which was rebroadcast several

times prior to the effective date of the regulation. Following the train-the-trainer sessions, we coordinated a town hall meeting; and we participated in weekly conference calls with regional offices and fiscal intermediaries to monitor progress in implementing these changes and answer questions. We performed similar activities for the Outpatient Prospective Payment System (OPPS). We continue to refine this process on an on-going basis by monitoring the training sessions conducted by our contractors.

- **Improving contractor responsiveness.** Our new Customer Service Initiative is aimed at improving contractors' responsiveness to the concerns of physicians and other providers. We are evaluating contractors' customer service efforts and surveying physicians and providers this year to see how the initiative is progressing, and where we can make further improvements.
- **Working to improve contractor outreach.** We also are strengthening and standardizing the way in which our contractors carry out education and customer service activities. We require all contractors to provide information via printed bulletins and newsletters, as well as via the Internet. This includes requiring each contractor to link to our website from its own website, giving physicians and providers immediate access to our Medicare learning network. And we are exploring the possibility of complementing our national e-mail listservs, which deliver valuable information as a broadcast email to thousands of providers, by making listservs available at the contractor level to address local as well as national concerns.

OUTREACH THROUGH OTHER CHANNELS

In addition to our contractors, we have a number of other channels for communicating with physicians, providers, and their professional organizations. We are:

- **Using our Regional Offices.** The ten HCFA regional offices are another key component of our outreach to physicians and other providers of healthcare in this country. Our regional offices oversee our contractors, assuring that contractual agreements are met and helping with solving problems between the contractor and physicians or providers. Most of our regional offices now have a Chief Medical Officer. These physicians serve as a liaison between HCFA and the local physician and provider community. And most importantly, the regional offices directly communicate with physicians, providers, and their professional organizations on a daily basis. Via organized meetings and through individual problem solving, they share information about the Medicare program and bring the issues of the physicians and providers in that region to the attention of the Agency.
- **Conducting monthly conference calls with physicians.** Each month, we conduct conference calls with physician organizations across the country to provide information and obtain feedback. The calls are open to the representatives of more than 100 national, state, and specialty associations. Participating associations often share information from these calls with their physician members. HCFA staff, including our physicians, also attend national, state, and local medical society meetings to talk with physicians, to hear their concerns, and to explain Medicare policies in greater detail.
- **Establishing toll-free information lines.** In 2000, we established toll-free lines for physicians and providers at our Medicare claims-processing contractors. The numbers are listed at www.hcfa.gov/medlearn/tollfree.htm. Each contractor also maintains a Website and electronic bulletin boards to provide information to physicians, providers, and their staff.
- **Distributing Medicare & You handbooks.** Responding to physician requests, we sent copies of the *Medicare & You 2001* beneficiary handbook to more than 500,000 individual physicians and group practice offices this past winter. The handbook is updated and mailed to all of the nearly 40 million Medicare beneficiaries as an easy-to-understand guide on Medicare's benefits and policies. In addition, we worked with the Interamerican College of Physicians and Surgeons to coordinate the mailing of Spanish versions of this handbook to more than 49,000 physicians.
- **Preventing errors through compliance guidance.** We worked with the HHS Inspector General to develop guidance for physicians and providers on how to comply with Medicare policies, and invited public comments on this guidance. Additionally, we are sharing feedback with physicians and providers, both on an individual and community level, about how to correct and prevent the types of errors identified in medical review of claims. This will help to reduce the number of improper claims among the vast majority of physicians and providers who make only honest errors.

- **Focusing on Medicare+Choice Organizations.** We also are working with managed care organizations that serve Medicare beneficiaries. We are holding numerous educational training conferences around the country for these organizations, as well as attending industry conferences to learn first hand where problems may be occurring and where there are areas of concern. Additionally, we are sponsoring conference calls with managed care organizations on specific subjects to provide guidance on emerging issues and facilitate additional training. We are reaching hundreds of managed care staff who participate in these calls from their work sites. And we consult extensively with the industry on the guidance we provide. For example, we are sharing our draft manual chapters and other policy guidance with our Medicare+Choice contractors to ensure that we fully consider their concerns before final publication.
- **Publishing articles in the Journal of the American Medical Association.** We highlight news and issues of interest to practicing physicians and others in the health care industry in quarterly articles published on the Federal Page of JAMA. These articles help to inform physicians on such topics as Medicare's new preventive benefits, Medicare+Choice encounter data collection, and Evaluation and Management Documentation Guidelines.

MEDICARE EDUCATION AND TRAINING: A PRIORITY

Through our contractors and a variety of other communication channels, we work hard to get providers the information they need to be reimbursed for caring for our beneficiaries. We communicate this information through a number of different products that employ the latest technologies and respond to the varying learning styles and needs among physicians and providers. These include:

- **Creating a Web-based Medicare education site.** We have a variety of resources available on the Internet at the Medicare Learning Network, www.hcfa.gov/medlearn. This Network provides timely, accurate, and relevant information about Medicare coverage and payment policies.
- **Providing free computer-based training courses.** Doctors, providers, practice staff, and other interested individuals can access a growing number of informational computer-based courses at the Medlearn website. Some courses focus on important administrative and coding issues, such as how to check-in new Medicare patients or correctly complete Medicare claims forms, while others explain Medicare's coverage for home health care, women's health services, and other benefits.
- **Issuing e-mail updates.** As of February 2001, almost 10,000 listserv subscribers are receiving timely updates about the two new prospective payment systems implemented in 2000 for outpatient hospital services and for home health services. We are exploring ways to provide similar listserv updates to physician and provider organizations.
- **Sponsoring satellite broadcasts.** We sponsor live, national satellite broadcasts for physicians and other clinicians about Medicare topics such as women's health, preventive benefits, and preventing billing errors. The broadcasts can be viewed in hospitals, medical schools, and virtually any other location across the country through satellite television.
- **Creating a Resident Training Program.** We are reaching out to new physicians, making Medicare information available to residents at teaching hospitals and medical schools to introduce them to Medicare and ensure they have an understanding of the program's policies early on in their careers. This program, which is currently being pilot tested and refined, includes an in-person training session, a video, a computer-based training course, and a comprehensive manual
- **Creating a Frequently Asked Questions resource.** We are developing a system to capture and compile the many individually answered physician and provider questions that come into the Agency. We will incorporate them into an ongoing compendium of Frequently Asked Questions (FAQ), and make them widely available via our website, publications, speeches, and other channels.
- **Creating a manual of Medicare basics.** We are developing an easy-to-use handbook of Medicare basics, which will be produced both on paper as well as CD-ROM. It also will be able to be downloaded from our website. The handbook will guide physicians through relevant Medicare laws and regulations. We are aiming to finalize and release the handbook by the end of this year.

PROGRAM REQUIREMENTS THAT SUPPORT PHYSICIANS

The efforts described thus far highlight our communications efforts with the physician and provider communities. Additionally, we understand that the particular

Medicare policy we are communicating must be sensible and supportive of physicians in caring for patients. In 1998, we created the Physicians' Regulatory Issues Team (PRIT) to improve the agency's responsiveness to the daily concerns of practicing physicians. This team is an agency-wide effort, and members include our leadership, HCFA physicians, technical experts, and regional office staff. The PRIT works in three broad ways. First, it has been invaluable to the agency in amplifying the voice of practicing physicians. The team has articulated for us the problem of excess Medicare burden as seen through the eyes of practicing physicians. Moreover, it has developed a vision for the agency in which Medicare requirements are not only less burdensome, but truly supportive of physicians in caring for patients. The strategy team members bring to dozens of discussions across the agency every week is that improving the integration of practicing physicians' input into our decision-making will result in better policies.

Second, the team members work within the agency to serve as catalysts and advisors to policy staff as changes and decisions are discussed. Examples include:

- **Simplifying evaluation and management guidelines.** These guidelines are cited frequently by physicians as excessively complex and fitting poorly with the way they provide care. Therefore, in cooperation with the American Medical Association, which develops the guidelines, we have undertaken a major initiative to simplify them. Since sharing new draft guidelines in a town hall meeting last summer, we have been seeking and receiving broad input from organized medicine, practicing physicians, and the Practicing Physicians' Advisory Council (PPAC), a formal committee comprised of practicing physicians who provide the Agency with a doctor's "bedside" perspective. We continue to refine the guidelines and are preparing to pilot test them later this year. Prior to implementation, we will educate physicians about the changes.
- **Streamlining Medicare forms.** With extensive input from physicians, providers, and their staff, we are developing better procedures to reduce the burden of the Medicare enrollment process on the large number of physicians and providers who provide health care to our beneficiaries. And we are exploring ways that we can use today's technology to further facilitate the enrollment process. Additionally, we are working to improve other Medicare forms, including our Advance Beneficiary Notices and Certificates of Medical Necessity.
- **Improving operational policies.** We are working to facilitate physicians' care through supportive policies. For example, we recently issued changes that allow physicians to fax their orders and "initial" changes for patients to receive wheelchairs and other needed equipment.
- **Paying for important services.** One of our overarching goals is to "pay it right," and that includes making sure physicians and other providers are compensated for the care they provide as allowed under law and regulation. For instance, as of January 1, 2001, we now pay physicians separately for their work determining patients' eligibility for the Medicare home health benefit.
- **Clarifying oversight policies.** Last year we issued a *Program Memorandum* that brings together in one place the processes for contractors to use in conducting medical review. The *Program Memorandum* responds to the comments from many practicing physicians, including that physician education and feedback are essential to the medical review process. In particular, we describe the expectation for communications between contractors and providers, noting that decisions to conduct medical review need to be data driven, and highlighting that the amount of review be only that necessary to address an identified problem.
- **Identifying and changing excessively burdensome requirements.** In a current initiative, the Physicians' Issues Project, we have identified some specific Medicare requirements that physicians frequently cite as problematic in their day-to-day practices. We received extensive input on these issues from the physician community at a recent PPAC meeting, and as a result, have chosen seven requirements for immediate review. We intend to change these requirements or reach out to physicians and providers to improve the supportiveness of the Medicare program.
- **Leveraging current channels of input from practicing physicians.** The PPAC is a valuable resource for information regarding the impact of our regulations on practicing physicians. Our staff has re-focused and re-energized our efforts and the open forum this group provides. We ask for their advice on specific issues in areas where we can benefit from the "bedside" perspective of PPAC members, other practicing physicians, and physician organizations.

Finally, the PRIT is responsible for several new initiatives aimed at increasing agency understanding of the reality of practicing physicians.

- **"Shadowing" physicians.** Working through our Kansas City regional office and the Medical Society of Johnson and Wyandotte Counties in Kansas, the PRIT has arranged for approximately 12 senior HCFA staff to spend three days next month observing primary care and specialist physicians. This same regional office is working with the Nebraska Medical Society and the National Rural Health Association to design a similar program with a rural focus for our staff.
- **Sentinel Clinicians.** We are designing a new process for querying practicing physicians from time to time, which will add to and complement our other information gathering efforts. We will use this process to listen to practicing physicians, asking them about aspects of their daily "bedside" experience of caring for patients while trying to satisfy the requirements of the Medicare program.

NEXT STEPS

We are continuing our efforts to strengthen and improve our physician and provider education programs, including the channels we employ, the products we generate, and the underlying policies of the program. We are delivering the information they need in a timely and consistent fashion, but we need to do more. We are:

- Developing a national network of "Medicare Learning Centers" to serve as host sites for satellite broadcasts, where physicians, providers, and their staff can come to view our satellite broadcasts in central locations.
- Developing a Medicare Learning Network faculty, to be available to develop and enhance our training resources. This faculty will feature nationally recognized experts on distance learning, professional education, and customer service.
- Continuing to improve our Medlearn website by offering convenient, one-stop information for Medicare physicians and providers.
- Developing special strategies for specific populations such as new physicians and providers, those who submit a high volume of claims, first time callers, and repeat callers.
- Attracting a wider audience of clinicians by integrating clinical topics with the billing and payment education aspects of our training tools.
- Upgrading our current computer-based training tools; including continuing education credits for completing certain training programs; and developing new web-based training tools.
- Developing focus groups, surveys, and other evaluation measures to help us understand how many physicians and providers use our education tools, confirm what they gain from the experience, and help us to improve continually.

CONCLUSION

Physicians and providers play a crucial role in caring for Medicare beneficiaries, and communicating clearly with them is an important aspect of administering the Medicare program. As we all know, strong communication entails both delivering and receiving information. We recognize that there is considerable concern regarding the way in which HCFA interacts with its providers and contractors. Many of these concerns are well founded. However, we hope that our new processes will improve our administration of the Medicare program. In addition, we hope that we can improve our relationship with physicians and providers. We have tried to improve our education efforts and share important information so it is easier for physicians and providers to follow Medicare's requirements. We have more work to do to ensure that we are paying physicians and other providers timely and fairly, and that they can understand Medicare's requirements. So we are actively seeking the health care community's input, paying attention to their concerns and suggestions, and working closely with our contractors to ensure we listen and explain effectively. I appreciate the opportunity to discuss our physician and provider education efforts with you today, and I look forward to answering your questions.

Mr. GREENWOOD. Thank you, Mr. Miller.

And we will now turn to Mr. Mangano.

STATEMENT OF MICHAEL MANGANO

Mr. MANGANO. Thank you, Mr. Chairman and members of the Committee. I appreciate this opportunity to be with you here this morning to talk a little bit about HCFA's activities related to educating health care professionals regarding their participation in the Medicare program.

HCFA administers this program with its contractors, and sometimes that administration requires pre and post-pay audits. Some of those audits have been reflected and are responsive to abuses that the Office of the Inspector General has found in doing our work.

When these pre-imposed pay audits uncover what they believe to be suspected fraud, they are referred to our office and that's when we begin our investigations. Clearly, the Medicare program over the years has grown far more complex and there's a number of reasons for it. There have been numerous amendments with the accompanying regulations that go to implementing those amendments, as well as the changes in the method of reimbursement from a cost based and charge based sysytem to prospective pay and fee schedules.

The structure of the healthcare delivery system has changed quite dramatically with far more vertical and horizontal integration, as well as the managed care initiatives that have taken place over the last decade. Periods of transition, as we all know, are more taxing and very uncomfortable for those persons involved in it. Since the passage of the Health Insurance Portability and Accountability Act of 1996 creating the Health Care Fraud and Abuse Control Program, our office has been seeking ways to help Medicare providers more accurately bill the Medicare program.

And when they do, Medicare pays the right amount for a covered service by a legitimate service provider to an eligible beneficiary. That's why we work so very closely with all sectors of the health care community to produce voluntary model compliance plans. We have issued so far nine of these to a variety of sectors in the health care community, including hospitals, laboratories, nursing homes, and many others.

We were pleased, by the way, just recently to hear from the Healthcare Compliance Association who completed their recent annual survey and found that 71 percent of health care organizations now have compliance plans in place. Other ways that we provide useful guidance to the healthcare community include our advisory opinions, fraud alerts, safe harbors and our publicly available work plan and final reports. All of these documents and many others are available on our OIG web site. The web site address is available in my written testimony.

I want to make it very clear that we believe the overwhelming majority of healthcare professionals in this country provide high quality care and are very honest in their dealings with the Medicare program. When we talk about fraud in the Inspector General's office, we are not talking about providers that make honest billing mistakes, but rather those very few who intentionally set out to defraud the Medicare program or its beneficiaries.

The cumulative effect of the fraud and abuse initiatives of HCFA, the Inspector General and others, has been the reduction in the improper payment rate by half, saving about $11 billion in the last 5 years, a decrease in the Medicare inflation rate to its lowest level in the history of the program and an extension of the solvency of the Medicare program by 30 years. In our most recent improper payment audit, we found that 93 percent of all Medicare payments

to healthcare providers are free of error and for that we can all be thankful.

But our job is not finished. Healthcare providers have told us and HCFA that they need more education and training and timely responses to their inquiries. Each year we have issued the improper payment report, as well as the individual reports we issue throughout the year that deal with erroneous payments of bills or troublesome regulations or report's, we have recommended that HCFA increase its education and training for its provider communities.

I am pleased to say that, at least in our view, HCFA has significantly increased its provider education activities, contributing to the 50 percent drop in the error rate. Nevertheless, even more is needed. Providers remain concerned. Their legitimate concerns about program complexity, inconsistency, burdens and hassles need to be addressed. We stand ready to help HCFA, healthcare providers and this committee, to make Medicare a more understandable program and free of the profiteers who seek to unjustly enrich themselves at the expense of the legitimate providers and the taxpayers.

Thank you, Mr. Chairman, and I look forward to answering any questions at the appropriate time.

[The prepared statement of Michael Mangano follows:]

PREPARED STATEMENT OF MICHAEL MANGANO, ACTING INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman and members of the Subcommittees. I appreciate the invitation to testify today on the important issue of the Health Care Financing Administration's role and activities related to educating health care providers and physicians regarding their participation in the Medicare program.

OFFICE OF INSPECTOR GENERAL

Let me first provide some background about the origin and purpose of the Office of Inspector General (OIG) within the U.S. Department of Health and Human Services (HHS). The HHS OIG, the first statutory Inspector General in the Federal Government, was established in 1976 because of congressional concerns that fraud and abuse were improperly inflating the cost of HHS health care programs, particularly Medicare and Medicaid. The OIG's mandated mission is to prevent and detect fraud, waste, and mismanagement, and to promote economy, efficiency, and effectiveness in all HHS programs and operations.

The core mission of the OIG is carried out through a nationwide program of audits, evaluations (called inspections), and investigations related to the operations of HHS programs. The OIG is prohibited from exercising specific "program operating" responsibilities. As part of its statutory mandate, the OIG is obligated to keep

> [T]he Congress fully and currently informed . . . concerning fraud and other serious problems, abuses, and deficiencies relating to the administration of programs and operations administered or financed by [HHS], to recommend corrective action concerning such programs, abuses, and deficiencies, and to report on the progress made in implementing such corrective action.

The Inspector General Act of 1978 ("IG Act"), § 4.

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

In contrast, HCFA with its contractors is responsible for administering the Medicare program, including the review and payment of claims submitted by health care providers, which may involve pre and post payment audits. Some of HCFA's payment review activities are the result of abuses identified in OIG audit and inspection reports. These abuses threaten the financial stability of the Medicare program and its beneficiaries. Where particular problems are identified which may be indicative of fraud, they are referred to the OIG for investigation. HCFA also has the primary responsibility for educating and working with providers to inform them on its rules.

HCFA is the largest single purchaser of health care in the world. With outlays of approximately $316.2 billion in FY 2000, HCFA is also the largest component within HHS. Medicare and Medicaid outlays represent 33 cents of every dollar spent on health care in the United States in 1999. The Medicare program is inherently at high risk for payment errors due to its size and decentralized operations (39.5 million beneficiaries, 890 million claims processed annually, 54 contractors).

THE COMPLEXITY OF THE MEDICARE PROGRAM AND IMPACT ON PATIENT CARE

Since the establishment of Medicare, numerous legislative changes have been made and amendments added to Title XVIII of the Social Security Act (the Medicare Program), which have led to a number of substantive changes. With each legislative enactment, HCFA is required to develop new regulations, as well as update its contractor and provider rules and guidelines. To illustrate, the Balanced Budget Act of 1997 contained 335 provisions related to the Medicare program, including mandates for new prospective payment systems, requiring the development of a substantial number of new regulations.

It must also be recognized that much of the complexity in the Medicare program is not inherent in the program itself, nor the result of legislative changes, but rather parallels the ever increasing complexity of the nation's health care financing and delivery systems. For example, the development of various forms of managed care and new models for vertical and horizontal integration of providers have led to the need for new Medicare rules and regulations.

Additionally, the way Medicare pays for health care has changed over time, from primarily "cost or charge based" systems to new fee schedule and prospective payment systems. For example, hospital inpatient, physician, laboratory, and durable medical equipment were the first Medicare coverage areas to be switched to prospective payment or "fee schedule based" payment systems. More recently, skilled nursing facility, home health, and hospital outpatient services have been or are being revised to become prospective payment systems. This transitioning from one type of payment system to another inevitably results in an intensive and difficult learning period for HCFA, its contractors, and health care providers. In the long run, it is hoped that these new payment systems will simplify and reduce administrative burden for providers.

While the focus of this hearing is HCFA's relationship with its contractors and providers, I would like to take this opportunity to briefly discuss the OIG's outreach activities.

HEALTH CARE PROVIDER COMPLIANCE PROGRAM GUIDANCE

The enactment of Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program under the joint direction of the Attorney General and the Secretary of HHS, acting through the OIG. This new program was designed to coordinate federal, state, and local enforcement activities with respect to health care fraud and abuse. Since HIPAA's enactment, the OIG has embarked on a major initiative to promote voluntary adoption of compliance programs by provider organizations. Our goal has been to help health care providers bill the Medicare program more accurately. When they do, Medicare pays the right amount for a covered service delivered to an eligible beneficiary.

Through its audits, inspections, and investigations, the OIG has confirmed that health care providers that have effective compliance plans including internal audit procedures and comprehensive staff training, not only provide quality services, but also have fewer systemic billing errors. In order to encourage the adoption of compliance measures by health care providers, the OIG has worked with health care industry groups to develop model, voluntary compliance plans. They identify steps that health care providers may **voluntarily** take to improve adherence with Medicare rules.

The OIG guidances are very specific in identifying risk areas for a particular health care industry sector. Since enactment of HIPAA, nine health care industry sector compliance guidances have been issued, including specific ones targeted to hospitals; home health agencies; clinical laboratories; third-party medical billing companies; durable medical equipment, prosthetics, and orthotics suppliers; hospices; Medicare+Choice organizations; nursing facilities; and individual and small group physician practices.

The OIG and the health care industry, through various organizations such as the Health Care Compliance Association (HCCA) and the Council of Ethical Organizations, have engaged in an ongoing dialogue on health care compliance to better understand and resolve the challenges associated with creating effective compliance

programs. We were pleased to read in the recent HCCA annual survey of health care compliance professionals, that 71% of health care organizations now have ongoing compliance programs in place.

HEALTH CARE INDUSTRY GUIDANCE

An important core element of the new HIPAA fraud and abuse control program is the provision of guidance to health care providers regarding potential liability for activities which may be considered fraudulent or abusive. Specifically, HIPAA requires that the OIG:

- Issue upon request *advisory opinions* regarding the applicability of the criminal and administrative sanction provisions of the Social Security Act;
- Issue special *fraud alerts,* upon request or otherwise, advising "the public of practices which the Inspector General considers to be suspect or of particular concern under the . . ." Medicare or Medicaid programs.
- Issue annually a public solicitation for proposals for issuance of both new and modified existing "*safe harbor*" regulations regarding the applicability of the Medicare/Medicaid Anti-Kickback Statute; and

The centerpiece of the OIG's implementation of the HIPAA guidance provision has been the advisory opinion process through which parties can obtain **binding legal advice** as to whether their existing or proposed health care business transactions run afoul of the Medicare/Medicaid Anti-Kickback Statute, the Civil Monetary Penalties Law, or the program exclusion provisions. Congress recently extended the authority for the "advisory opinion" process in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Over 50 formal advisory opinions have been issued since establishment of this function in 1997. The advisory opinion process also serves to improve the OIG's understanding of new and emerging health care business arrangements and guide the development of new safe harbor regulations, fraud alerts, and special advisory bulletins.

Since HIPAA's enactment, the OIG has promulgated nine new "safe harbors" under the Medicare/Medicaid Anti-Kickback Statute, and clarified or modified seven existing regulatory safe harbors. These OIG issuances have all being published in the Federal Register and are also available on the OIG's web site (www.dhhs.gov/oig).

In addition, all of the OIG's final audit and inspection reports, as well as its annual workplan and other issuances are published on its web site. Health care providers and other interested parties are regularly advised of new OIG issuances through a free "List Server" on its web site which currently has approximately 9,000 registered subscribers.

OIG/HEALTH CARE PROVIDER PARTNERSHIP

The OIG is actively engaged in working with health care providers and believe we are making good progress. We continue to believe that most health care providers do their best to provide high quality care and are honest in their dealings with Medicare. When we talk about fraud, we are not referring to the vast majority of providers who make innocent billing errors, but rather those unscrupulous few who intentionally set out to defraud the Medicare program. The importance of our ongoing work is to not only protect the integrity of the Medicare program and ensure that high quality health care services are furnished to Medicare beneficiaries, but to also make the Medicare a program in which honest providers can operate on a "level playing field"—and not at a competitive disadvantage with those who choose to defraud or abuse the program.

Continued participation of all types of health care providers—hospitals, nursing homes, home health agencies, physicians, laboratories, and suppliers—is critical to the continued success of the Medicare program. All of these providers have been profoundly affected by recent Medicare reforms. Their operations are also affected by Medicare regulations and procedures.

Provider concerns relating to inappropriate investigations and audits are unfounded and both HCFA and the OIG are reaching out to provider groups to reassure them. Under law, physicians and other health care providers are **not** subject to criminal or civil penalties for honest mistakes, errors, or even negligence. The Government's primary enforcement tool, the False Claims Act, covers only conduct undertaken with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of a claim. The False Claims Act simply does not cover mistakes, errors, or negligence. The other major civil remedy available, an administrative remedy called the Civil Monetary Penalties Law, has exactly the same standard of proof. For a criminal case, the standard is even higher. As a result of the high standards of proof

needed to establish liability under current law, the number of criminal and civil penalty actions initiated against physicians is very small.

RESULTS

OIG Medicare Fee-for-Service Audits

Over the past five years, the OIG has undertaken audits of Medicare's fee-for-service claims to estimate the extent of the resulting payments that did not comply with Medicare laws and regulations. For FY 1996, we estimated that Medicare made improper payments of approximately $23 billion, or about 14% of Medicare program expenditures. Most of the identified improper payments resulted from improperly documented claims, medically unnecessary claims, or improperly coded claims. In FY 1997, after enactment of HIPAA, the percentage of improper Medicare payments began to decrease. And most recently, the OIG audit of FY 2000 claims (issued on February 5, 2001) estimated that improper Medicare payments had dropped to $11.9 billion, or about 6.8% of the $173.6 billion in Medicare payments. The improper payment rate declined by over 50% or $11 billion in five years.

Medicare Inflation Rate

The decrease in improper payments has had a positive effect on Medicare's financial situation. From 1991 to 1996, the Congressional Budget Office (CBO) reported that Medicare's rate of inflation averaged 10.9% per year. In FY 1998, the rate of inflation for the Medicare fee-for-service program dropped to the lowest in the program's entire history (since 1965): 1.5%. Overall, CBO calculated the average Medicare inflation rate for FY 1997 to FY 2000 at 3.2%. CBO commented that: "Most of the decline can be explained by a strong effort to ensure compliance with payment rules." (The Budget and Economic Outlook: Fiscal Years 2002-2011, CBO, January 2001).

Medicare Part A Trust Fund Solvency Projections

As of 1996, the Trustees of the Medicare Part A Trust Fund projected that the Trust Fund would be insolvent in 1999. However, over the past 5 years, the Trustees have extended their estimate of the financial life of the Trust Fund by thirty years, from 1999 until 2029. One of the primary contributing factors cited by the Trustees has been "the continuing efforts to combat fraud and abuse." (Status of the Social Security and Medicare Programs, Trustees Annual Report, March 1999).

We believe that these positive economic findings with respect to the financial integrity of the Medicare program, which will positively impact on both taxpayers and beneficiaries, are due in large part to the fact that the vast majority of health care providers are engaged in submitting accurate claims to HCFA and providing high quality, medically necessary services.

FUTURE EDUCATION AND GUIDANCE ACTIVITIES

Obviously, more can be done to provide information to health care providers and physicians regarding compliance with the laws, rules, and policies governing their participation in and submission of claims to the Medicare program. At an OIG physician roundtable in July 2000, a number of concerns were raised by physicians regarding their inability to receive comprehensive and timely responses to questions raised to Medicare contractors. It was the general consensus of participants that "education and training resources would be a key factor in implementing an effective compliance program." To accomplish this goal, further use of web-based technologies should be explored, making them as "user friendly" as possible. This might include quarterly updates from HCFA regarding new policies and interpretations. Physicians also encouraged HCFA to reduce regional variations in interpretation and enforcement as much as possible. 1Finally, I want to also note that in the report relating to the OIG's recent Medicare fee-for-service improper payment audit, we made the following recommendations.

- HCFA should continue to direct that Medicare contractors expand provider training to further emphasize the need to maintain medical records containing sufficient documentation, as well as to use proper procedure codes when billing Medicare for services provided;
- HCFA should continue to highlight to Medicare providers specific procedure codes and DRGs having the highest incidence of error in our audits, as well as those codes and DRGs identified by Medicare contractor payment safeguard projects; and
- HCFA should continue to refine Medicare regulations and guidelines to provide the best possible assurance that medical procedures are correctly coded and sufficiently documented.

We have made these same recommendations with each annual payment audit, as well as with individual audits and inspection reports identifying specific improper payments. We are pleased to say that HCFA has quite dramatically increased its provider education activities over the past few years leading to the dramatic 50% drop in improper payments described earlier. Nevertheless, even more educational initiatives are needed and sought by health care providers.

Are Medicare program rules and requirements too difficult for providers to understand? In some cases our audits and evaluations do indicate that some rules are unnecessarily complex and burdensome. In such cases, we make recommendations for simplification. However, our recent Medicare improper payment audit indicated that providers are doing a very good job of negotiating their way through Medicare rules and procedures, and we estimated that 93% of all Medicare payments to health care providers were free of error. In the substantial majority of cases, legitimate providers are billing appropriately for Medicare covered services.

However, providers remain concerned. Their legitimate concerns about program complexity, inconsistency, burdens, and hassles need to be considered. Providers need reassurances that they will not be assessed penalties for honest errors. I expect that ways will be found, primarily through education and communication, to provide honest health care providers with the understanding and assurances they deserve in furnishing health care items and services to Medicare beneficiaries. We look forward to working with HCFA and health care providers in finding ways to do this.

At the same time, we must be vigilant in our efforts to protect the integrity of the Medicare program. Due to the tremendous number of claims and amount of federal dollars involved, there will always be those who will continue to take advantage of program vulnerabilities for their own unjust enrichment.

We stand ready to help the Subcommittees and all parties involved in identifying better ways to administer the Medicare program. Thank you for the opportunity to present the OIG's views.

Mr. GREENWOOD. Thank you.

Dr. Becker?

STATEMENT OF DAVID BECKER

Mr. BECKER. Good morning Chairmen Bilirakis and Greenwood and members of the Subcommittees. Thank you for the opportunity to comment this morning.

The eloquent summary statements of the committee members covered many of my issues, but allow me to illustrate some points with examples. My name is David Becker. I am a Gastroenterologist from Clearwater, Florida in a practice with two partners. Medicare patients represent 50 percent of our practice. Doctors provide precious care and support for people in what are frequently their most desperate moments. Patients come to us scared and anxious. We do our best to help them with their illness, pain and worry. Accessibility to medical doctors remains a vital national resource. Patients seeing a well-trained, up-to-date physician continues to be the cornerstone of the U.S. healthcare system.

There is a threat to this universal access for Medicare patients. More and more of doctors' time is being consumed by the morass of bureaucratically complex paperwork. Regulatory compliance requires study and knowledge of over 100,000 pages of rules and policies. A doctor's time is already restricted by the essential activity of continuing medical education needed to deliver excellent patient care. Learning a complex bureaucracy takes time away from direct patient contact. In fact, some doctors are limiting or no longer seeing Medicare patients for fear of retribution in a system they don't understand. Doctors fear retribution for errors as simple as a keystroke mistake on a computer that will miscode a charge or a diag-

nosis. These inadvertent and innocent errors can lead to time consuming and costly investigations by Medicare carriers.

Medicare patients ultimately suffer when doctors and their office staffs are diverted from patient care. Patients end up waiting longer for appointments, may have shorter time with their doctor, or in the worst care scenario lose their doctor if she or he leaves the Medicare system. In my State for example, a colleague from Deland received a notice from Medicare of an alleged overpayment, requesting a refund in the amount of $66,960 be paid within 30 days. Dr. Taylor sent the refund in to Medicare, and requested in writing a fair hearing. It was more than a year before the hearing date. Before Dr. Taylor's hearing date, Medicare sent a letter to his patients stating that they had been overcharged and a refund was due them from the physician.

Of course, this had an extremely adverse effect of his reputation and damaged his practice. After the hearing, it was determined that all but 1 percent of the claims reviewed were accurate and appropriate at the original time of filing and that he was entitled to $66,357. It took another 15 months before he received the refund. However, no letter was sent to his patients correcting the mistake Medicare had made even though he requested this in writing. Clearly, the Medicare carrier infringed upon the relationship between Dr. Taylor and his patients before any due process.

Another example is that of neurologist, Dr. Loh, in Bradenton. Dr. Loh was a physician in good standing with the Medicare program who practiced neurology in New York. He relocated to Bradenton, Florida where he applied for a Florida Medicare number. Dr. Loh has been dealing with Florida's Medicare carrier for 4 months with no apparent progress in obtaining a number to bill for neurology services. Sixty to 70 percent of his Florida practice is Medicare patients, and he is slowly running out of startup capital. Medicare beneficiaries will lose a needed, yet undeserved subspecialty practitioner if Dr. Loh's practice collapses under the behemoth of Federal regulation.

In my own practice, I brought a partner in 2 years ago who simply moved from one Florida city to another. He moved up from Key West, which may be considered another country by some, but is still part of Florida as far as I know. And he could not see Medicare patients for 4 months in our practice, which is what it took the Medicare carrier just to change his address. This was difficult for our group, but because we are a group practice, we could sustain this. But clearly for individual practitioners, this would be very difficult to sustain.

My final example involves a friend who is an internist from Winter Park, Florida. Dr. Cecil Wilson gave influenza shots to patients during the months of October and November, year 2000 during regular office visits. When his bills were filed with the Medicare carrier of Florida, payment was received for the shot, but the office visits were denied. The carrier was called and Dr. Wilson was advised that the shots should have had a modifier to be properly reimbursed. The carrier agreed that this rule had not been advertised in Medicare publications. Dr. Wilson asked the carrier if the charges could be resubmitted using this modifier. And he was told they could not. In January of 2001, Dr. Wilson's office manager at-

tended a meeting at which the Medicare staff person indicated that the action by the carrier had been an error and a correction could be obtained by calling the newly established physician phone line. Ultimately, the payments were made in February, over 4 months late for this individual physician.

Doctors are intelligent people. We have the intellectual capacity to learn and comprehend as much of the labyrinth regulatory system as anyone else. But we are not attorneys, we are physicians. Our time is dedicated to patients. Doctors should not fear that a computer keystroke error will miscode a diagnosis, which will trigger an audit that can be statistically extrapolated to a demand in the hundreds of thousands of dollars. This prevents us from practicing our chosen careers, and more importantly, denies our patient the care they need in order to live a healthy life.

Many physicians have been ruined by this system. We need due process for overpayment allegations consistent with the ideals upon which the founding fathers built America. We need a system that all parties can easily interpret. Training provided by our HCFA carriers to ensure correct coding and documentation would make an excellent start. Streamlining the mountainous regulations would further simplify life for all concerned. Communication and education as opposed to regulation and retribution will is the best way to improve ourselves and our system. Thank you.

[The prepared statement of David Becker follows:]

PREPARED STATEMENT OF DAVID BECKER ON BEHALF OF THE PINELLAS COUNTY MEDICAL ASSOCIATION

Good morning Chairmen Bilirakis and Greenwood and members of the subcommittees. Thank you for the opportunity to comment this morning.

My name is David Becker. I am a gastroenterologist from Clearwater, Florida in a practice with two partners. Medicare patients represent 50 percent of our practice

Doctors provide precious care and support for people in what are frequently their most desperate moments. Patients come to us scared and anxious. We do our best to help them with their illness, pain and worry. Accessibility to medical doctors remains a vital national resource. Patients seeing a well-trained, up-to-date physician continues to be the cornerstone of the U.S. healthcare system.

There is a threat to this universal access for Medicare patients. More and more of doctors' time is being consumed by bureaucratically complex paperwork. Regulatory compliance requires study and knowledge of over 100,000 pages of rules and legislation. A doctor's time is already restricted by the essential activity of continuing medical education needed to deliver excellent patient care. Learning a complex bureaucracy takes time away from direct patient contact.

In fact, some doctors are limiting or no longer seeing Medicare patients for fear of retribution in a system they don't understand. Doctors fear legal liability for errors as simple as a keystroke mistake on a computer that will miscode a charge or a diagnosis. These inadvertent and innocent errors can lead to time consuming and costly investigations by Medicare carriers.

Medicare patients ultimately suffer when doctors and their office staffs are diverted from patient care. Patients end up waiting longer for appointments, may have shorter time with the doctor or in the worst care scenario lose their doctor if she or he leaves the Medicare system.

My first case of the burdensome HCFA bureaucracy involves a Florida physician from Deland who received a notice from Medicare of an alleged overpayment, requesting a refund in the amount of $66,960.01 be paid within 30 days. Dr. Taylor sent the refund in to Medicare, and requested in writing a fair hearing. It was more than a year before the hearing date. Before Dr. Taylor's hearing date, Medicare sent a letter to his patients stating that they had been overcharged and a refund was due them from the physician. Of course, this had an extremely adverse effect of his reputation and damaged his practice. After the hearing, it was determined that all but one percent of the claims reviewed were accurate and appropriate and that he was entitled to $66,357.10 back. It took another 15 months before he received the

refund. However, no letter was sent to his patients correcting the mistake Medicare had made even though he requested this in writing as well, nor attempting to correct the damage done to his reputation or his practice. Dr. Taylor requested interest from Medicare on the fifteen months that his funds were held by Medicare. Medicare's response was that they only paid interest on "clean claims" that were not paid in a timely manner. As the hearing proved, these were clean claims, thus the refund. Medicare further stated that the Treasury Department has very specific criteria outlined in their regulations on when interest can be paid on claims, and that his situation did not fall into that criteria. I might add that Dr. Taylor was prohibited from submitting electronic claims for the first three months of this investigation also further affecting the practice.

Another example is that of neurologist Dr. Loh in Bradenton. Dr. Loh was a physician in good standing with the Medicare program who practiced neurology in New York. He relocated to Bradenton, Florida where he applied for a Florida Medicare number. Dr. Loh has been dealing with Florida's Medicare carrier for 4 months with no apparent progress in obtaining a provider number to bill for neurology services. 60-70% of his Florida practice is Medicare patients, and he is slowly running out of start up capital. Medicare beneficiaries will lose a needed, yet underserved subspecialty, practitioner if Dr. Loh closes his doors.

In my own practice I brought a partner in two years ago who simply moved from one Florida city to another. He could not see Medicare patients for the four months it took the carrier to change his provider number address—just the address. This was very harmful to our group practice, and for solo-practitioners, this bureaucratic delay can be devastating. From what I understand, HCFA is attempting to vastly extend this provider enrollment process—we are very concerned that this could lead to even more billing number delays for physicians wishing to see Medicare patients.

My final example involves an internist from Winter Park, Florida. Dr. Cecil Wilson gave influenza shots to patients during the months of October and November of 2000 during regular office visits. Bills were filed with the Medicare carrier of Florida. Payment was received for the shot, but not the office visit. The carrier was called and Dr. Wilson was advised that the shots should have had a .59 modifier to be properly reimbursed. The carrier agreed that the rule had not been advertised in Medicare publications, but was available from another publication, the NCCI which is published by the National Technical Information Service (NTIS) for which a one-year subscription is $265. Dr. Wilson asked the carrier if the charges could be resubmitted using the -59 modifier. The reply was no. Appeal. In January, 2001, Dr. Wilson's office manager attended a meeting at which a Medicare staffer indicated that the action by the carrier had been an error and a correction could be obtained by calling the newly established physician phone line. A call was made and subsequently the office manager faxed the names of the denied claims, as there were too many to list over the phone. In mid February payment was finally received.

Doctors are intelligent people. But we are not attorneys, we are physicians. Doctors should not fear that a computer keystroke error will miscode a diagnosis which will trigger an audit that a can be statistically extrapolated to a liability in the hundreds of thousands of dollars. Many doctors have been bankrupted by this system. We need due process for overpayment allegations. We need a system everyone can understand. We need training from our HCFA carriers for correct coding and documentation. Communication and education as opposed to regulation and retribution will greatly improve today's Medicare program.

Thank you for your time and attention and for the opportunity to present my views.

Mr. GREENWOOD. Thank you, Dr. Becker.

Ms. Bradley?

STATEMENT OF JYL D. BRADLEY

Ms. BRADLEY. Good morning. On behalf of MGMA, I would like to thank Chairman Bilirakis and Greenwood for convening today's hearing on the health care financing administration's relationship with providers and contractors. My name is Jyl Bradley, the administrator of Dunning Street Ambulatory Care Center, a Medicare licensed ambulatory surgery center located in Claremont, New Hampshire.

I am a member of the Medical Group Management Association and am the immediate past president of the New Hampshire MGMA. MGMA members work on a daily basis ensuring that their practices provide the best care possible to Medicare beneficiaries, while at the same time navigating their medical groups through a sea of complex and contradictory rules, regulations, and policy memorandums. As a result, our members are uniquely familiar with the administrative requirements of Medicare's regulations.

I have worked in healthcare since 1973, managing special team primary care practices ranging in size from three to 15 physicians. As a group practice administrator, I am charged with many diverse responsibilities. I have detailed those duties and those of my administrative team in my formal testimony.

With three physicians and six administrative support staff, our practice is representative of small group practices nationwide, as well as those predominantly found in rural areas. Generally, the ratio of administrative staff to physicians ranges from two to 10 staff per physician. Small practices, such as mine, struggle with limited resources to deal with the magnitude and complexity of multiple Medicare regulations as well as the difficulties caused by the program's poor administration.

My comments today focus on the administrative ills of the Medicare program and how they lead to inefficiencies in medical group practices as well as in the Federal Government. While MGMA agrees with the current and previous administrations that additional HCFA funding is warranted, the efficiencies resulting from improving HCFA's organization, communication and responsiveness will vastly improve the system without creating additional cost.

Let me provide you with examples of breakdowns in the administration of Medicare. I begin my discussion with two examples of problems experienced by my practice followed by another experience by colleagues nationwide. Included in my written testimony are many more examples, which I would be happy to share with you during the Q&A.

My first example pertains to when our ambulatory surgery center completely stopped receiving Medicare facility reimbursements for services performed. After I placed numerous phone calls to determine the source of the problem, a carrier representative finally told me that our provider number had been inactivated due to a mail return from our facility. Without even so much as a phone call to my practice, all reimbursements stopped. It took months of letters and telephone calls to identify the appropriate person who had the knowledge and the authority to correct this situation. During this time, the financial hardship on our practice was enormous.

This was a simple mistake that should have had a simple solution. Instead, it took approximately 6 months to resolve. This problem highlights the inefficiencies within the Medicare program whereby a seemingly small problem through a series of carrier breakdowns resulted in a substantial cost to my practice as well as that of the carrier.

My second example occurred when HCFA implemented new Congressionally mandated regulations initiating coverage of screening colonoscopies for Medicare beneficiaries with high risk. The system

developed by the carrier was not equipped to handle the facility codes, which reimbursed costs to ambulatory surgery centers. Claims were routinely denied. It took months of telephone calls to the carrier and persistence to resolve this matter, only then to lead to a different problem. That is, claims for the anesthesia necessary for the procedure began being rejected. In other words, a beneficiary could have a colonoscopy, but only without anesthesia.

Our carrier was not prepared to handle these new rules. Now I am concerned about the new rules that will take effect on July 1, 2001, which expand the coverage for screening colonoscopies for individuals with average risk. Based on my prior experience, I can only imagine how long it will take before this new coverage policy will be properly implemented.

This second example illustrates a routine program change whereby the Medicare program failed to undertake a close examination of the system changes necessary for proper implementation. Again, this implementing breakdown caused inefficiencies that resulted in a drain of resources for my practice as well as that of my carrier, and ultimately the program.

My third example pertains to the October 30, 2000 quarterly update of the correct coding initiative, or CCI. Without any prior notice to providers or carriers as to its contents, the CCI disallowed the billing of over 800 procedures when performed on the same day as 66 different evaluation and management codes. Providers were never told that as a result of this revision, they were required to use a 2-5 billing modifier, or annotation. Implementation of the CCI update resulted in thousands of claim denials. To further exacerbate the situation, carriers denied claims that actually used the correct modifier.

In a memo sent out to the provider community outlining the problem in late January, HCFA admitted that unfortunately a number of carrier processing systems do not recognize the 2-5 modifier with certain codes. While parts of the October update were rescinded on February 8, 2001, the original implementation occurred at a tremendous cost to both providers and carriers. Not only did this communication breakdown between HCFA, the carriers, and ultimately providers result in physician practices around the country having to resubmit thousands of denied claims billed from October 30, 2000 to February 8, 2001. It undermined the trust and credibility necessary to preserve a good working relationship between practices and carriers.

As a side note, if my, or any other practice, desires access to the quarterly CCI update, it is only available for purchase at a cost of $300 annually. There are many more examples such as these that I could share with you as well as possible solutions that MGMA has identified. However, for the sake of brevity, I have included these in my written testimony. As you continue your oversight of this program and developed recommendations for improvement, I urge you to personally visit a group practice in your district and discuss Medicare's complexities with the practice administrator.

On behalf of the Medical Group Management Association, I thank you very much for the opportunity to share our thoughts with you today. MGMA realizes that both the carriers and HCFA are called upon to accomplish an extremely difficult and complex

task. MGMA members and staff are available as resources as you continue your examination of this critical issue. Thank you.

[The prepared statement of Jyl D. Bradley follows:]

PREPARED STATEMENT OF JYL D. BRADLEY ON BEHALF OF THE MEDICAL GROUP MANAGEMENT ASSOCIATION

Good morning. My name is Jyl D. Bradley, MHP, FACMPE. I am the administrator of Associates in Surgery and Gastroenterology, LLC, a three-physician multi-specialty practice, and Dunning Street Ambulatory Care Center, LLC, a Medicare licensed ambulatory surgery center located in Claremont, New Hampshire.

I am a member of the Medical Group Management Association (MGMA) and the immediate past president of the New Hampshire MGMA. I have a Bachelor of Science in Health Care Administration from The University of New Hampshire and a Masters in Health Policy from Dartmouth College. I have worked in health care since 1973, managing specialty and primary care practices ranging from three to fifteen physicians.

MGMA is the nation's oldest and largest medical group practice organization representing more than 18,000 administrators working in organizations in which over 176,000 physicians practice medicine. MGMA's membership reflects the full diversity of physician organizational structures today. MGMA members work on a daily basis ensuring their practices provide the best care possible to Medicare beneficiaries, while at the same time navigating their medical groups through a sea of complex, and contradictory rules, regulations, and policy memorandums. As a result, our members are uniquely familiar with the administrative requirements of Medicare's regulations.

On behalf of MGMA, I would like to thank Chairmen Bilirakis and Greenwood for convening today's hearing on the Health Care Financing Administration's (HCFA) relationship with providers and contractors. My comments today will focus on the administrative ills of the Medicare program and how these problems lead to federal government and medical group practice management inefficiencies, unnecessarily diverting limited resources away from patient care. While MGMA agrees with both the current and previous Administrations that additional HCFA funding is warranted, the efficiencies resulting from improving HCFA's organization, communication and responsiveness will vastly improve the system without creating additional costs.

As a group practice administrator, I am charged with many diverse responsibilities. The physicians in our practice rely on my expertise to guide them through the innumerable and continually changing federal rules and regulations, including coding, documentation, billing, physician referral rules, Local Medicare Review Policies, physician credentialing and assignment and reassignment of patient and physician billing rights. As the physician's time is consumed by providing patient care and documenting that clinical care, they depend upon my business acumen to maintain smooth daily operations.

My tasks include but are not limited to: managing information systems; serving as corporate compliance officer; monitoring and negotiating contracts with our many private payers; staffing board meetings; and developing relationships with lending institutions and area hospitals. Furthermore, I am responsible for staff training and development; facilities management; and the employee/physician compensation and benefit plans. In addition to being responsible for Medicare compliance, the typical administrator must also deal with a host of other federal, state and local laws and regulations including tax, CLIA, OSHA and other labor requirements.

My staff's responsibilities include managing patient flow, submitting and monitoring claims, helping patients with insurance questions, determining medical necessity of certain services such as laboratory tests, and completing encounter and referral forms. These are full-time tasks for myself and my administrative team—6 full-time equivalent support staff including medical secretaries, transcriptionists, billers, accounts receivables personnel and patient coordinators.

With three physicians and six support staff, our practice is representative of small group practices nationwide, as well as those predominantly found in rural areas. However, our ratio of physicians to administrative staff is extremely low. Based on the experience of MGMA members, physician practices maintain anywhere from double to ten times the number of administrative staff to support the physician workload. Small practices, such as mine, struggle with limited resources to deal with the magnitude and complexity of multiple Medicare regulations as well as the difficulties caused by its, at times, poor administration.

There is a chasm between the amount and complexity of federal regulations, the level of communication, organization, and responsiveness of HCFA and its contractors to medical group practices and the ability and time of most managers to understand these regulations, much less to comply. Regulations such as the recently released privacy rule create a gold mine for attorneys and consultants, but an administrative landmine for our medical group practices.

Examples of Breakdowns:

Let me provide you with actual examples of breakdowns in the administration of Medicare. I will begin my discussion with two examples of problems I have personally had with HCFA and my particular carrier followed by those experienced by my colleagues nationwide. Through these examples, I hope to give you some insight into medical group practice management and the constant battles and inefficiencies in the Medicare system we struggle to overcome. As you continue your oversight of this program and develop recommendations for improvements, I urge you to personally visit a group practice in your district and discuss Medicare's complexities with the practice administrator.

• *Lack of Organization and Responsiveness of Contractor:* In 1998, our ambulatory surgery center stopped receiving Medicare facility reimbursements for services performed. After many phone calls, I discovered our carrier had received a "mail return" from our facility. Without so much as a phone call investigating the matter, the carrier automatically inactivated our provider number and halted reimbursement. It took months of letters and telephone calls to correct this situation, much of which time was spent merely trying to locate the appropriate contact person. During this time, the financial hardship on our practice was enormous.

• *Lack of Preparedness of Carrier to Handle HCFA Changes:* In January 1998, HCFA implemented new regulations initiating coverage of screening colonoscopies for Medicare beneficiaries with high risk. When the new regulations were introduced, our carrier created a "special" code for billing purposes. The physician component received reimbursement with minor delays. However, the system developed by the carrier was not equipped to handle the "special" facility codes which reimburse overhead costs to ambulatory surgery centers. Claims were routinely denied. It took months of telephone calls to the carrier and persistence to resolve this matter—only then to lead to a different problem. That is, anesthesia claims began being rejected when attached to this "special" code. This problem has been extremely difficult and time consuming and again was only recently resolved. Our carrier was not prepared to handle these new rules and I am now concerned about the upcoming rules that will take effect on July 1st 2001, making screening colonoscopies a covered benefit for individuals with average risk. Based on my prior experience, I can only imagine how long it will take until this new coverage policy will be properly implemented.

• *Lack of Communication from HCFA to Contractors and in turn to Providers as well as Ineffective Routine System Changes:* On October 30, 2000, HCFA sent carriers an electronic quarterly update of the Correct Coding Initiative (CCI). The CCI contains more than 121,000 pairs of codes that cannot be billed on the same claim to Medicare. Each quarter it is "updated" to add or delete various code combinations. Under the CCI, claims are scanned and scrubbed electronically for "disallowed" code pairs, which are then automatically denied.

Without any prior notice to providers or carriers as to its contents, the October version of the CCI disallowed the billing of over 800 procedures when performed on the same day as sixty-six different evaluation and management (E&M) codes. Providers were never told that as a result of this revision, in order to bill for any one of the 800+ procedures on the same day as a physician visit or other E&M code, they were required to use the "-25" billing "modifier" or annotation. Implementation of the CCI update resulted in thousands of claim denials. However, many carriers did not become aware of the cause of the denials until the provider community notified them of the problem. The carriers simply implemented the electronic edits received from HCFA without knowing how the action would affect their claims processing operation. To further exacerbate the situation, carriers denied claims that actually used the correct modifier. In a memo sent out to the provider community outlining the problem in late January, HCFA admitted that, "Unfortunately, a number of carrier processing systems do not recognize the -25 modifier" with certain codes.

While parts of the October update were rescinded on February 8, 2001, the original implementation occurred at tremendous cost to both providers and carriers. Not only did this communication breakdown between HCFA, the carriers and ultimately providers, result in physician practices around the country having to resubmit thousands of denied claims billed from October 30, 2000 to February 8, 2001, it undermined the trust and credibility necessary to preserve a good working relationship between practices and carriers. As a side note, members of the Committee might

be interested to know that if my, or any other practice, as a participating provider in the Medicare program, desires access to a copy of the quarterly CCI update, it is not accessible online and *only* available through NTIS Products (HCFA's authorized distributor) for an annual $300, four issue, subscription fee or $85 per single update, plus shipping and handling.

• *Inconsistencies between HCFA manuals and Medicare Statute:* Frequently, the relationship between providers, carriers and HCFA is strained due to the ambiguous and, at times, incorrect information in the Medicare Carriers Manual itself. The Medicare Carriers Manual contains HCFA's instructions to its carriers on how to administer the program. The following technical, yet illustrative example shines light on one such example of this problem. Under 1861(s)(3) of the Social Security Act, "diagnostic x-rays, diagnostic laboratory services and other diagnostic tests" are covered *separately* by Medicare from physician services. However, section 2070 of the Medicare Carriers Manual states "for diagnostic X-ray services and other diagnostic tests, payment may be made *only* if the services are furnished by a physician or incident-to a physician service (which requires direct-supervision by the ordering physician). This carrier manual provision is contrary to the Social Security Act Section 1861(s)(3) coverage provisions for these services and has caused numerous interpretive problems between providers and carriers concerning the appropriate level of physician involvement and supervision.

• *Lack of Notice to Medical Group Practices of HCFA's Intentions to Change Billing and Payment Rules:* Medical group practices trying to play by the rules are often blindsided by policies implemented without notice or input by the effected parties. For example, in May of 1998, HCFA issued Transmittal No. 1606, which drastically changed the rules for billing for allergy immunotherapy. The new rule, which amended the definition of "dose," meant that physicians could, in most situations, only bill for half as many doses as they had actually prepared. HCFA's interpretation went against longstanding practice and was inconsistent with the Current Procedural Terminology (CPT) Code definition and the American Medical Association's CPT guidance. This change was announced with no notice to the physician community. The effect of the adjustment reduced reimbursement in half for allergy immunotherapy billed under CPT Code 95165. It took the affected physician practices and their representatives two and a half years to get HCFA to see the error of its policy. The policy was finally rescinded effective January 1, 2001 with the implementation of the 2001 Medicare physician fee schedule.

• *Carrier Mistakes Unresolved:* While some Medicare carriers and intermediaries are quite good, others are plagued with problems that may take months to resolve. Prompt action by Medicare carriers and intermediaries to resolve their own mistakes is critical to the Medicare program. The following example from a colleague of mine illustrates this point.

In September 1999, a large multi-site practice organized as a rural health clinic, located in Michigan, received Medicare checks totaling $1,260,184.84, far in excess of their billed charges. The management service organization (MSO) that does billing for these clinics, immediately notified United Government Services, LLC, (UGS) their Medicare fiscal intermediary, about this overpayment and were told that the intermediary would get back to them on the issue. The MSO asked if they could return the checks but UGS instructed them to retain the payment until the problem had been sorted out. The MSO contacted the intermediary once a week for a month before they were told that there had been a problem with UGS' processing system that had produced this overpayment. UGS' Detroit office instructed the MSO to retain the money and that it would be recouped via withholdings from future payments. The MSO informed the Medicare intermediary that recouping the money in this way would take a minimum of five years. UGS' response was that the same type of erroneous payments had been sent to a number of other physicians. These incorrect payments were direct deposited to the physicians' accounts and as a result the physicians were drawing interest on the money. The clinic in question's payment had been sent in the form of a paper check and it did not want to cash it in the first place.

To resolve this problem the MSO spent an extensive amount of time attempting to obtain corrected explanations of benefits so that they could ascertain what the correct payment should have been and then return the difference. This process took months and involved a great deal of back and forth between the MSO and the Medicare Intermediary. Finally, on September 21, 2000, more than a year after the initial overpayment by the fiscal intermediary, these problems appeared resolved and the overpayment was returned to UGS the Medicare intermediary.

The problem, however, was not resolved at this point. During the year in which the clinic and its MSO billing entity had been attempting to sort out the problem, UGS, the intermediary had, as they originally proposed, been withholding Medicare

payments due to the clinic to make up for their original erroneous overpayment. When the MSO returned the overpayment, UGS *continued* to withhold payment for current claims. To date the withholding has not ceased and UGS now owes some $88,000 for services provided by the clinic.

• *Lack of HCFA Oversight and Enforcement of its Requirements Over Contractors:* The Medicare Carriers Manual, under Section 1030.1 (enrollment instructions to the carriers) states "absent extenuating circumstances, [a carrier must] process an application for non-certified providers within 45 calendar days of receipt of the application. For certified providers, process the application within 30 calendar days, absent extenuating circumstances. If you need to review the application for incomplete or missing information, the processing time stops. *Complete the review of the application and annotate what information is missing prior to returning application* (emphasis added)." In reality, this is not what occurs. If a carrier finds an error in the application, it sends it back to the provider at the first instance of an error taking place. Once corrected by the provider, the application goes to the "back of the line" to begin the process anew. Due to the complexity of the 34 page application and instructions, this resubmission process sometimes may occur several times before a physician is enrolled in the program. If a review was actually done in a complete manner as per the Medicare Carrier Manual, and the information annotated in its entirety, *before* being returned to the provider for correction, the process would work much more efficiently. Instead, it now may take up to 6 months to enroll a physician in the program. During this time period, a physician can examine and treat Medicare patients, but all claims resulting from those services cannot be submitted for payment until the certification process is complete. Situations like this are particularly aggravating given that the physician enrollment process has no statutory foundation in the Medicare Act and HCFA has spent years trying to develop regulations governing the enrollment process.

• *Lack of Provider Education Tools and Recent Action in the Wrong Direction:* Education of providers concerning how to comply with rules and regulations is fundamental to the efficient administration of the Medicare program. I know of few, if any, physician practice managers who also happen to be lawyers. What is needed in the Medicare program are written materials and other unambiguous communications that explain the rules and regulations in a clear and concise manner. It is distressing to see directives from HCFA to its carriers that impede the system's delivery of such necessary tools to its participating Medicare providers. For example in a January 25, 2001 Program memo (AB-01-12), from HCFA to its carriers, HCFA permits its carriers to charge a fee to providers for "reference manuals, guides, workbooks, and other resource materials developed by the contractor designed to supplement or provide easy reference to formal Medicare provider/supplier manual and instructions." For practice managers, the idea that we may now have to pay carriers a fee for access to simplified and reasonable reference materials is difficult to understand. At a minimum, this type of guidance is clearly the wrong direction to take in providing proper education and communication between providers, HCFA and the carriers.

Proposed Solutions:

There are many more examples such as these that I could share. The system is in dire need of change. But, instead, let me turn to solutions. While these are far from exhaustive, attending to the following would provide necessary first steps toward healing this ailing program.

• Congress should require the Secretary of Health and Human Services (HHS) to publish in the Federal Register, on no less than a quarterly basis, a notice of availability of all proposed policy and operational changes which may affect providers and suppliers including but not limited to changes to be issued through amendments to its carriers manuals and other HCFA manuals, or program memoranda, program transmittals or operational policy letters, and of all such policy and operational changes issued in final form during the previous quarter. Simultaneous with publication in the Federal Register, the Secretary should transmit such proposed and final policy and operational changes to its Medicare contractors. The Secretary should require that its contractors notify all providers and suppliers in their service areas of such changes within 30 days of this Federal Register notice. The Secretary should further provide that any changes issued in final form will take effect no earlier than 45 days from the date such final change was noticed in the Federal Register. The Secretary should not make a change in policy or operations that affects providers and suppliers without going through the public notice process unless such change is required to meet a statutory deadline or is otherwise required by law. In that event, the Secretary must publish such change in the Federal Register along

with the Secretary's justification for issuing such change in a manner other than that required.

• Congress should require the Secretary of HHS to create and distribute a user-friendly manual that contains all the information necessary for Medicare compliance. The manual should be organized, accessible (including on-line), free and updated quarterly. It should contain, in addition to actual regulations and program memorandum, etc., a summary of each issue, Q&A and other explanatory/supplemental material. I would be remiss not to note that as part of its small group compliance guidelines, the Office of Inspector General suggested that small groups create such a document on their own. Can you imagine that if HHS has not even accomplished this task with its many employees, how medical group practices such as mine with only 6 support staff could accomplish such a feat?

• Congress should require the Secretary of HHS to develop a site on the Internet, similar to what HHS has already developed for the Health Insurance Portability and Accountability Act section of their Web site, where Medicare providers and suppliers can post questions and obtain feedback. Responses should be maintained on the Internet site for reference.

• Congress should require the Secretary of HHS to furnish all education and training materials and other resources and services free of charge for providers, eliminating all user fees. The education materials should be drafted in easily understandable language with contact information should questions arise. The materials should be free and accessible on-line.

• Congress should require the Secretary of HHS to make every effort to educate not only the provider community but also its own staff and those of its contractors.

• Congress should instruct HHS to provide better oversight of its contractors to ensure uniform application of national policies and efficient administration of the Medicare program.

• Congress should require the Secretary of HHS to enhance and make public its contractor evaluations. The report should include all components of training, education, auditing and payment. Medicare providers and suppliers should be granted a formal process to provide feedback on the evaluation directly to HCFA.

• Congress should require the Secretary of HHS to annually conduct a review of, and report to Congress on, the sources of complexity in the Medicare program as is required of the Internal Revenue Service in Section 4022 of the IRS Restructuring and Reform Act of 1998.

• Congress should provide the Secretary of HHS with the resources necessary to adequately manage the Medicare program without provider user fees.

On behalf of the Medical Group Management Association, I thank you very much for the opportunity to share our thoughts with you today. MGMA realizes that both the carriers and HCFA are called upon to accomplish an extremely difficult and complex task. MGMA members and staff are available as resources as you continue your examination of this critical issue.

Mr. GREENWOOD. Thank you, Ms. Bradley.

Dr. Wood?

STATEMENT OF DOUGLAS L. WOOD

Mr. WOOD. Good morning Chairman, Chairman Greenwood, Chairman Bilirakis, Mr. Brown, and members of the subcommittees. I am privileged to have this opportunity to share with you my insights regarding the complexity of the management of the Medicare program and in my short time, I hope that I can give you a better understanding of the impact of these actions on the daily practice of medicine.

My experience is over the last 10 years working in coding and nomenclature activities, functioning as the Chair of the Carrier Advisory Committee in Minnesota and my privilege to sit as a member of the Practicing Physicians Advisory Counsel and have given me a set of insights which I hope will be productive in the discussion, especially listening to the opening comments of many of the members of the Subcommittees.

Now there has been much made, even this morning, about the complexity of regulations of Medicare including the thousands and

thousands of pages of regulations. But if you take even the most conservative estimate, and that I think is HCFA's estimate of 35,000 pages, and consider that the leading textbook of cardiovascular diseases now has 2,000 pages in it, then it means that I have to learn about the equivalent of 15 textbooks of administrative rules and regulations for my practice. And even just a few of these policies, when applied in an inconsistent or an erroneous fashion by a Medicare carrier, can have an even more deleterious effect on the daily practice of physicians.

Indeed and perhaps most cases, the most adverse circumstances that physicians encounter are those that come more from the carriers in their attempt to interpret the rules and regulations rather than from HCFA Central or even from my colleagues at the OIG.

My written statement includes a number of detailed descriptions of events that have surrounded the care and the billing of patients in the Medicare program. And in one of these circumstances, a colleague of mine who spent nearly 50 minutes counselling a patient with heart failure about changes in medications is detailed. After a 2-year saga, including the denial of payment and then finally ending up with a hearing in which the service was downcoded, the physician now confronts a circumstance where he still is considered to have filed an erroneous claim. The error on the part of the carrier will never be recognized.

And it is not hard, I submit, for you to imagine the impact of this experience on the physician. The next time that he confronts a patient like this, he will have several choices. One choice is to spend less time with the patient. Unfortunately, the result of this might be a hospitalization, one that would have been preventable. At an average case cost of $10,000, it is clear that HCFA cannot afford to have many of these preventable hospitalizations when it would have been more reasonable to pay the $100 office visit for the counseling necessary to manage the patient's medications.

But more likely, what will happen is that the physician next time will simply downcode the service to avoid an interaction with the carrier and instead take care of the patient in the most appropriate way. This is not how I believe the Congress intended Medicare to work. Carriers often implement local medical service or policies or local medical review policies to address problems in variation of utilization. Minnesota has some 100 of these policies, Wisconsin next door has over 220. I can tell you that the practice of medicine between these two States is not sufficiently different to account for such a difference in regulation.

My written statement also includes information to show you that this regulation, this excessive regulation in one State, does nothing to improve the quality of care, nor to have a substantial impact on the spending for physician's services on a beneficiary basis. Indeed, additional carrier decisions that limit the payment for services for Medicare beneficiaries with chronic diseases like cancer, heart disease, hypertension and diabetes cause profound confusion for beneficiaries and providers alike. And in that circumstance, this overemphasis on regulation and the pressure to develop these policies then is an unhelpful distraction that keeps us from devoting the needed attention and resources to making sure that Medicare beneficiaries around this country receive the best possible care.

In my statement, I have summarized for you some specific actions that I think should be taken in the short term to improve this circumstance. HCFA should work as fast as possible to develop national payment policies for some commonly performed procedures that would reduce the necessary regulation at a local level. HCFA should work with its carrier medical directors to develop a uniform approach to payment for services for patients who have chronic diseases like cancer, heart disease, diabetes and hypertension.

HCFA must better supervise to the performance of the carriers. There should be some different solutions for providers to demonstrate their compliance with these regulations as well as restore the ability of the physician to become an advocate for the patient and being able to get the most appropriate care. HCFA should aggressively pursue and resolve all of these issues that have been identified by Dr. Barbara Paul and her colleagues working as the physician's regulatory issues team at HCFA. And their recent statement to us that the PPac, it was indicated that limited resources meant that they had to focus on only a few of those issues, although I know that they have the interest in addressing all of them.

And the Congress should now allocate a reasonable administrative budget for beneficiary and provider service and have a greater expectation for service to beneficiaries and providers. Recently, HCFA leadership has been criticized for its inattention to PPAC recommendations, but my recent experience demonstrates that PPAc can have a positive effect. There, however, remains considerable opportunity for improvement.

The comments that were made earlier and referred to in testimony about the advance beneficiary notice are illustrative. When I joined the Minnesota Carrier Advisory Committee in 1992, the advanced beneficiary notice was one of the first items on our agenda, and it has taken a long time to get this particular problem solved. The changes that have occurred at PPAC give me tremendous optimism for the future, but there does remain a need for more effective leadership within HCFA to try to more effectively get groups to work together to achieve the goals of providing the best care to Medicare beneficiaries, while at the same time doing everything necessary to ensure the integrity of the program for future beneficiaries.

It is simply too important that we all be successful in meeting the increasing needs of our elderly that we risk success in this endeavor by being unable to work collaboratively to achieve these solutions.

I thank all of you for your concern and for your leadership in pursuing Medicare Program improvements.

[The prepared statement of Douglas L. Wood follows:]

PREPARED STATEMENT OF DOUGLAS L. WOOD, MAYO CLINIC

Good morning Chairman Bilirakis, Chairman Greenwood, Mr. Brown, Mr. Deutsch, and members of the subcommittees. I am privileged to have this opportunity to share with you my insights regarding the complexity of the management of the Medicare program and its adverse impact on the care of Medicare beneficiaries. I will try, in my short time, to give you a better understanding of the impact of actions of HCFA and the Medicare carriers on physicians in the daily practice of medicine.

I am a practicing cardiologist at the Mayo Clinic in Rochester, Minnesota, where I often care for elderly patients. For the last decade, I have been involved in the work of coding and documentation, interaction with Medicare carriers and with the Health Care Financing Administration. I have served on the CPT Editorial Panel (where I chaired the first ad hoc subcommittee on development of documentation guidelines for evaluation and management services), and continue to serve on the CPT Advisory Committee. I am a member of the Medicare Carrier Advisory Committee in Minnesota and have been the physician chair of this committee for the last four years. In this work, I have direct interactions with the medical directors and staff of the Medicare Carrier. I have worked with the PRO in Minnesota to improve the quality of care for heart attack patients. And, for the last year, it has been my privilege to serve on the Practicing Physician's Advisory Council for HCFA.

INTRODUCTION

Much has been made of the complexity of Medicare regulations by reference to the sheer volume of regulations. The number of pages of regulations is not as relevant to practicing physicians as the daily impact of only a few of these policies and regulations. I hope to give you a real and more practical understanding of the impact of regulations by sharing recent experience with documentation guidelines, local medical review policy and their impact on patient care. My examples will be those of real patients and physicians. Then I will speak about the Practicing Physicians Advisory Council. Last, I will suggest to you several possible solutions to the problems we discuss today.

DOCUMENTATION GUIDELINES FOR EVALUATION AND MANAGEMENT SERVICES

Medicare has tried to develop guidelines for documentation of physician visits since the current coding system was adopted in 1992. Three separate attempts have been made since 1993 to develop a set of guidelines that would be simple, not interfere with the process of care and be useful for carriers in their administration of the Medicare program. Unfortunately, none have been satisfactory to all users, and so we are in the midst of yet another effort. It is not difficult to imagine the cost of these repeated efforts, both for physicians and for HCFA.

Consider this example. An elderly man with heart failure was seen by his cardiologist in March of 1999 for evaluation of his progress with his cardiomyopathy and adjustment of his medication. The physician spent 50 minutes with the patient, the majority of which was devoted to counseling the patient about his medications and changes in the regimen. The physician billed Medicare for a level five visit based on the counseling services and time required. The physician documented the time spent delivering the service and his counseling, emphasizing that "many questions were answered", and consistent with HCFA documentation guidelines[1] that the physician should document the total time required and the nature of the counseling service. However, this service was denied by the carrier in February 2000, and when the denial was appealed by the physician, a hearing officer held that the coding based on time was irrelevant and thus down-coded the service. This ruling (which came in March of 2001, two years after the original service) was made despite a clear direction from the Medicare Carrier's Manual that the carrier should pay for counseling services when appropriately documented. Thus, in this case, the physician provided a medically necessary and appropriate service, documented the service according to existing guidelines and ultimately required two years and a hearing to be paid even a part of what was appropriately due the provider. Even worse, this obvious error on the part of the carrier will not be recognized or used in the development of improved review mechanisms. And, it will still ultimately be considered that the physician made an error in billing when, in fact, the carrier simply decided that it did not want to pay for the service. More frustrating is that the physician has no other appeal rights since the amount in dispute does not meet a $500 minimum for appeal to an administrative law judge.

This example illustrates the adverse impact of a single set of regulations developed at a national level, applied improperly by the carrier on the local level and an unnecessarily burdensome and flawed appeals process. One possible effect of this experience for the physician will be to make him less likely to spend necessary time in the counseling of patients in the future if he knows that the carrier will not pay

[1] 1995 Documentation Guidelines for Evaluation and Management Services, http://www.hcfa.gov/medicare/1995dg.pdf. "DG: If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care."

for the service and will consider that he codes inappropriately. The other, and most likely, option for the physician is simply to down-code his services, since the patient would be otherwise poorly served. The latter option is occurring more often than we might imagine; the frequency of this action is difficult to measure with precision. It is not difficult to imagine that this physician feels uncertain in his coding, and worried about what future sanctions he might face. The more serious effect of this kind of activity is to threaten the care of Medicare beneficiaries. Over 10% of hospital admissions of the elderly are related to adverse drug reactions; most of these hospitalizations are preventable with careful office management of patients, involving counseling patients about their treatment, dosage changes and possible medication side effects. The application of a payment policy that discourages appropriate office counseling will result in greater expense to HCFA because of the costs of inpatient care, and greater risk to patients. This is not how Medicare should work.

LOCAL MEDICAL REVIEW POLICY

Consider the example of local medical review policy. Local medical review policies are often created in response to utilization variation, and there seems to be some pressure from HCFA for carriers to demonstrate their capability of implementation of such policy. These local policies, however, serve mostly to create additional burden for physicians (including risks for errors in coding and billing) and have little apparent effect in controlling cost or improving care.

In the upper Midwest, four states are served by a single part B carrier. There are 107 local medical review policies in Minnesota; but 244 local medical review policies in Wisconsin[2]. It is not likely that there is so much difference in medical practice between these two states that one carrier should have twice as many medical review policies that affect how physicians can bill for their services. This discrepancy is even more dramatic if you consider carrier differences for patients with heart disease; Minnesota has nine policies for cardiovascular disease, Wisconsin has twenty-seven. None of this has a direct positive influence on the quality of care or per-beneficiary cost of physician services. Minnesota, in a study done by Dr. Steven Jencks[3] and colleagues from HCFA, has the highest quality performance of these Midwestern states (in fact, Minnesota ranks fourth in the country in quality). This excess regulation has not achieved a substantial reduction in spending; there is only a 6% difference between Minnesota and Wisconsin in spending for physician services. And, for the other two states, quality is worse (both are below the national median) and per beneficiary spending is even greater in the other states than in Minnesota.

CARRIER MEDICAL DIRECTOR DECISIONS

Other problems created by carrier decisions may cause undue distress for beneficiaries, providers, and even HCFA. Consider the coverage of physician's services for patients with chronic disease. Medicare does not pay for routine preventive visits. Most physicians would consider this prohibition to apply to patients without an acute or chronic medical condition who seek preventive services for an undiagnosed condition. However, Medical director decisions in Minnesota in the last two years that visits for routine care are not covered by Medicare have caused considerable difficulty for Medicare beneficiaries and physicians. Beneficiaries are confused and face more out-of-pocket costs for care they and their physicians believe is appropriate for their medical problems. Providers are confused and cannot understand when visits are covered and when they are not. When a carrier makes a decision to deny the claim after the fact as being non-covered, the provider has no appeal right and must then re-bill the beneficiary. Cancer, heart disease, hypertension and diabetes are common conditions in elderly Americans. These conditions are often treated with medications (the typical elderly patient fills 13 prescriptions a year). In all of these conditions, the patient's status may remain stable for months or years, but it is important to regularly evaluate the status of a patient's disease and make certain that there is no evidence of disease progression or a regimen of medications is satisfactory to improve quality of life and/or likelihood of survival. These services are, therefore, part of the continuing care of patients with these chronic conditions and should not be subject to an arbitrary local decision regarding coverage. I do not believe it is the intent of the Congress, or of Medicare, to have coverage decisions for our nation's elderly with chronic conditions subject to individual medical director policy at a local level. A similar decision regarding coverage of pre-

[2] Wisconsin Physician Services. www.wpsic.com.

[3] Jencks SF, Cuerdon T, Burwen DR et al. Quality of care delivered to Medicare beneficiaries. JAMA 2000;284:1670-1676.

operative evaluations caused similar confusion and has required considerable effort by HCFA central staff to attempt to resolve. The lack of a clear, consistent national payment policy creates this unnecessary confusion in the local application of Medicare payment rules.

IMPACT ON PHYSICIAN-PATIENT RELATIONSHIP

Underlying these two examples is a fundamental change in the way in which carriers seem to approach physicians. The intensity of efforts to uncover fraud and abuse has disrupted relationships between physicians and carriers, and, more worrisome, has begun to undermine the physician-patient relationship. It is the responsibility of the physician to be the patient's advocate in discussions with insurers where there may be questions about payment policy that would adversely affect a patient's care. But, in the Medicare program, the effects of the examples I have cited are to create an uncomfortable situation where the physician is supposed to be the agent of Medicare and is fearful of making a mistake in billing or interpretation of policy. The physician must know Medicare payment policy and inform patients when services are not covered by Medicare; failure to do so has the potential for significant adverse consequences. Thus, in my daily practice, not only do I have to understand the myriad of Medicare rules, but I must also be able to translate a local medical review policy and to try to understand the case-by-case decision making of the medical director. If I make a mistake, in addition to not being reimbursed, I face the risk of other sanctions. This is a demanding task for any reasonable human being. Perhaps more disconcerting is that physicians and carriers are no longer working together to improve the care of Medicare beneficiaries.

What are the contributing factors to this state of affairs and what might be done to resolve these problems? A significant factor is the loss of talent at HCFA and the carriers. For whatever reason, the reorganization that occurred at HCFA was followed by the departure of a number of very talented people from the agency. Reassignment of remaining staff meant that people were placed in new areas having to learn new jobs. Carriers around the country have had similar problems; carrier changes and the lack of significant oversight of the carriers by HCFA have allowed poor carrier performance to go on without intervention to improve performance or service. Minnesota has had three different part B carriers in the last five years (as well as 3 changes in part A fiscal intermediary), and had no effective medical direction in the part B carrier for nearly eighteen months. As a consequence, medical record reviewers have been making decisions about payment and coverage without medical oversight. The result has been an exponential increase in pre- and post-payment reviews that consume excessive resources for both the carrier and provider, resources that could have been used more productively to provide better service to beneficiaries and providers.

And, carrier efforts to reduce administrative expense may cause other problems for beneficiaries and providers. The Minnesota part B carrier recently announced a reduction in its budget for beneficiary outreach after receipt of a communication from HCFA indicating that the carrier should manage its telephone service lines to have at least a ten per cent busy signal rate. Providers were told they might expect to hear more questions from beneficiaries given the reduction in level of service at the carrier. Providers should not be expected to provide telephone backup service to the carrier.

RECOMMENDATIONS FOR ACTION

The Health Care Financing Administration can effectively reduce regulatory burden and improve its relationship with providers. This will require several actions, including more stringent oversight of carriers, the most common point of contact between providers and HCFA. The following actions are recommended:

1. HCFA should work as fast as possible to develop national payment policies for commonly performed services that would eliminate the need for local medical review policies along with the confusion these policies create.
2. HCFA should work with its carrier medical directors to develop a uniform approach to payment for services required in the care of patients with chronic conditions like cancer, heart disease, hypertension and diabetes.
3. HCFA should better supervise the performance of the carriers; too often, carrier problems create unnecessary additional burdens for physicians and beneficiaries, as well as for HCFA in Baltimore.
4. Different solutions to allow providers to demonstrate their compliance with regulation should be implemented that would restore the ability of the physician to be an advocate for patients.

5. HCFA should accelerate efforts to eliminate or simplify regulations that affect physicians in daily practice by aggressively pursuing and resolving issues that have been identified by its Physicians Regulatory Issues team.
6. The Congress should allocate a reasonable administrative budget for beneficiary service or have a greater expectation for HCFA service to beneficiaries.

PRACTICING PHYSICIANS' ADVISORY COUNCIL

I am aware that HCFA has been criticized for its lack of recognition of PPAC recommendations and for not effectively utilizing the council. I have been a member of PPAC for one year and in these months it is evident that HCFA is beginning to address some of the problems I have described, as well as other chronic issues. Though there is now evidence of progress, it is slow and could be considerably accelerated. Let me illustrate with two examples.

First, the Physicians' Regulatory Issues Team (PRIT) has spent much of the last year trying to understand issues that affect physicians and has recently completed a survey of physicians to provide guidance in prioritizing its work. The highest priority for regulatory relief in the minds of American physicians is that of Advance Beneficiary Notices (ABNs). A simpler and easier to use notice, free of derogatory language about the provider, and some notification of the physician when a patient decided not to have a recommended test or procedure have been requested by providers for years. In fact, in 1992, in the first meetings of the Minnesota Medicare Carrier Advisory Committee, this issue was identified and a letter was sent to HCFA requesting these improvements. In my first meeting of the PPAC, an ABN proposal was presented to the Council and PPAC made many suggestions. To the credit of the staff at HCFA, they changed their direction entirely, adopted the suggestions of the council and moved forward to implement our suggestions. The work of the staff has been very gratifying, and it is clear from this example that staff can make changes that are helpful not only to physicians but beneficiaries (field testing of the simplified ABN found better beneficiary response to the new, simpler form). However, it is difficult for me to understand why it has taken a decade to resolve an issue that required only a year of development and testing. We should be able to make faster progress than solving one problem every ten years. Unfortunately, HCFA staff members have informed PPAC members that at least two of the issues important to physicians (and included on the PRIT physicians' issues list) are nearly impossible to resolve (notably, claims resubmission and the requirement for prior hospitalization for skilled nursing facility placement).

Second, HCFA has asked PPAC to take a central role in the supervision of the process to develop new documentation guidelines. This is encouraging, and I hope this new effort will produce changes in both coding and documentation that will solve problems that are also ten years old. This will require a cooperative effort between HCFA and the CPT Editorial Panel of the American Medical Association and significant leadership on the part of both organizations. I do harbor some concerns about our ability to resolve this problem because of difficulties within HCFA. The group at HCFA with responsibility for implementation of the guidelines proposes to undertake a series of pilot projects to field test the new guidelines before national implementation. However, such a trial will inevitably have a period where there will be disagreements about interpretation and payment. Physicians who participate in these pilots do not want to be exposed to the current set of risks of making a mistake in coding (as in the example I described earlier). However, Program Integrity staff seem insistent that there can be no provision made for these pilot projects and that any mistakes made must be aggressively pursued to make sure that no improper payments are made. Unless Program Integrity staff, Health Plans and Providers staff and carrier medical directors can develop an effective structure for pilots that promotes the learning necessary to successfully implement a new system that will be effective, we will have gone through ten years of work in four major efforts without being any farther than we were in 1993 when I chaired the first ad hoc committee on the development of documentation guidelines. If HCFA cannot reasonably consider the views of PPAC in a process where its involvement has been specifically sought, then it seems unlikely that PPAC will ever serve any useful purpose.

HOW COULD HCFA WORK BETTER WITH PPAC?

The examples I have cited indicate the recent efforts of leadership within HCFA to use the PPAC effectively and demonstrate the utility of PPAC. Though these changes give me optimism about the future role of PPAC, there remains a need for more effective leadership to achieve better coordination between groups within HCFA. These groups should be working together to achieve the goals of HCFA to

provide the best care for Medicare beneficiaries in partnership with physicians and other providers while working to assure the integrity of the program for all. It is simply too important that we be successful in meeting the increasing needs of the elderly that we risk our success by not being able to work effectively together.

There must be an increased emphasis on resolving problems of regulations. Proposed regulations are not regularly reviewed by PPAC to understand their potential effect on practicing physicians; it is extremely difficult to change regulations after they have been implemented. HCFA could use PPAC more effectively to help it avoid problems with regulations by making a more intensive effort to present proposed regulations for review very early in the process of development.

CONCLUSION

I appreciate the opportunity to share my experiences with you this morning and I hope that my observations and suggestions will be helpful in making improvements in the administration of Medicare, a vitally important program for our elderly. Thank you for your dedication to the success of Medicare and for seeking ways to make it better for patients and physicians.

Mr. GREENWOOD. Thank you, Dr. Wood.

Finally, Mr. Friedman.

STATEMENT OF HARVEY FRIEDMAN

Mr. FRIEDMAN. Thank you. Good morning. Mr. Chairmen and members of the subcommittees, I am Harvey Friedman, the Medicare contracting officer at the Blue Cross and Blue Shield Association. The association represents 45 independent Blue Cross and Blue Shield plans throughout the Nation. Together, Blue Cross Blue Shield plans are, by far, the largest Medicare fee-for-service contractors, as well as the largest Medicare Plus Choice and Medigap insurers. I appreciate the opportunity to testify before this joint subcommittee hearing on how Medicare contractors communicate new rules and regulations to providers.

I will make a brief oral statement at this time. My full statement has been submitted for the record.

Medicare contractors have several areas of responsibility on behalf of the Federal Government. Most relevant to the purpose of this hearing, contractors are the main points of routine contact with the Medicare Program for both beneficiaries and providers. Contractors educate providers and beneficiaries about Medicare and respond to about 40 million inquiries annually.

I would like to focus on the following three areas in my testimony today: How contractors communicate in the rules and regulations to providers, challenges facing contractors, and BCBSA's recommendations for improving the contractor program.

Contractors use several methods to communicate instructions to providers. The process begins with the creation of an annual provider education and training plan, so-called PET. This plan is reviewed, typically quarterly, with a PET Advisory Committee, consisting of representatives from State and local medical societies, providers, and other entities that submit Medicare claims.

Contractor communications with providers throughout the year take the form of quarterly newsletters, special bulletins, desk manuals, training seminars and publication of Internet web sites. HCFA's own Internet web sites contain copies of all the instructional program memoranda and transmittals which are sent to the carriers and intermediaries, as well as some computer-based training modules.

In fiscal year 2001, the Blue Cross Blue Shield Medicare contractors have been funded with $16.5 million for Part A provider education and training and $24.6 million for Part B. Although this is less than we would like to have, which I will address shortly, you can see that a considerable amount of resource and effort goes into communicating new rules and regulations.

The Medicare Program continues to grow more and more complex. Furthermore, new rules are being changed with greater frequency. In the Balanced Budget Act of 1997, Congress created new payment mechanisms. Since 1997, Congress has acted twice, in 1999 and 2000, to amend the Balanced Budget Act, requiring additional major changes and creating additional confusion. All of this translates into more change orders to the Blue Cross Blue Shield contractors. Just as Members of Congress hear from providers about the difficulties in understanding these new rules, so too do contractors who must answer the questions and concerns about new payment methodologies.

Medicare contractors were allocated about 6 percent less in overall operating funds this year than they received in fiscal year 2000. An area hit particularly hard was provider education. Blue Cross Blue Shield plans estimate that fiscal year 2001 funding for provider education is about 18 percent below the amount they need to effectively educate and train providers. And, frankly, the picture for fiscal year 2002 looks even grimmer, although that budget is in process.

The fact is that when Medicare budgets are tight, provider education is one of the first areas to be cut by HCFA. Over the past 2 fiscal years, the customer service functions, including inquiries, education, and outreach efforts have been particularly hard hit. We urge Congress and the Administration to explore new methodologies to develop Medicare contractor budgets.

The Blue Cross and Blue Shield Association supports congressional efforts to reform and improve the Medicare Program. However, such efforts must have as one of its goals a reduction in the complexity of the program. The program has been micromanaged to the point where a clear and consistent understanding of the rules and regulations is simply impossible. Blue Cross Blue Shield plans constantly hear from providers that the complicated payment rules and paperwork required of them is overwhelming, and some are being driven out of the program. BCBSA applauds the efforts of these subcommittees to review and address this issue and we offer our assistance in implementing improvements.

Finally, we recommend against awarding contracts in a way that would fragment and weaken Medicare administration, as has been proposed by HCFA in past reform plans. Competition does not have to mean fragmentation. By breaking up contracting functions and spreading them among a large pool of new entities, many of whom would be inexperienced in Medicare, the claims payment process would become fragmented. The Blue Cross and Blue Shield Association cannot emphasize enough the potential confusion and difficulty that would arise from using a multitude of independent specialty contractors who share work but do not share accountability for the outcome; that is, for a correctly and efficiently processed claim.

In conclusion, Blue Cross and Blue Shield Medicare contractors believe more can and should be done to improve the communication among HCFA, contractors, and providers. However, two considerable obstacles stand in the way of any significant improvement: The complexity of the Medicare Program and insufficient funding. BCBSA urges Congress to streamline the Medicare Program, a goal we know these subcommittees share, and provide adequate funding to Medicare contractors. BCBSA strongly recommends against fragmenting contractor functions, an action that would certainly lead to more confusion, more inconsistency, and more delays in payment and customer service.

We look forward to working with the subcommittees and HCFA to make these needed improvements. Thank you, and I would be pleased to answer any questions.

[The prepared statement of Harvey Friedman follows:]

PREPARED STATEMENT OF HARVEY FRIEDMAN, MEDICARE CONTRACTING OFFICER, BLUECROSS AND BLUE SHIELD ASSOCIATION

Mr. Chairmen and members of the Subcommittees, I am Harvey Friedman, the Medicare Contracting Officer at the Blue Cross and Blue Shield Association (BCBSA). The Association represents 45 independent Blue Cross and Blue Shield Plans throughout the nation. Together, BCBS Plans are, by far, the largest Medicare fee-for-service contractors, as well as the largest Medicare+Choice and Medigap insurers. I appreciate the opportunity to testify before this joint Subcommittee hearing on how Medicare contractors communicate new rules and regulations to providers.

As background, the Medicare program is administered through a long-standing partnership between the private health insurance industry and the Health Care Financing Administration (HCFA). Since 1965, Blue Cross and Blue Shield Plans have played a leading role in administering the program. They have contracted with the federal government to handle much of the day-to-day work of paying Medicare claims accurately and in a timely manner. Nationally, 26 Blue Cross and Blue Shield Plans serve as Part A fiscal intermediaries and/or Part B carriers and, collectively, process about 90 percent of Medicare Part A claims and about 60 percent of all Part B claims.

Medicare contractors have three major areas of responsibility on behalf of the federal government:

1. **Paying Claims:** Medicare contractors process all the bills for the traditional Medicare fee-for-service program. In fiscal year 2000, it is estimated that contractors processed over 900 million claims, more than 3.5 million every working day. Contractors also process the initial appeals of adverse claim decisions.
2. **Special Initiatives to Fight Medicare Fraud, Waste, and Abuse:** All contractors have separate fraud and abuse departments dedicated to assuring that Medicare payments are made properly. It is estimated that these activities saved the government $11 billion in 1999.
3. **Providing Beneficiary and Provider Customer Services:** Most relevant to the purpose of this hearing, contractors are the main points of routine contact with the Medicare program for both beneficiaries and providers. Contractors educate providers and beneficiaries about Medicare and respond to about 40 million inquiries annually.

With this as background, I would like to focus on the following three areas in my testimony:

I. How contractors communicate new rules and regulations to providers;
II. Challenges facing contractors; and,
III. BCBSA's recommendations for improving the contractor program.

I. HOW CONTRACTORS COMMUNICATE NEW RULES AND REGULATIONS TO PROVIDERS

Contractors use several methods to communicate instructions to providers. The process begins with the creation of an annual provider education and training (PET) plan. The plan is reviewed with a PET advisory committee consisting of representatives from state and local medical societies, providers, and other entities that submit Medicare claims.

Contractor communications with providers throughout the year take the form of quarterly newsletters, special bulletins, desk manuals, training seminars and publication of new instructions on contractor Internet websites. PET advisory committees are often used to review written communications and website changes for clarity.

HCFA's own Internet websites contain copies of all the instructional Program Memoranda and Transmittals which have been sent to the fiscal intermediaries and carriers, as well as some computer based training modules. In particular, training modules for the new outpatient prospective payment system and the new home health prospective payment system were developed by the BlueCross and BlueShield Association at HCFA's request, and are available on HCFA's website.

In fiscal year 2001, the BCBS Medicare contractors nationally have been funded with $16.5 million for Part A provider education and training and $24.6 million for Part B provider education. Although this is less than we would like to have—which I will address shortly—you can see that a considerable amount of resource and effort goes into communicating new rules and regulations to the provider and billing communities.

II. CHALLENGES FACING CONTRACTORS

Medicare contractors face two key challenges to success in communicating with providers: 1) increasing complexity of Medicare rules; and, 2) inadequate funding levels.

Increased complexity of Medicare rules: The Medicare program continues to grow more and more complex. The new payment mechanisms for outpatient departments, home health agencies, and skilled nursing facilities, to name a few, are very complicated and require a great deal of resources to implement. Just as Members of Congress are hearing from providers about the difficulty in understanding these new rules, so too are contractors who must answer their questions and concerns about new payment methodologies.

Furthermore, the new rules are being changed with greater frequency. In the Balanced Budget Act of 1997 Congress created the new payment mechanisms listed above. Since 1997, Congress has acted twice—in 1999 and 2000—to amend the Balanced Budget Act, requiring major changes and reeducation of providers. All of this has translated into more change orders. In calendar year 2000 contractors received 719 formal change orders—more than 2-1/2 times the number received in fiscal year 1998. This fiscal year, through February, contractors have already tracked 513 changes. If this rate continues, we will receive more than 1,230 changes in fiscal year 2001—a 70% increase over last fiscal year.

Exacerbating this problem is the fact that these rapidly multiplying change orders are rarely accompanied by sufficient funding or transition time for proper implementation. This leads to the second challenge facing contractors.

Inadequate Funding Levels: Every change transmittal from HCFA must be implemented by the contractors and then communicated to the providers. This is a time-consuming and costly process and, frankly, contractors have not been provided all the resources they need to successfully carry out this important function.

In spite of a 9 percent increase in the overall Medicare Program Management appropriation for fiscal year 2001, the operational budgets of Medicare contractors have been cut 6 percent below fiscal year 2000 levels. An area hit particularly hard has been provider education, at a time when so many changes resulting from the Balanced Budget Act and the subsequent amendments are being implemented. BCBS Plans estimate that fiscal year 2001 funding for provider education is about 18 percent *below* the amount they need to educate and train providers effectively.

In response to this funding shortfall, BCBS Plans have been forced to take such actions as eliminating opportunities for individualized training, declining invitations to speak at conferences, and, in general, cutting back on personal training interactions.

The picture for fiscal year 2002 looks even grimmer. Based on conservative assumptions of workload growth, BCBSA estimates that a funding increase of 7 percent above the fiscal year 2001 level will be necessary to meet current obligations. This estimate does not include the millions of dollars that will be necessary to implement privacy and administrative simplification requirements that are on the horizon, or the changes included in the Medicare Benefits Improvement and Protection Act of 2000.

The fact is that when budgets are cut, provider education is one of the first areas to be cut by HCFA. Over the past two fiscal years, the customer service functions including education and community outreach efforts have been particularly hard hit due to budget cuts and resource constraints.

III. BCBSA RECOMMENDATIONS TO IMPROVE THE MEDICARE CONTRACTOR PROGRAM

Blue Cross and Blue Shield Medicare contractors are committed to achieving outstanding performance levels. We want to work with the Congress and HCFA to attain this objective. We recommend consideration of the following recommendations:

1. **Reform the Medicare program:** BCBSA supports congressional efforts to reform and improve the Medicare program. Such efforts must have as one of its goals a reduction in the complexity of the program. Over the past 35 years federal policymakers have micromanaged the program to a point where a clear and consistent understanding of the rules and regulations is simply impossible. BCBS Plans constantly hear from providers that the complicated payment rules and paperwork required of them is overwhelming.

   BCBSA applauds the efforts of these Subcommittees to review and address this issue and we offer our assistance in implementing improvements.

2. **Provide adequate and stable funding levels:** Congress should provide adequate funding levels to assure that contractors can perform the range of functions necessary for the efficient operation of the Medicare program. As highlighted earlier, funding has not kept pace with programmatic needs—important functions such as provider education and training are not being fully funded. We urge Congress and the Administration to explore using a new methodology to develop Medicare contractor budgets. This method should assure that workload growth and the costs of claims administration are reviewed annually and that each time a new Medicare law is passed, there are sufficient administrative resources to handle the new workload. While BCBS Medicare contractors are committed to continually achieving greater efficiencies, it is simply not realistic to expect contractors to continue to attain outstanding performance levels with greater workloads and tighter budgets.

   It is imperative that Congress provides a stable and adequate funding stream for all contractor activities. Underfunding contractor activities can result in ineffective provider education and training, as well as payment slowdowns to providers and beneficiaries, deterioration in effective anti-fraud efforts, and significant delays in responses to provider and beneficiary inquiries.

3. **Avoid counterproductive reforms:** Finally, we recommend *against* awarding contracts in a way that would fragment and weaken Medicare administration, as has been proposed by HCFA in past reform plans. Instead, potential contractors should compete on a level playing field to be the *single* manager of a contract, and—as needed—be held responsible for subcontracting more specialized work to other entities. By breaking up contracting functions and spreading them among a large pool of new entities—many of whom would be inexperienced in Medicare—the claims payment process would become fragmented. This is likely to disrupt effective management of the program and exacerbate current provider concerns. For example, if one e entity received the contract to educate providers while another received the contract to process claims there will undoubtedly be more errors since educator will not be as familiar with the policies of the processor.

   In addition, fragmenting the claims payment process would destroy the current single point of accountability now available to HCFA, providers, and beneficiaries. BCBSA cannot emphasize enough the potential confusion and difficulty that would arise from using a multitude of independent specialty contractors who share work but do not share accountability for the outcome (that is, for a correctly and efficiently processed claim). Such contractors may even consider themselves competitors to each other and not work cooperatively. It is conceivable that under HCFA's proposal that an individual claim could be handled by three or more separate contractors before it is finally processed. This fragmentation would increase claims payment timeframes and remove the single point of accountability for processing a claim properly—from beginning to end.

CONCLUSION

Blue Cross and Blue Shield Medicare contractors believe more can and should be done to improve the communication between HCFA, contractors and providers. However, two considerable obstacles stand in the way of any significant improvements: the complexity of the Medicare program and insufficient funding. BCBSA urges Congress to streamline the Medicare program and provide adequate funding to Medicare contractors. BCBSA strongly recommends against fragmenting contractor functions, an action that would certainly lead to more confusion, more inconsistency and more delays in payment and customer service.

We look forward to working with the Subcommittees and HCFA to make these needed improvements.

Mr. GREENWOOD. Thank you, Mr. Friedman. You reached for the gold star. The Chair recognizes himself for 5 minutes for purpose of questions.

My thinking has been on this issue that there probably isn't much of a problem in terms of bad faith on the part of HCFA, the providers or the physicians. It is a question of systems and incentives that are difficult to work with. And the question I want to start with Dr. Miller on is—and I should know the answer to this, but I don't—can the health care provider file a Medicare claim online today?

Mr. MILLER. Most claims in Medicare are filed electronically, and the vast majority are filed electronically, if that is what you mean by online.

Mr. GREENWOOD. Explain to me how that works.

Mr. MILLER. There are standard forms, 1500's, that is—there is an interface between the provider, whether it is a hospital or a physician's office. Information is put into the forms, the I.D. of the provider, the I.D. of the beneficiary, codes for services, and it is transmitted to the carrier along telephone lines. I believe so, yes.

Mr. GREENWOOD. But that is not an interactive process, I assume.

Mr. MILLER. That is correct. I think if you are saying can somebody log onto the Internet and see the status of their claim at any given point in time, I don't believe that they can do that, if that is your question.

Mr. GREENWOOD. Okay.

Mr. MILLER. In terms of an interactive effect.

Mr. GREENWOOD. And has HCFA—what I have been grappling with is the extent to which—and if your associate there would like to speak for herself, she is welcome to do that as well.

Mr. MILLER. She was saying that it is not interactive.

Mr. GREENWOOD. The next question then is, is that under consideration? It would seem to me that in the information age, with the information technology that we have, if I go to order something from Amazon.com—if I were to file every request that I ever made online to purchase a product, for instance and had to wait until I received information back as to whether or not I had done that accurately, I would probably be experiencing some of these similar problems. The health care provider is sending in a claim, waiting, and finding out I didn't—it was a wrong keystroke or a mistake, and the we do it over again.

On the other hand, when I make a transaction online, it can be interactive in that I can get instantaneous feedback as to whether or not I made a mistake. And then I get some sort of a clearance, "Okay, your t's are crossed or i's are dotted, claim is ready for acceptance," and I can get almost instantaneous response. Is that kind of approach under consideration by HCFA?

Mr. MILLER. There have been discussions about that. There was an article in the newspaper a few months back where some private insurance firms were beginning to look at these types of systems. And I know myself and a few other people within HCFA noticed those, and there were discussions about it. But to move to some-

thing like that, I think would require—and I am not a systems person, so I am stepping out here a little bit—would require, I think, a significant investment and significant reconfiguration of our systems. So these are certainly things we are aware of and are thinking about, but I can't point to plans that say that this is going to happen soon.

Mr. GREENWOOD. Well, okay. You don't have plans that it is going to happen soon, but I think—let me refine my question. It would certainly take a significant investment, but it would seem to me that, in terms of both missions that we have discussed this morning, that is preventing waste, fraud, and abuse and having a workable, user-friendly relationship with the providers, that such an interactive system could take us down both of those paths simultaneously with fewer conflicts between those goals. So if HCFA doesn't have such plans, is HCFA engaged in a process of ascertaining whether that is feasible, what it would cost, how long it would take to implement so that HCFA could make an informed decision as to whether that is where it can and should go?

Mr. MILLER. Certainly, nothing in my answer was intended to imply that we didn't think that this is a worthy idea to consider. I think your point about being able to interactively check where you are at any given point in time is well taken. I just don't want to—and my understanding is in the private sector, this is sort of just coming up to speed, just being considered. And I could be wrong about that, but that is my understanding.

HCFA, I think, can think about this, but I just don't want to mislead you. We are not down the road to how feasible, how much does it cost, those kinds of things, but we certainly would be open to considering that.

Mr. GREENWOOD. Okay. My time has expired.

Mr. MILLER. Can I just say one other thing?

Mr. GREENWOOD. Sure.

Mr. MILLER. Apparently, you can log on and check online where your claim stands, but it is not interactive. That is true. But, apparently, you can log on and check the status of your claim.

Mr. GREENWOOD. Well, my time has expired. The subtle difference between there and being open to think about it is important. What my recommendation to HCFA is, is that HCFA ought to be completely engaged in the process of determining whether that is—what it would take to do that, what it would cost, what the timeframes would be, the feasibility, and conferring with your providers to see how attractive that might be to them.

Mr. MILLER. Can I just say one other thing? Apparently, our information systems people have been meeting with the private sector to discuss the privacy issues associated with that interactive issue, because you would have to have protections in on that, just like Amazon.com has privacy protections. And there is some discussion.

Mr. GREENWOOD. My guess is if Amazon.com can do it, the United States of America could probably do it.

Mr. MILLER. I would think so.

Mr. GREENWOOD. The Chair recognizes the gentleman, Mr. Brown, for 5 minutes.

Mr. BROWN. Thank you, Mr. Chairman. I am particularly interested, Dr. Miller, in the area of HCFA's oversight of contractors. Ms. Bradley had two interesting examples of areas where a contractor, with respect to provider enrollment forms and the provider overpayment, where a contractor appears to be performing badly but apparently has no relation to HCFA guidance. I am interested in your oversight of contractors. How does HCFA hold contractors accountable in those areas?

Mr. MILLER. There are a couple of things. There is a process inside HCFA that is called contractor performance evaluations, and there are a set of requirements that are given to contractors regarding performance standards. And these have to do with things like claims processing, customer service. Customer service in this instance is how fast you answer the phone, how accurate is the information that you give over the phone, responding to inquiries—written inquiries, I am sorry, how much time it takes to respond to those, those kinds of things. There are also payment safeguard requirements, fiscal oversight kinds of requirements.

There is at least an annual evaluation process that goes on, and all of the carriers are ranked on their performance. And then each of the contractors—and I won't describe this really well, because, again, it is a slightly different area than the one I deal with—but there are people in HCFA who are responsible for each of the sets of carriers and go out regularly and spend time with the carriers to look at how they are performing, what kinds of problems are being encountered in response to problems, working problems through with the carriers, the intermediaries.

Mr. BROWN. Putting aside funding for a moment, does HCFA have the proper authority to do sufficient oversight of the contractors?

Mr. MILLER. I don't want to talk about proper. I just want to talk about the authorities that they have. And I think what your question is getting at is the question that was raised by Blue Cross Blue Shield, the idea of additional flexibilities in HCFA's contracting authority. In the past, there have been proposals that have looked at contracting flexibility in a couple of ways: Moving to performance-based contracting, which is not allowed by law now, and also the ability to contract with entities in addition to the ones that we are able to contract with now. And then, finally, the idea of being able to contract out for pieces of the work. So, say, for example, you have some group in a given area who is particularly good at customer service, the ability to go and contract separately with them. Again, that is not something that we have the authority to do at this point, if that is your question.

Mr. BROWN. Mr. Mangano, would you talk about your view of the authority, the need for contract reform, if there is a need, your view of if the authority is sufficient that HCFA now has to oversee contractors properly? Give us your rate on that.

Mr. MANGANO. Our view is consistent with the positions we have taken in the past, as well as today. It is that HCFA ought to have the kinds of authorities they need to have to be able to select contractors on whatever basis they deem appropriate. Given that fact, we have strongly supported in the past HCFA being able to select for part of the process, contractors who are not insurance compa-

nies, to be able to competitively bid and experiment with some other ways of doing it.

If we are going to hold HCFA responsible for the performance of its contractors, they ought to have more say in selecting who their contractors are and terminating contracts when they deem it in the best interest of the Government.

Mr. BROWN. What percentage—just a ballpark figure, what percentage of carriers are or have recently been investigated, either by OIG or by DOJ?

Mr. MANGANO. Since 1993, we have reached either a criminal conviction or a civil settlement with 13 contractors across the country in which they ended up returning to the Medicare Trust Fund $350 million. And today we have a number of others under investigation as well.

Mr. BROWN. This is money from the contractors or from providers?

Mr. MANGANO. This is from the contractors.

Mr. BROWN. From contractors only.

Mr. MANGANO. Yes. And for a variety of offenses, either not being diligent in terms of how they bill providers, making false statements to the Medicare Program, turning off edits, which are designed to identify false claims, and a variety of other——

Mr. BROWN. Would some of that money then be recoverable by the contractors from providers or typically no?

Mr. MANGANO. Yes, it would. We recently had a case in which a contractor in the Northeast basically was sending checks to hospitals on the basis of improving their performance ratings. This particular contractor was basically saying that they pay bills very quickly, and they were paying money to hospitals that shouldn't have been paid. We reached a settlement of over $70 million with that particular contractor.

Mr. BROWN. One last real quick question. The purpose of paying these contractors, my understanding, these private, generally for-profit contractors, is to safeguard tax dollars, correct? And to administer the program, but ultimately to safeguard taxpayers as they administer it.

Mr. MANGANO. Sure.

Mr. BROWN. Okay. Thank you.

Mr. BILIRAKIS. [presiding] We have more than one vote. So it may be—Nathan, would you like to inquire for 5 minutes? We could probably get you in.

Mr. DEAL. I can do one real quickly, and I will try to get a gold star and keep under the 5 minutes if I can.

I would just like to maybe get some broad parameters here, because we all seem to be focusing on the same general issues, but sometimes I think we lose sight of perhaps what the cost is, what the overall objective might be. And let me start with this, and it may be facts and figures that nobody has. If you do not have, then I would like to ask if you could provide them to me at a later date.

First question I would have is, considering the overall Medicare budget, how many cents out of every Medicare dollar is paid to medical providers?

Mr. MILLER. Medical providers?

Mr. DEAL. Yes. Doctors, hospitals—medical providers.

Mr. MILLER. Well, I mean, virtually all of the Medicare dollars go to payments to providers of one kind or another. Is there a particular category you are looking for?

Mr. DEAL. I said medical providers. I am not—I want to know how much of the Medicare budget is syphoned off at HCFA paying for things that are not for services rendered? How much is syphoned off paying to carriers to administer the program? How many cents out of every total Medicare dollar goes to providers?

Mr. MILLER. Okay. I think the two figures that you are looking for are there is about $210 billion in payments made every year, and HCFA's budget is $2.2 billion, of which contractors receive about half of that. So $1 billion out of $210 billion, if that is what you are asking.

Mr. DEAL. One billion?

Mr. MILLER. Out of $210 billion goes to the contractors. And HCFA's total budget, when you consider the central office and the regional office, is $2 billion, in round numbers.

Mr. DEAL. Two billion?

Mr. MILLER. That is correct. Out of $210 billion in payments per year.

Mr. DEAL. So we have $3 billion out of the $210 billion that goes to things other than paying for medical services.

Mr. MILLER. Yes. And I think if—you were saying how many cents on every dollar, that is about two cents of every dollar.

Mr. DEAL. Two cents of every dollar. All right.

Mr. MILLER. If I understand your question.

Mr. DEAL. I think you did. The next question, then, is at the provider level, and Dr. Becker, you and Dr. Wood, I suppose, would be—well, Ms. Bradley, you probably too—at the provider level, how many cents out of every Medicare dollar that you receive do you consider is spent in complying and, in effect, getting the dollar in something other than paying for time spent in providing care or medication or supplies related to that care? Do you have any estimates?

Mr. BECKER. Well, it would only be an estimate, but I can tell you that in Florida, where we have a large HMO population, the HMOs, in general, take 20 percent of the Medicare money that they are given, which is strictly for administration. They take 20 percent, and they pay out about 80 percent to providers. Then out of that 80 percent, of course, for my office administration, there is some percent that would go to administration as well. That is probably a low figure, maybe 15, 20 percent also.

But a significant—once it leaves the carrier, and I have understood the carrier cost also to only be around 2 percent, which is fairly reasonable, I suppose, for a larger system, but once it leaves the carrier, when it gets to an individual area HMO, they usually take 20 percent, and then out of what I get, which would be 80 percent of that, I will probably have to spend another 20 percent for administration as well.

Mr. DEAL. Assuming it is not an HMO situation but a direct reimbursement, what percentage would you estimate would be consumed?

Mr. BECKER. Well, again, in my office, probably at least 20 percent of my expenses go for strictly administrative costs, for dealing with the paperwork and bureaucracy, so to speak.

Mr. DEAL. Is that comparable, do you think?

Mr. BRADLEY. All due respect to physicians, the administrators are the ones who deal with this every day, and I would say a considerable amount of our dollar is spent trying to understand the rules and regulation, trying to get these issues straightened out. So I would say it is well over 50 percent.

Mr. DEAL. Fifty percent out of every dollar?

Mr. BRADLEY. Fifty, 5-0. Fifty cents, at least.

Mr. DEAL. Out of every dollar that——

Mr. BRADLEY. That is correct.

Mr. DEAL. Dr. Wood?

Mr. WOOD. I think that figure is relatively reasonable. The circumstances are that there are——

Mr. DEAL. Which figure, the 20 or the 50?

Mr. WOOD. The 50.

Mr. DEAL. Okay.

Mr. WOOD. Because you have a series of rules and regulations from the carrier, and there are additional things that you have to do for compliance. If you put all of those together, it is a rather substantial number.

What your question perhaps doesn't represent very well is what the impact is of having to deal with then audits and payment reviews.

Mr. DEAL. Which you are not compensated for.

Mr. WOOD. Right. And it may cost $14, $15, $20 to pull the record, get the record ready, send it to the carrier for review. The amount in question for payment may be only $20 on a low-level service. So from that circumstance, then, a physician may decide do I just forgo the payment or do I just go through all the administrative work to get a few dollars back?

Mr. DEAL. Could I ask one very brief follow-up question on that?

Mr. BILIRAKIS. Very quickly. We will have a second round. I just wanted to advise those that are still here.

Mr. DEAL. All right. Mr. Friedman, Blue Cross Blue Shield is in the business of providing health insurance in a non-Medicare environment. Do those percentages, are they comparable in the non-Medicare health insurance area that Blue Cross Blue Shield supervises? Are those percentages comparable?

Mr. FRIEDMAN. No insurance company would dream of trying to administer a program for two cents on the dollar, because you simply can't do a very good job. More typically, administrative costs run 15 to 20 percent in administering insurance plans other than Medicare, if I am understanding your question.

Mr. DEAL. So you are saying, then, in the non-Medicare environment that it would be more than the percentages we have heard referenced here.

Mr. FRIEDMAN. Certainly in terms of the cost of administration versus the cost of benefit payments, absolutely.

Mr. DEAL. Then why do you ask to be an administrator in the Medicare environment then?

Mr. FRIEDMAN. I think the question is perhaps best answer historically. Going back to the beginning of the program, most of the Blue plans who entered into these contracts saw it as part of their community involvement, their community mission.

Mr. DEAL. So your administration is community service.

Mr. FRIEDMAN. That is correct.

Mr. DEAL. That is a unique answer, Mr. Chairman, unique. Thank you.

Mr. BILIRAKIS. I thought his answer might be, "Well, we are probably asking ourselves that same question."

We are going to recess until 12:45, because we do have these two votes. That will give you an opportunity to grab a bite for lunch. So we will recess until then.

[Whereupon, at 11:57 p.m., the joint subcommittees recessed, to reconvene at 12:49 p.m., the same day.]

Mr. BILIRAKIS. Thank you for your indulgence, Ms. Bradley and gentlemen. Those of you who have testified up here before know what it is like. The rest of you probably feel that we are very discourteous, but that is the name of the game up here, votes left and right.

I would like to enter into the record, without objection, a letter dated April 4 from Secretary Tommy Thompson to the chairman of the full committee, Mr. Tauzin. The minority has had a chance to look at the letter. And also a statement of Dr. Kenneth Webster, executive director of the Pinellas County Osteopathic Medical Society, and a statement of Randy O. Shuck, Chairman of the Pinellas County Osteopathic Medical Society. Without objection, those will be made a part of the record.

[The material follows:]

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, DC
April 4, 2001

The Honorable W.J. "BILLY" TAUZIN
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

DEAR CHAIRMAN TAUZIN: Thank you for your letter concerning the Health Care Financing Administration's (HCFA's) relationship with physicians and other providers who participate in Medicare. I agree with you that it is significant that the Medicare error rate, as reported by the Inspector General, has continued to decline. While the reduction is a good sign, the current error rate is still unacceptable. The reduction of fraud and errors in Medicare is critically important and we must continue to build on our success. I also share your concern over the provider community's perception that Medicare rules are burdensome and HCFA's oversight is intrusive.

With respect to reducing fraud and errors in the Medicare program, more needs to be done, and the Department will make this a priority. Let me assure you that we will work with you and members of your committee on our plans in this area. Likewise, I support your efforts to examine how best to educate our providers in order to make the program work better. You are correct. If providers have the right information from the start, then the whole process of submitting and paying claims is greatly enhanced. HCFA has already begun a number of ongoing Medicare provider education efforts that will help increase the level of understanding in the provider community. But here again, more needs to be done.

I understand that my staff has already begun this process of consultation by providing a briefing for your staff covering many of the issues raised in your letter. We will continue to work with your staff to provide additional material in response to your specific questions. Finally, I have asked HCFA to provide me with options that

I can use in working with you and others in Congress to further improve on these provider education efforts.

Again, I look forward to working with you on these issues. Once our new HCFA Administrator has been confirmed, I believe we can make significant progress in improving the administration of the Medicare Program. A similar response is being sent to the cosigner of your letter.

Sincerely,

TOMMY G. THOMPSON

PREPARED STATEMENT OF KENNETH WEBSTER, EXECUTIVE DIRECTOR, PINELLAS COUNTY OSTEOPATHIC MEDICAL SOCIETY

I am Kenneth Webster, Executive Director of the Pinellas County Osteopathic Medical Society. While I am appearing only on behalf of that organization, I believe I can speak for all of the physicians—D.O.s and M.D.s alike—who have found themselves caught up in a unfair and unwarranted criminal investigation that threatens their reputations and livelihoods.

There is ongoing a series of federal investigations and prosecutions in the Middle District of Florida that should be of great concern to anyone who takes the time to learn the facts. Over a dozen physicians who, in the past, had modest or *de minimus* financial relationships with health care service providers, to whom they referred patients, have been indicted. They have had their ongoing Medicare reimbursements suspended, causing them to declare bankruptcy or cease practicing. Hundreds more have been threatened with indictment, subpoenaed or otherwise targeted for criminal investigation. These physicians collectively represent the core of the family and general practitioners in three counties; their indictments or prosecutions and resultant exclusion from Medicare and Medicaid have had and will have enormous repercussions for the health care delivery system in an extensive area of Florida. And worst of all, almost all of these doctors were totally unaware that their conduct was improper, let alone criminal. They were lied to by the real criminals—the service providers—and lulled into a situation that the United States Attorney for the Middle District of Florida proclaims to be a violation of the Medicare anti-kickback law.

These doctors ordered medically necessary tests for actual patients; the alleged crime is that the doctors sent the blood work to a laboratory that improperly procured the work. The government acknowledges that the doctor's activities here did not involve any harm to patients and "did not result[] in a loss to the Medicare program." The government has chosen to criminalize this conduct in only this one federal district; no where else in the country has the government indicted doctors who have made similarly-poor judgments about relationships with Medicare referral recipients. The facts of these cases under indictment, and the ones under investigation, simply do not warrant ruining the careers of this large group of well-meaning family practitioners.

I do not defend doctors who defraud Medicare. Like everyone, we believe that doctors who willfully defraud Medicare, or knowingly engage in financial relationships that induce unnecessary medical services, are a stain on the profession and should be dealt with appropriately. But these cases in Tampa do not involve doctors who defrauded Medicare. None of the indicted physicians have had their billings to Medicare challenged. The government has never claimed that they ordered tests or services that weren't medically necessary or in any way performed medicine inappropriately. Rather, the government has criminalized the poor judgment of these doctors by charging them with kickback violations—and suspending their wholly unrelated Medicare payments—due to their acceptance of very modest payments from a corrupt clinical laboratory for services that the doctors believed were legal and appropriate.

The background to these cases needs to be understood to put these matters in the proper context. The doctors in the Tampa area have been caught up in a federal investigation known as "Operation Takeback" which apparently is part of the nationwide Operation Restore Trust conducted by HHS. As part of Operation Restore Trust, HHS auditors visited Clearwater Clinical Laboratories (CCL), a local clinical blood lab, in January 1998. For years, CCL had a history of renting space from doctors clinics in order to have strategically situated draw stations and sub-leasing equipment from physicians that had previously had small laboratory draw stations in their clinics. CCL had also recruited doctors to be Medical Review Officers for each of the draw stations to monitor lab tests and consult with other physicians on lab results of blood drawn at the draw station for the other physicians' patients. These practices, widespread in the industry, were especially commonplace in the Tampa area, with a large Medicare population and heavily subscribed to managed

care. Many ancillary service companies, such as home health and laboratories, rented space from physicians to lower overhead and provide convenience to practitioners and patients.

Based on documents seen by the auditors, a search warrant was executed on CCL in June, 1998. Government agents seized numerous contracts with physicians who referred their patient's blood work to CCL. The owners and sales manager of CCL agreed to plead guilty and told investigators that the contracts with physicians—for personal services, equipment rental and space rental—were "shams" designed by CCL to disguise CCL's corrupt purpose in proposing such contracts to the physicians: to obtain their business. The doctors, of course, were never told by CCL how it viewed these contracts; to the contrary, part of CCL's marketing strategy was to tell physicians it approached that the contracts were legal and supplied a written legal opinion to support the claim. These physicians were asked by CCL to rent office space for CCL to establish a draw station for blood collection, to rent certain medical equipment, or to perform test interpretation services as a Medical Review Officer (MRO) or a Test Review Officer (TRO). The prosecutors acknowledge that a MRO or TRO can appropriately be employed by a clinical lab; they chose to view these as "shams" based on the CCL executives' confession of criminal intent as opposed to what the doctors legitimately understood. The compensation provided by CCL to the physicians under any of these contractual arrangements was very modest—typically several hundred dollars monthly, with none exceeding $1,500. None of these contracts required the physicians to refer their patients' blood work to CCL. Some of the physicians were already doing so, others did so after entering into the contract. Again, the physicians were assured that these arrangements were legitimate business relationships, and the March 1994 opinion letter from CCL's lawyers, Conklin & Sauey, that these arrangements met the "safe harbor" requirements of the law, appeared to be written confirmation.

Unfortunately, the doctors were too naive, and too trusting. CCL's sales manager testified that one of the first physicians he enrolled as a TRO was "very naive and believed everything [we] told him about TRO payments being in accordance with Medicare guidelines." One doctor, now indicted and convicted, was concerned about the ethics of one laboratory. Serendipitously, his office manager knew a FBI agent, who offered to advise him of a reputable lab to use. The agent was the case agent for "Operation Takeback", recommended CCL, and the rest is history. In hindsight, these doctors should have aggressively pursued independent advice as to whether the "safe harbors" of the Anti-Kickback Act were met in all respects. But because they did not, and because they entered into these contractual arrangements and received modest payments from CCL for the services actually rendered or the space and equipment rented—some as little as $14,000—14 of these doctors were indicted on multiple felony count violations of the Medicare Anti-Kickback Act. At the same time, their own Medicare receipts—for their own patients, having nothing whatsoever do to with CCL—were suspended. *Under HCFA regulations, suspension decisions are made without a hearing and are not appealable.* These suspensions had the effect of putting these physicians out of business, even before trial. Those who are convicted, of course, will receive the mandatory 5-year exclusion from participating in Medicare and Medicaid, further ensuring the end of their careers. All this for being naive, and for receiving a few thousands of dollars for services actually provided, when no one has ever challenged their billings or questioned the quality of their care.

The real culprits in this story, of course, are CCL and their executives. Not only did they engineer a corrupt scheme to obtain referrals, but once having the business, the lab proceeded to implement a scheme to defraud Medicare in two separate billing schemes: unbundling requested tests to bill components separately and testing for cholesterol or iron when they weren't ordered by the physician. This isn't just my assessment; I'm quoting from the United States Probation Office's Presentence Investigation Report. Medicare paid hundred of thousands of dollars to CCL for fraudulently-billed tests. While the government prosecuted CCL and its executives, they entered into plea agreements that will result in minimal sentences by virtue of their cooperation in testifying against the physicians they duped. They will receive no jail time, they can continue in the industry, and no restitution will be required for the massive fraud that CCL perpetrated on Medicare.

And that is the real injustice here. The government lets the masterminds off the hook with lenient treatment and goes after the small fish with a vengeance. And it is a vengeance unique to the Middle District of Florida, even though Operation Restore Trust is a nationwide investigation. None of the doctors who had MRO or TRO agreements with CCL, or leased space to CCL, who lived in the Southern District of Florida were prosecuted by the United States Attorney in that district. Moreover, I am reliably informed that none—or virtually none—of the numerous physi-

cians who received kickbacks from the many other clinical laboratories that have plead guilty to kickback charges elsewhere in the country have been charged. I am informed that the government had evidence that some of those physicians received hundreds of thousands of dollars in research grants, educational grants or consulting agreements when little or no work was done. According to statistics compiled by our local newspaper, this one federal prosecutor in this one (out of 94) federal judicial district has accounted for 10% of the Medicare kickback cases nationwide all by himself. Outside of the Middle District of Florida, the government has exercised its prosecutional discretion in these situations appropriately by prosecuting the initiator of this conduct and the party truly responsible—the laboratory or other service provider.

While all of us are pained mightily at what has happened, our overriding interest is in preventing further repetition of this tragedy. In July 1998, the prosecutor in charge of these prosecutions in the Middle District of Florida stated that his plan was to investigate approximately 400 physicians; his expectation was that he would secure 100 criminal convictions, with an additional 100 doctors who would not be criminally convicted but who would have to pay money back to the government together with civil fraud penalties; 100 physicians who would have to repay the government without paying civil penalties and the last 100 physicians who might get out without any payments or criminal investigation. He appears to be implementing his plan. According to local reports that appeared last October, more than 100 subpoenas have been issued to Tampa-area physicians for documentation of any relationship they may have had with Home Health Corp. of America, a Pennsylvania-based provider of home health nursing, respiratory care, durable medical equipment and other services. We have reliable information that subpoenas have been served on physicians that did business with another service provider as well.

We do not think it fair that physicians in the Middle District of Florida should be held to a standard that is applied no where else. We do not think it fair that we appear to be the object of some vendetta by a single prosecutor. If his performance in the CCL case is any harbinger, we will have dozens—if not hundreds—more doctors in this community singled out. Their reputations will suffer, and if an equal number of prosecutions ensue, their wholesale exclusion from Medicare will cause the entire health care delivery system in Tampa to be affected. The core of family practitioners, who are the main medical resource of the elderly population here, is in jeopardy.

We need to make known to the country at large what is happening in Tampa. We need to restore some semblance of sanity. We need the spotlight from outside the Middle District of Florida to shine into the abyss that we find ourselves in. We need your help.

Thank you.

PREPARED STATEMENT OF RANDY A. SHUCK, PINELLAS COUNTY OSTEOPATHIC MEDICAL SOCIETY

Good morning Mr. Chairman, I am Dr. Randy Shuck, Chairman of the Special Advisory Committee dealing with Medicare Fraud, to Pinellas County Osteopathic Medical Society. I am a Doctor of Osteopathic Medicine, a D.O., but I believe I can speak for all physicians both D.O. and M.D. alike, who find themselves caught up in the unfair and unwarranted criminal investigations that threatens their reputations and livelihoods.

I am currently in private practice in St. Petersburg, Florida, and I am at risk for being accused of Medicare Fraud. I say this because of the trend affecting the "middle district" of Florida, under the "Operation restore trust" program supervised by US Attorney Bucella. To date, 140 of my fellow physicians have been subpoenaed, 14 have been indicted, and 2 have been tried and convicted. Based on the 2 convictions, the 14 indicted physicians have been goaded into accepting pleas which effectively ends their medical careers. One of the indicted physicians had an office 2 miles from my office. He has been stripped of his dignity, financially bankrupted, and embarrassed publicly, by being arrested in his office and handcuffed and paraded out through his waitingroom full of patients. He has not been tried or convicted, but his medical career is over. I am at risk of losing my practice just as this physician if I am placed under suspicion. We practice medicine largely by reputations based on ethics and moral behavior. If this reputation is put in question, our ability to gain the trust of the patient suffers.

I am further at risk of being charged with Medicare fraud because of where I practice. The Middle District of Florida has the highest number of inquires into Medicare fraud. This is not because there is more fraud here than anywhere else

but because of an aggressive Prosecuting Attorney looking to make a name for himself at the expense of the physician. This is based on questionable practices, threats, extortion and misconduct that appears common place under the supervision of USA Donna Bucella. Several high profile cases have been overturned , and charges dropped due to prosecutors misconduct according to an recent article in the St. Petersburg Times by Graham Brink on 3/24/01. According to this article, The Aisenburg's case charges that the investigators lied, fabricated evidence and raised questions that the federal prosecutors knew, and intentionally mislead the Grand Jury. There are similar issues raised by the lawyers defending the physicians involved here as well.

The defense has stated that the physicians were "duped" into questionable contracts. The prosecutors have questioned how intelligent physicians could be "duped". In order to understand how this could have occurred, you have to understand the practice of medicine in today's HMO driven market.

I specialize in Family Practice. I usually work 12 to 16 hours each day. I usually start with rounds at the local hospitals before office hours. Office starts at 8:30 am, and I usually see on average 25-35 patients over the next 8½ hours. In-between seeing patients, I answer questions from staff, answer telephone calls from patients and other physicians, and see representatives of supply companies, pharmaceutical companies, diagnostic testing services and facilities. The average time I have to see these representatives is less than 10 minutes. In this 10 minute session, these rep's will try to sell their services, by giving information, written material and supportive evidence. This information is placed on the desk, and I move onto the next patient or rep. My day usually ends as it starts, rounding at the local hospital after office hours. The remainder of the day is on call, knowing I could be called back to the hospital at anytime.

The physician does not have enough time to set up meetings or verify every legal claim made by the reps. A great deal of trust is placed in the rep, and other physicians with similar agreements. The physicians who were prosecuted are similar to myself. They were in private practice, without sufficient time to verify contracts proposed to them. They also did not have the funds available to hire a lawyer everytime a rep made a claim, or offered a contract. These physicians did not enter into these contracts with any intent to defraud the government. The basic premise was to take care of the patient. The convience of a medical test, the ability to follow up immediately allows the physician to take care of the patient.

A methodical, well thought out plan such as the one involved in this case required time and planning. This was produced by the businessmen working on the fringes of medicine. These individual businessmen have no care for the patient, they only care about the money.

I am not inferring that no physician has ever defraud Medicare, and further I am not supporting any physician who has defrauded Medicare not be punished. True justice protects the innocent and punishes the guilty. It is equal and fair. It is not to advance one's career goals. It does not cater to the ones with the most money, or the ability to hire the most lawyers. It treats all suspects with respect and thinks them innocent until proven guilty in a court of law, not the prosecutor's office.

We ask that you look at the facts presented today both in testimony as well as in the white paper prepared by our attorney. We wish to ensure a spotlight shines into the abyss that we practice in today, so that further lives are spared the indignity of being wrongfully accused. We are only asking that fair and just measures are used to enforce Medicare fraud. We ask that the physicians are treated with respect, and allow them to take care of the patient. We ask that you punish the true criminal no matter how layered they are with lawyers and false companies. The physicians are easy targets, with the most to lose, but the true losers are our patients. If you allow the current standards of prosecution to remain, young physicians like myself, will not be around to take care of the patient, and an already overburdened system will deteriorate even faster.

We are asking for your help. Thank you for the opportunity to bring these issues to light. We truly appreciate your diligent investigations into this disturbing trend in the criminaliztion of medicine.

Mr. BILIRAKIS. I will go ahead and kick off my questioning.

I don't have to tell you good people that there is an awful lot at stake here, and what is at stake, of course, is the quality of medical care to our constituents. We hear these stories. I don't know how many of them are isolated, although I might tell you we hear an awful lot. As the good people from HCFA might know, we have requested input from all the Members of Congress regarding the

problems some of the providers have had. And once we get those, those will be a part of a forthcoming hearing.

I would like to ask Dr. Miller and Mr. Mangano, you have heard these other people testify regarding specific situations. I am one of those people who feels that you are conscientious, that generally HCFA officials are conscientious, they are trying, they are working hard. I have said this before a few times—I have been disappointed over the years when we have asked HCFA officials to tell us what they need from us in terms of changes in the laws and changes in authority so we can help them do a better job. Really, not too much was forthcoming in that regard.

Even from the money standpoint, I am not sure that I remember anybody from HCFA specifically saying, "Give us X amount of millions of dollars or whatever the case may be, and we will do a better job." If they would do that, I would like to think that they would tie it into specific functions so that we could have an idea of where the money might be going.

Let me ask you, Dr. Miller, we have worked together, but some of these stories that you have heard from these good people, are they acceptable? I mean are they acceptable from the standpoint of where there are 1 billion claims transactions in a year's time? Some of this conduct that they have talked about, which can be multiplied many times, is that basically acceptable from the standpoint of so many claim transactions where a few things are going to fall through the crack?

Mr. MILLER. They are unacceptable, and——

Mr. BILIRAKIS. They are not acceptable.

Mr. MILLER. [continuing] and all of them are regrettable. You are right. There is a billion claims. It does mean that transactions will go off track at times. All of these, the transactions that have occurred here, give us raw material to listen and to make changes. The enrollment form was underlying one of the problems or a couple of the problems that were brought up today. We recognize that the enrollment form is complicated, and there are several steps we are taking to make that better.

We have broken the enrollment form out so that it is specific to the type of provider. Before it was all together, and that was confusing to people. We have put the instructions with each of the items on the form, and we are moving to setting strict timelines, that when a form comes in, all questions must be dealt with a physician and the provider and settled and the enrollment form done.

Another situation that has been discussed here is the advanced beneficiary notice when a service is not going to be covered so that the beneficiary knows that they may be liable for it. And it may have taken a long period of time, but we worked with the Practicing Physicians Advisory Council, and we have designed a much more streamlined, single-page form to deal with that, and that was done in consultation with the medical societies—or with the physicians.

They aren't acceptable. These things need to be corrected. We take all these transactions seriously, and when we are aware of them, the regional office, the carrier, and HCFA central office deal with these problems.

Mr. BILIRAKIS. Well, all right. Let us go into the carrier or the contractor, whatever term might be used there. My understanding that HCFA's authority over the carriers is very limited?

Mr. MILLER. Well, there are certain strict authorities in the law about who we can contract with, in terms of our contractors, carriers, and intermediaries.

Mr. BILIRAKIS. So we tell you who you can contract with.

Mr. MILLER. That is correct. And I believe the contracts are cost based so they are not performance based or competitively bid. But then behind that, we have budgets that we set, and we have criteria and performance standards for each of the contractors, and we try and manage contractors through those mechanisms. And then also some of the problems that have been discussed here are issues of consistency, that you get the same message from the same carrier and the same message from within the same carrier or contractor. And the efforts there are through education, standardized materials that we give to carriers to, in turn, give to the physicians and other providers to assure that that aspect of managing the carriers results in consistent messages.

Mr. BILIRAKIS. I was told just this morning in a meeting by a group of providers—one provider indicated that Medicare reimburses a particular procedure in one part of the country. Under a different carrier, and in another part of the country, for exactly the same procedure, there is no reimbursement. Is that true? Can that possibly be?

Mr. MILLER. We had a hearing here a couple of weeks ago, this same committee, you as the Chair, on coverage of technology. And in fact, carrier medical directors do have flexibility to cover procedures differently across the country. And some of the logic behind that is the idea that different marketplaces may be at different levels of development in terms of procedures that are being used for their populations, and that flexibility actually gives, again, information that can then be used to make a national coverage decision, a national payment decision, and a national coding decision. But the answer is, yes, that can happen.

Mr. BILIRAKIS. The answer is yes. And it should be that way, in your opinion.

Mr. MILLER. There are people who argue that that flexibility is necessary to assure that technology and new procedures get to beneficiaries as quickly as they possibly can.

Mr. BILIRAKIS. Thank you. Dr. Becker. Now, we have heard 50 cents on the dollar is basically spent to handle the regulations, to learn about the regulations, and to complete the paperwork. In terms of time, does that translate into 50 percent of a doctor's time?

Mr. BECKER. Well, fortunately, it doesn't translate into 50 percent of the doctor's time, but what we end up doing is we have to hire a staff to do that for us. So, generally, I would say—and it does come out to about 50 percent——

Mr. BILIRAKIS. It does.

Mr. BECKER. [continuing] because it turns out that I probably have one administrative clerk for every one health care providing staff on my staff. And so we have a staff of 10 people who are the

team members in my office, about 5 of whom provide health care and about 5 of whom do billing and administrative bureaucracy.

For the physicians, as it turns out, where it encumbers our time more than anything else because we have a dedicated office, and we are going to do what we have to do for our patients, it takes away time from my evenings and my family, and it takes away time from me on the weekends with my family, because I have to go down to the office and take care of administrative responsibilities.

Mr. BILIRAKIS. I want to get back at that maybe in the second round, but Mr. Stupak, you haven't had an opportunity to inquire, I don't think, have you?

Mr. STUPAK. Have not.

Mr. BILIRAKIS. All right. Please proceed.

Mr. STUPAK. Thank you, Mr. Chairman. You know, in looking at this whole situation here and some of the questions that Mr. Deal asked I was quite interested in, because if you take a look at the Balanced Budget Act of 1997 alone, Congress, us up here, added 350 new Medicare and Medicaid policies, many of them which were very complex and gave you a relatively short time to implement it. But did you receive, Mr. Miller or Mr. Mangano, whoever wants to answer, did you receive any extra money to do these new 350 new programs, to administer them, to contract out, whatever you did?

Mr. MILLER. There was money included in the budget to try and implement those programs, but your larger point is that the responsibilities have been significant. I think the number is 900 provisions have been added over the last 4 years, and that the resources are very strained now to try and implement.

Mr. STUPAK. Well, for the last 4 years, you must be talking about HIPAA then and children's health initiatives.

Mr. MILLER. I am talking BBA, BBRA, the most recent Benefits Improvement Act, and HIPAA.

Mr. STUPAK. What do you do when you get those mandates like that from Congress? Do you do them internally or do you contract out?

Mr. MILLER. The mandates? Perhaps one point that should be made here is that you should understand, and perhaps you do, that there is HCFA central office, HCFA regional offices, but then there are 50 private carriers. These are private insurance companies. And what happens at HCFA central office is you define policy, you define procedures and how the program will be implemented. That information is given to the carriers——

Mr. STUPAK. And they do the implementation.

Mr. MILLER. The systems and the communication, that is correct.

Mr. STUPAK. So even though you try hard not to, it is not unusual then to get 50 different interpretations of your own policy then.

Mr. MILLER. The carriers?

Mr. STUPAK. Sure.

Mr. MILLER. From us?

Mr. STUPAK. No. That they could interpret it—I mean you give them as much structure as you can, but it is for them to administer it, so it would not be unusual then to get different administration of the same rule out in the field to the doctors.

Mr. MILLER. I wouldn't go to 50, hopefully.

Mr. STUPAK. All right, 49.

Mr. MILLER. I believe that with 50 different carriers, you can get some variation. I think that has been obvious from some of the comments here. But part of our education efforts are to standardize the information that is given to the carrier so that doesn't happen.

Mr. STUPAK. Well, let me go to the carriers, Ms. Bradley and maybe Mr. Friedman. You know, I have been on this what my fourth term now going on this subcommittee and on Commerce Committee where we deal with Medicare and Medicaid. Can anyone just tell me in really simple terms—and maybe you can't, maybe it is just too complex—but what really is broken? Whose fault is it? Is it HCFA? Is it the carriers? And how do you fix it? Try that one in 5 minutes.

Mr. BRADLEY. Well, I will start, because I am not a carrier. I represent physician offices.

Mr. STUPAK. All right.

Mr. BRADLEY. But MGMA represents—really has its pulse on the physician offices across the country. And I believe that it is a complex task, and it is accomplishable, but it does take input from the providers. And just this communication that we are having right now is a step in the right direction.

Mr. STUPAK. How would you fix it? How would you fix the problem?

Mr. BRADLEY. One step at a time.

Mr. STUPAK. Okay. Give me a "for instance."

Mr. BRADLEY. For instance, if there were quarterly reports from the Federal Register that we could depend upon, we knew that they were coming every quarter with any changes that were coming down the pike, if the Federal Government required the contractors to notify providers and give us a time limit, we would know at certain times check the Federal Register, check with our carriers, let us know what is happening, and then open up the lines of communication in that manner.

Mr. STUPAK. But you would want the communications before the changes were made, I would take it.

Mr. BRADLEY. Before the changes are made, that is correct.

Mr. STUPAK. So in that quarterly report, you would like to see here is the proposed change, certain time limit to respond, and then finalize the rule?

Mr. BRADLEY. That is correct. Give us enough time to implement the changes, give the carriers enough time to get the system working correctly.

Mr. STUPAK. How much time is usually that? I mean up here we usually hear 180 days, things like that.

Mr. BRADLEY. I would say 45 days from the time of the Federal Register publication, perhaps.

Mr. STUPAK. Okay. Mr. Friedman, you want to add anything there?

Mr. FRIEDMAN. Absolutely. From the carrier point of view, the pace of change is probably the most difficult to deal with. And the 180 days is a very different number. I don't want you to think of that at all from what the carriers have to do. The 180 days comment was that—provided, a community would like 180 days to un-

derstand a new policy, but it takes much more than 180 days to change your electronic systems to actually process a new policy. As a matter of fact, there is supposed to be roughly 8 weeks of testing time for putting something of any significance new into a system. That has never happened. We have never gotten 8 weeks of actual testing time.

And so while you have got, on the one hand, lots of things to do, on the other hand, very complicated things to do, you don't, in the final analysis, get enough time to implement and test what you are doing. And all of this becomes a vicious cycle, because then the next set of changes come along.

The other area has to do with funding, but funding not in the simple sense that you probably need a few more dollars because you have got a few more claims. What has happened over the last several years, because of dealing with less money, is that the infrastructure is gone. It isn't so much that there aren't enough people to process claims, but there aren't enough people to stop and say, "Are we doing it well?"

When you have to give things up, the things you give up appear to be intangible, but they are very important in running an organization from a quality point of view. And so we have got to get back to the point where there is sufficient money so that an organization can not only do what it has to do but look behind itself and see that they are doing it well.

Mr. STUPAK. Thank you, and thank you, Mr. Chairman. I see my time has expired.

Mr. NORWOOD. [presiding] Thank you very much. I want to first start by saying to all of you how much we appreciate you being here, particularly those of you that have taken time away from your practices and are here on your own buck. This is a very, very important hearing, leading to, I hope, some very important solutions.

Dr. Miller, I wouldn't have your job for anything on Earth. I want to say to you that I have come to the conclusion that no matter how many smart people you have an no matter how big your computers are, this issue is out of hand and simply too complex, I think, to deal with on the path that we have been going over the last year.

And I also want to say to you that I think there is a lot to be said—a lot of truth in the fact that Congress is micromanaging. I think Congress certainly aids in many of the problems that we see from HCFA today. We lay down laws, and you lay down rules, and somewhere in the process we have all made a large, large mess. Can you simply tell me how many new rules and regulations that you have put out in the year 2000?

Mr. MILLER. No, I can't. I can come back to you on that, but, no, I don't know the answer to that.

Mr. NORWOOD. Would you care to even guess? Are we talking about 3 or 30 or 500?

Mr. MILLER. I couldn't hazard a guess, because I would say two things in response to your question. Remember that there has been several pieces of major legislation passed on a couple of years, and so the volume of rules and instructions to providers and so forth

may be significantly more than it would be in an average year, if such an average year exists.

Mr. NORWOOD. Well, when you come back with the answer of how many in 2000, why don't you come back with the answer of how many in 1990? Let us just see how this thing has grown over the last 10 years.

[The following was received for the record:]

In 1990, we issued about 40 final rulemaking documents. Similarly, in 2000 we also issued about 40 final rulemaking documents. It is important to note that we counted only final rulemaking documents, or substantive changes to final documents, not proposals. Additionally, although these numbers are similar, they do not reflect the breadth nor thr comlexity of each final rulemaking document.

Mr. NORWOOD. Mr. Friedman, I thought I heard in your statement something to the effect you put out a number or an explanation of how many rules you as a contractor have had to deal with in the year 2000.

Mr. FRIEDMAN. One of our contractors had put together—done a count in 2000 that 719 significant change transmittals had come through.

Mr. NORWOOD. The number again, please.

Mr. FRIEDMAN. Seven hundred and nineteen in the year 2000, which was about 2.5 times what it was in 1998. I am talking fiscal years, actually, Federal fiscal years. So it is growing considerably.

Mr. NORWOOD. And those are simply rules you as a contractor get, which typically you pass on to Dr. Wood, Dr. Becker, and others. Is that correct?

Mr. FRIEDMAN. That is correct, sir. And also what it doesn't really tell you is that some of them may be extremely significant.

Mr. NORWOOD. Let me stop a minute and try to make sure we get this record straight. I know everybody says there are a different number of thousand rules. HCFA says they only have 35,000. I tend to say there is 130,000, and I am looking at it from the point of view of not HCFA, but the provider that sits there and has the 35,000, which is probably a conservative number that could be questioned. And all the rules then that come from all of the contractors for a physician who deals with numerous contractors.

And the point I make here is about educating the provider. That is a very interesting concept. Doctors spend 4 years in college, 4 years in medical school, 1 year as an intern, 2 to 6 years as a resident. My understanding is that they deal with the equivalent of about 12 dictionaries a year in terms of their learning process all the time in medical school. And I am saying a dictionary, perhaps, is 1,000 pages, for example.

Now, if we are going to educate the provider, that means that the provider—if you take all your rules and regulations and you put them into a textbook, the provider has to deal with about 10 dictionaries a year to get educated. And I am wondering do we need to add another year of medical school in order for the provider to become educated with all the rules and regulations?

A lot of our colleagues talk about educating the physician who typically is fairly able to be educated. But the system, I contend, is so out of hand that there is absolutely no way that a doctor can treat his patients and tend to all the rules and regulations. And Congress, through HCFA, has made it then even that more dif-

ficult, because now if you don't pay attention to the rules, we may put you in jail or we can make you have a bad day. And this kind of situation has got to change.

Dr. Miller, you talked a lot about your emphasis on provider education. Remember I ask you this question in the context that we are looking at 10 dictionaries worth of education. I see in this program memorandum that, quote, "Provider feedback in education is an essential part of solving problems," end quote. So my question is why, in the October 31, 2000 Federal Register on critical standards for evaluating carrier performance is, quote, "provider education optional," in that Federal Registry rather than mandatory? The question basically is, if you really believe that we are going to solve this problem by having another year of medical school, and that is the only thing that is going to solve it, why is it optional?

Mr. MILLER. Just a couple things. On the 35,000, the other thing to keep in mind there is those are not all for physicians. That is 35,000 for all providers, so I wouldn't expect that the physician would know all of that.

Mr. NORWOOD. So now we are back to eight dictionaries. I mean, come on, you get the point of this.

Mr. MILLER. I realize it, and page counts are not the point here. Education and communication is the point, which I think is your point, and I agree with you. I am not aware that provider education is optional as one of the criteria for carriers. We have budgets for the contractors to do education, and my understanding is, is that they are all doing it.

Mr. NORWOOD. Well, look under the criteria standards in the Federal Register and see if I am not right.

Let me ask Mr. Mangano?

Mr. MANGANO. Mangano.

Mr. NORWOOD. Mangano. You said in your testimony that you are really saving the Federal taxpayers all these billions of dollars. And, certainly, none of the things you are dealing with happens to be an honest billing mistake. That is not a problem. Why don't you explain to us what happens if a physician makes an honest billing mistake.

Mr. MANGANO. If a physician makes an honest billing mistake, what will happen in almost every case is that HCFA will ask that provider to return the money. If the case happens to be turned over to us in which we are asked to investigate it and we discover it was an honest billing mistake, we turn it right back to HCFA and just say, "Repay the overpayment."

Mr. NORWOOD. Sort of like they did with Dr. Becker's friend after they wrote all of his patients and said, "Geez, you are going to a doctor that is overcharging you." I mean I expect that from Blue Cross Blue Shield; I have been on that end of it. But I don't expect that from the Federal Government.

Mr. MANGANO. None of those cases were given to the Inspector General.

Mr. NORWOOD. None of the cases that——

Mr. MANGANO. Dr. Becker talked about.

Mr. NORWOOD. —Dr. Becker talked about.

Mr. MANGANO. They all stayed within HCFA and its contractors.

Mr. NORWOOD. But don't—first of all, if a mistake is made, you don't know if it is honest or not.

Mr. MANGANO. Well, I would just mention that for us to prosecute someone criminally, we would have to prove criminal intent to defraud the Medicare Program.

Mr. NORWOOD. I appreciate that, but this is more than just prosecution. If a mistake is made, though inadvertent, you don't know that, and that triggers an audit.

Mr. MANGANO. If we were asked to go in and to take a look at a provider because HCFA suspected, or its contractor suspected, that they were overbilling the program intentionally, we would go in and take a look at it, and review the facts of the matter.

Mr. NORWOOD. Well, if they made a mistake, you don't know if it is intentional or not, so therefore an audit is—you either deny the payment or you have an audit, don't you?

Mr. MANGANO. At the beginning of the process, if we were involved in it, we obviously don't know what has happened. We want to go in there and find out what the facts are.

Mr. NORWOOD. Which is an audit.

Mr. MANGANO. It could be an audit or it could be an investigation, depending on what the allegations are.

Mr. NORWOOD. All right. It is an investigation. Now, when you start investigating people, if they are really, really nice and cooperate in every way, how long is this type of thing? How disruptive is this type of thing? How many patients aren't treated while you are auditing or investigating?

Mr. MANGANO. If we are doing an audit, we will draw a sample of claims from that particular provider. We ask them to send us the medical records so we don't even have to go in to the office to do that. They send us the records, we review the records, review any other information that is available around the case. As we go through the records, if we find that there has not been a problem here or that the problem is what we believe to be an inadvertent billing error, we end it at that point, give the records back to the health care provider, and tell HCFA that they probably need to go collect an overpayment.

Mr. NORWOOD. I am not going anywhere. Please don't leave, Dr. Wood and Dr. Becker. I have got a bunch of questions I want to ask you two. My time has expired, and I believe, Sherrod, you are next. Mr. Brown is next.

Mr. BROWN. Thank you, Mr. Chairman. You know, I hear over and over the threat of doctors going to jail, and I hear it from my district, I hear it from committee members, that if doctors make a mistake, they go to jail. I am just real curious, Mr. Mangano, how many doctors have actually gone to jail, and what do they go to jail for?

Mr. MANGANO. Since I knew this hearing was going to be dealing primarily with physicians, we went back and took a look at our records for the last 3 years. In the last 3 years, we criminally prosecuted an average of 18 physicians a year, out of the 650,000 physicians.

Mr. BROWN. Do all 18 of them—since I hear so much about it—do all 18 live in my district?

Mr. MANGANO. No, they don't. These are physicians that—I will give you some examples. One case we had physicians that were billing for acupuncture. They were claiming it was physical therapy—1,300 times. It is interesting, because Medicare doesn't cover acupuncture, but it does cover physical therapy. Even when we got into the case, we found out something even more interesting, that most of the patients weren't even around when the physician said that they were around. Some of them were in jail; some of them were in the hospital so they couldn't have been treated.

We have physicians that are signing certificates of medical necessity, which are required in order for a patient to get durable medical equipment. The durable medical equipment company would go to the physician and say, "Sign this stack of certificates of medical necessity, a whole stack of them. We are going to give you $100 for every one you sign. And, by the way, you are not going to see the patient." And then the physician not only takes the kickback arrangement, but often bills Medicare for office visits that never happened. This is the kind of case that we deal with.

So 18 isn't a lot. We don't have enough investigators to go out and look at every allegation, so we are picking what we believe are the worst cases. In addition to the 18, we also were successful civilly with another 20 on average per year. There is not a lot of physicians that are coming under our scrutiny.

Mr. BROWN. Eighteen a year were criminally prosecuted successfully?

Mr. MANGANO. Correct.

Mr. BROWN. And 20——

Mr. MANGANO. Civilly.

Mr. BROWN. [continuing] a year civil. How many of those were criminally or civilly prosecuted for making what one might call an honest mistake?

Mr. MANGANO. None of them, because none of the criminal or civil statutes would allow us to do that. It would be illegal. Criminally, we would have to prove criminal intent to defraud the Medicare Program. When we go after somebody on a civil case, we have to prove that they had actual knowledge of the false claim they had submitted or a reckless disregard for the truth. So honest billing mistakes don't come under our purview.

Mr. BROWN. If you were to explain each of those cases, those 38, say, last year—18 and 20—to this whole panel, do you think there would be any doubt that all of us—do you believe that all of us would think that was a legitimate prosecution?

Mr. MANGANO. I believe so. We speak about 75 times a year before professional organizations, compliance organizations, and the bar that represents them. And every time we go out and we talk about the kind of work that we would be doing. When we get to specific cases, there is no argument over that. In fact, we ask people to send to us examples of where they believe we have misapplied our investigative resources for a particular case of a physician or other health care provider they think we should not have been investigating. And to this date, in the 20 some years that I have been in the Inspector General's Office, no one has ever come to us with a case like that. Because when you get to specifics, everybody realizes that these are bad cases.

And what happens is, probably the worst damage of all is that these few bad apples, these bad physicians, are tarnishing their whole profession, because when the public sees in the newspaper Dr. So-and-So was convicted of criminal fraud in the Medicare Program, it tends to put a taint on all physician practices, and that is unfair.

Mr. BROWN. Do you ever prosecute anyone, a doctor, when he or she gets conflicting information from carriers, and they take the more lucrative choice, if you will?

Mr. MANGANO. No. As a matter of fact, one of the first things that we do in an investigation and in an audit, is to go back and look at the information that was sent to them by the contractors and we ask them about that: "What information did you have in terms of how to bill for this procedure?" And when the contractors says, "Bill it this way," and they did, even if they had conflicting arrangements, that is the end of it for us.

Mr. BROWN. So going back, that is 38 physicians out of how many physicians in the United States?

Mr. MANGANO. Six hundred and fifty thousand, approximately.

Mr. BROWN. Okay. That is a better percentage than Members of Congress, I would say.

Mr. MANGANO. Every profession has bad apples.

Mr. BROWN. Speak for yourself.

Mr. MANGANO. Every profession has bad apples, and unfortunately the medical community has theirs.

Mr. BROWN. All right. Thank you.

Mr. BILIRAKIS. First, the February 4 letter from Secretary Thompson that I inserted into the record is in response to a March 22 letter sent by the committee to Secretary Thompson, signed by Mr. Greenwood, Mr. Tauzin, and myself. So I would ask unanimous consent that that letter be placed in the record. And then there is a February 19, 2001 article in USA Today by Julie Appleby and additionally an article in the Denver Post, dated January 12, 2001, entitled, "Doors Closing for Medicare Patients." I would to, with unanimous consent, insert those into the record.

[The material referred to follows:]

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DAVID V. MARVENTANO, STAFF DIRECTOR

U.S. House of Representatives
Committee on Energy and Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

March 22, 2001

The Honorable Thomas Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Thompson:

We are following up on our February 15, 2001 letter regarding the Energy and Commerce Committee's initiative "Patient's First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage." Our inquiries are aimed at improving the operations of the Health Care Financing Administration (HCFA) and making federal health care programs more accountable to patients.

As you know, Congress, HCFA, the Department of Justice, and the Office of Inspector General have focused resources in recent years on preventing, detecting, and eliminating fraud and abuse in Federal health care programs. These efforts have contributed to reducing the Medicare program's improper payment rate by almost half from FY 1996 to FY 2000.

While this progress is a positive development, some Medicare providers have voiced their concern over the increased burdens and intrusiveness of these oversight efforts. Specifically, they have stated that they feel that their involvement with the Medicare program has not been accompanied by basic information on what physicians need to know about Medicare and the most common problems that occur. We are concerned that improper Medicare payments continue to persist and we support HCFA's efforts to reduce improper payments. However, we also want to explore ways to reduce the needless complexities of the Medicare program and identify additional ways to educate providers about how to comply with existing rules and regulations.

To help our Committee achieve these goals, we would appreciate answers to the following questions about the Department's current policies on fraud and abuse and HCFA's efforts to educate the provider community on some of its existing laws, regulations and policies.

(1) Please describe all forms in which HCFA informs providers of changes in rules, regulations and policies to the Medicare program. Does HCFA, or its contractors, maintain a listserve and a searchable website for providers wishing easy access to this information?

(2) As you know, there are multiple ways of issuing policy statements to affected stakeholders in the Medicare program, including carrier transmittals, program memoranda and published regulations. Under what circumstances does HCFA believe that a policy change requires issuance of a formal regulation or alternatively, can be accomplished through the release of a program memorandum? What criteria does HCFA employ to determine the method it will use to disseminate changes in policy to stakeholders?

(3) Do contractors consistently provide written responses to providers' questions regarding billing, coding and documentation issues? Do you have any mechanism in place for tracking the consistency in answers provided by different fiscal intermediaries and carriers to the same questions?

(4) How does HCFA educate providers? Are there any consistent training or educational materials available to the provider relations personnel at different carriers and fiscal intermediaries? If so, please provide us with a copy of these educational materials.

(5) How does HCFA identify specific billing, coding and documentation problems that it believes may jeopardize program integrity? Please provide to us in detail any specific protocols it employs to determine whether a particular code is being improperly utilized.

(6) Is HCFA planning any national education campaign to assist providers and medical students on understanding major new policy developments, such as the newly-released self-referral regulations or the proposed Evaluation and Management guidelines?

(7) On January 22, 2001, HCFA issued a memorandum to all Peer Review Organizations (PROs) telling them that "effective immediately" they were no longer allowed to accept "physician query forms" as documentation in the medical record to support DRG coding. Why couldn't hospitals include the query form as part of the medical record, rather than require the physician to make a separate and duplicative entry directly into the medical record?

(8) HCFA, the Department of Justice and the HHS Office of Inspector General all play an essential role in the detection of fraud and maintaining the integrity of the Medicare program. How often do these governmental entities meet to discuss ways to improve program integrity and develop procedures for reducing the volume of fraud and abuse in the system? What specific recommendations have come from these meetings? Describe the manner in which recommendations have been proposed and implemented. Have the participating agencies complied with internal recommendations? Please explain how HCFA assesses the performance and compliance levels with these recommendations.

(9) What procedures are in place to ensure that HCFA is consulted, when appropriate, by investigatory agencies to discuss the Agency's interpretations of the rules or regulations that will be relied on to justify a prosecution?

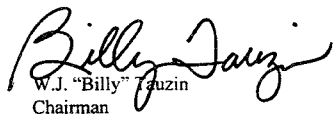
(10) Every year, the American Medical Association (AMA) conducts a coding clinic to educate providers about ambiguities in its CPT Code system. Does HCFA conduct a similar clinic? If HCFA does conduct such a clinic, how does it coordinate with the AMA to ensure that it can answer all of the providers questions at this clinic?

(11) What specific mechanisms do you have in place to ensure that providers have a speedy resolution of audits? Do you have any internal time frames in place for how quickly these audits should be completed? Please provide documentation regarding whether these internal time frames have been honored.

(12) How many provider audits has HCFA conducted within the past four years? What percentage of these audits have caused providers to return overpayments or enter into voluntary settlements with the Inspector General or other law enforcement agencies? Please provide a breakdown by year.

We are requesting that HCFA provide its responses to the above questions to the Committee by April 2, 2001. If you have any questions, please do not hesitate to contact us or have your staff contact Tom Giles or Joe Greenman of the Energy and Commerce Committee staff at (202) 225-2927. We look forward to working with you on this important matter.

Sincerely,



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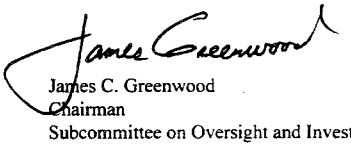

James C. Greenwood
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

cc: The Honorable John D. Dingell
The Honorable Sherrod Brown
The Honorable Peter Deutsch

Rejections rise for Medicare patients Crisis
feared as more urban doctors refuse
insurance plan

By Julie Appleby
USA TODAY

When Helen Edmonds moved from one Atlanta suburb to another, she began to look for new doctors.

"The first thing they ask is what insurance do I have," Edmonds says. "When I say Medicare, they say the doctor doesn't take Medicare."

In Colorado, Charlotte Sennett, 72, and her husband stayed in traditional Medicare for years rather than switching to an HMO, even though it cost more. "We felt it was more stable," says Sennett.

But now the Sennetts face a problem they never expected: Their Denver-area doctor will no longer accept the traditional government insurance program.

After years of using an insurance plan just about all doctors and hospitals accepted, Medicare patients are now shocked to find they aren't wanted.

In some cities, doctors frustrated with what they say are low Medicare payments and onerous rules are limiting the number of Medicare patients they take -- or refusing to accept new Medicare patients at all. Some physicians are even telling longtime patients that they have to find new doctors when they hit 65 and qualify for Medicare.

Once confined to rural areas, the problem is being reported in Denver; Atlanta; Austin, Texas; Spokane, Wash.; and other urban areas.

"We're getting more calls from people requesting assistance in finding a physician who will accept Medicare," says Glenda Rogers of the Area Agency on Aging in Austin. "Tm not sure we're in a crisis yet, but we could be in the not-too-distant future."

To be sure, the vast majority of doctors nationally still participate in Medicare. Yet two recent surveys of doctors were conducted in Colorado: One showed only 15% of doctors accepting new Medicare patients.

The pockets of insurgency reflect doctors' impatience with insurance in general and also highlight Medicare's main problem: how to provide more

benefits to more people, pay enough to keep health care providers interested – yet keep spending in check.

Medicare, which covers 39 million disabled and elderly patients at a current annual cost of $212 billion, will be an agenda-topper for Congress this year, as it debates whether to add a prescription-drug benefit, overhaul the entire program or both. In addition to frustrated doctors, Medicare faces other challenges:

* Medicare spending is projected to at least double by 2030.

* Managed care, which was supposed to save the program money, isn't proving as successful as hoped. Many managed care plans dropped out of the Medicare HMO program during the past 3 years, saying the government doesn't pay them enough.

* Medicare generally doesn't offer incentives to doctors or patients to choose less expensive but equally effective treatments.

Losing money on Medicare

Some doctors say the program can be downright frustrating. They complain that it doesn't pay enough, has burdensome rules and puts them under the threat of being audited by government agencies searching for fraud. Because of those issues, "We decided that Medicare just wasn't going to work for us," says David Downs, an internist with the 50-member New West practice in Denver. "We were losing about $100 per patient per year among Medicare beneficiaries."

The practice stopped accepting new Medicare patients about two years ago but will take those enrolled in Medicare HMOs. Downs says HMOs pay better, have fewer hassles and provide more benefits.

It wasn't an easy decision.

"The thing that's really difficult is when patients turn 65, and they don't want to go into an HMO. If they go into Medicare, they have to leave our practice," Downs says.

But if doctors are frustrated, some patients are, too.

"I've been paying taxes since I was 17 years old," says Margaret Grinnell, 65. "Now all of a sudden, these doctors are saying, 'You're old now. We really don't want to take care of you.' That's terrible."

Grinnell, a Denver resident, was bounced from two doctors in the past year after they decided not to accept the Medicare HMO in which she's enrolled. "Something has to be done so seniors get protection," she said.

When Edmonds received a letter saying her longtime doctor in Atlanta would stop accepting Medicare in January, she made an appointment to talk with her.

"I said, 'Ann, how can you do this to old ladies?' " But after the doctor explained the finances, Edmonds, who preferred not to identify the doctor fully, says she understood her dilemma. "She (the doctor) had to take money out of her savings to meet her office responsibilities."

The Sennetts decided to join a Medicare HMO so they could stay with their doctor after she joined the New West practice. The irony of leaving the traditional government plan, which is thought to give patients a wider choice of doctors, in favor of a more restrictive HMO was not lost on the couple.

"We went into an HMO to keep our doctor," Charlotte Sennett says. "This is exactly backward."

Frustration increasing

The problems the Sennetts faced in Denver and Edmonds faced in Atlanta come as doctors are increasingly frustrated with insurance, not just Medicare. Some refuse all insurance, seeking cash-paying patients.

Jettisoning Medicare may be easy for doctors who have few Medicare patients, but such action troubles some in the profession.

"I understand some of the reasons physicians feel increasingly frustrated, but I feel that physicians have a responsibility to be available to all Americans," says Richard Roberts of the American Academy of Family Physicians. "I would find it hard to say, 'You're gone,' or 'Sorry, I won't take care of your sister because I don't accept new Medicare patients.' "

The agency that oversees Medicare, the Health Care Financing Administration (HCFA), says reports of doctors refusing Medicare patients are not widespread. The administration has asked a regional office to look into the concerns of the doctors in Colorado, where Medicare payment rates are among the lowest in the nation. "We do take these reports seriously," says Barbara Paul, medical adviser to HCFA.

Still, the government notes that the physician participation rate in Medicare has increased and stands at about 91% of doctors, although its information

does not include what percentage of doctors have closed their doors to new patients.

One study that did look at that issue was done in late 1998 by the Medicare Payment Advisory Commission (Medpac). It found that 95% of doctors said they would accept new Medicare patients, about the same percentage as in 1997.

The size of the study meant it wasn't able to pick up problems that might be limited to particular regions, however, such as those reported in Denver, Austin and other cities.

"The level of frustration with the traditional program is very high among physicians," says Kathy Lindquist-Kleissler, executive director of the Denver Medical Society. "It pays poorly. There is a lot of paperwork and hassle. And there's the continuing threat of fraud investigations."

Her group, along with seven other Colorado medical societies, recently polled their members about Medicare, and found that only 58% of primary care doctors say they are taking new Medicare patients.

A separate poll of 350 Denver-area doctors by a patient advocacy group found only 15% willing to take new Medicare patients.

"The health care system is in a mess," says Hal Prink of the Patient Advocacy Coalition, which did the survey. "Medicare may need to look at reimbursement levels and say that because older patients take more time, the doctors need more reimbursement," Prink says.

Economist Paul Ginsburg, of the Center for Studying Health System Change, says the retrenching by some doctors, while now limited to pockets of the country, should be watched carefully. "If this becomes a widespread problem, that will be the signal that payments have to be increased," Ginsburg says. "If not, that will be a signal that payments are OK."

Are doctors paid enough in Medicare? The answer isn't clear.

Colorado has one of the lowest reimbursement levels for physicians in Medicare, often about 20% less than the highest-paid areas, based on a complex formula that considers geographic variations in the cost of running a business.

For example, a Colorado physician would get paid $47.35 for an office visit, while a doctor in Los Angeles would be paid $53.41 and one in New York City, $59.33. Yet even within Colorado, Medicare payments are not always

lower than what private insurers pay.

According to data prepared for USA TODAY by the Medstat Group, a benefits and data firm, Medicare pays 5% to 45% more than private insurers for a typical office visit in a sample of nine cities or regions, based on claims data submitted by large employers. Only one city in the sample, Austin, had a Medicare office visit rate lower than the average private insurance payment. In Colorado, the rate Medicare pays for an office visit is 7.6% higher than that paid by private insurers.

But it's a different picture for specialists or more complicated procedures. In the same sample, Medicare paid 5% to more than 50% less than private insurers in most regions for services such as colonoscopy, echocardiograms and in-hospital exams.

No means of comparison

The government doesn't have comparative data about what private insurers pay.

"That's one of the key things we need to know more about," says Marilyn Moon, an economist at the Urban Institute. The doctors' uprising against Medicare may simply reflect their drive to increase the amounts private insurers pay.

"For a while, the real market was tougher on them than Medicare," economist Ginsburg says. "But now their success (in winning contract increases from private insurers) makes Medicare a less attractive payer than it was a few years ago."

Even so, in Denver and some other areas, doctors say they can do better than Medicare. Although doctors have a responsibility to see Medicare patients, they have to balance that with the need to run a business, Debra Friesen says.

Friesen, the Sennetts' doctor, recently joined the Denver-area New West practice after the hospital-owned clinic she worked for closed. To fix Medicare, Friesen says Congress should pay doctors competitive market rates or face continuing access problems in the coming decades.

"As baby boomers age, who else are we going to have but elderly on Medicare? If we (doctors) are only going to take so many, who will serve them?"Cover storyCover storyCover storyCover story

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CASTLE PINES
V I L L A G E

Doors closing for Medicare patients

By Marsha Austin
Denver Post Business Writer

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Jan. 12, 2001 - Colorado's elderly could find it increasingly difficult to switch doctors or find a new physician if they get their health care benefits through the federal Medicare program, a new report says.

Physicians and Medicare

A survey by nine Colorado county medical societies found Medicare patients could find it increasingly difficult to switch physicians or find new physicians willing to treat them. The problem is less severe in Denver than other parts of Colorado, but still a major concern, the survey found.

Percentage of doctors now seeing Medicare patients

	Non-HMO		HMO	
	Colorado	Denver	Colorado	Denver
Specialists	95	95	77	85
Primary-care physicians	86	84	63	72

Percentage of doctors now taking new Medicare patients

	Non-HMO		HMO	
	Colorado	Denver	Colorado	Denver
Specialists	94	97	80	88
Primary-care physicians	58	62	46	64

Percentage now taking new Medicare patients, but restricting the number they see

	Non-HMO		HMO	
	Colorado	Denver	Colorado	Denver
Specialists	8	7	16	13
Primary-care physicians	53	31	48	41

The Denver Post

"There aren't a lot of doctors in Colorado throwing the doors of their practices open to Medicare beneficiaries," said Kathy Lindquist-Kleissler, a spokeswoman for the Denver Medical Society.

The physician organization and eight other Colorado county medical societies surveyed doctors to find out why - and where - patients are having trouble getting care.

The study is the first of its kind and provides state health officials with much needed data on how many physicians are closing their practices to new Medicare patients. The medical societies also gathered the top reasons doctors say they're dragging their feet when asked to take on more elderly patients.

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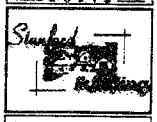

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They plan to take those concerns to Congress to force Medicare reform.

"Even without the baby boom population, we still have a growing aging population in Colorado and it's raising concerns," Lindquist-Kleissler said.

The problem is greatest for Medicare patients when it comes to getting in to see a primary care doctor.

Fifty-two percent of Colorado family and internal medicine physicians are accepting new Medicare patients, according to the report. Of those, half are opening only a handful of new spots or limiting enrollment of Medicare patients to family members of current patients or longtime patients who have just become eligible for the federal program.

The city and county of Denver fared best in the survey. The metro area's south and eastern suburbs didn't do as well, reporting fewer physicians with openings.

Colorado Springs and El Paso County posted substantially lower numbers of doctors willing to take new Medicare patients. In the Springs region, only 10 percent of primary care physicians will take new Medicare HMO members and 34 percent will accept non-HMO Medicare plan members.

Of those taking new patients, an average of 71 percent are limiting new enrollment, according to the survey.

"Given the current level of frustration among physicians with the Medicare program, reported intentions to further limit acceptance of Medicare patients should be cause for concern," the survey concluded.

Medicare beneficiaries have inundated state and federal officials, physicians and consumer groups with phone calls in recent months, complaining about the inability to find a doctor who will see them.

"It's really scary for the Medicare beneficiaries that are having to make 15 phone calls to find a doctor," said Lindquist-Kleissler.

In a separate, more informal survey, Hal Trink, a Medicare specialist from the Patient Advocacy Coalition in Denver called 350 primary care doctors across the metro area.

He found only 15 percent who would accept a new

Medicare patient.

"The three reasons everybody is getting out are that the level of reimbursement isn't enough to cover costs, the amount of paperwork is too onerous, and the fear of retribution because of fraud and abuse issues," Trink said.

But such evidence had little weight with national lawmakers, who wanted more hard evidence of Colorado's Medicare problem, said Penny Finnegan, a Health Care Finance Administration spokeswoman in the Denver office.

Now state health officials are armed and ready to lobby federal lawmakers for changes in Medicare that will encourage more doctors to open their doors to the elderly.

Regional officials from the Health Care Finance Administration, the Colorado Division of Insurance, county medical societies and patients' rights groups plan to submit the information to state congressional representatives.

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Mr. BILIRAKIS. Dr. Becker, you have heard the statistics—18 convicted, 20 civilly. I think Mr. Mangano has told us. Have you told us, basically, sir, that of those 18, or whatever the case may be, are any of them technically wrong in terms of billing mistakes, things of that nature or are they the onerous type of situation that you shared with us?

Mr. MANGANO. No, I believe they are the onerous conditions that we talked about. As I said, the requirement for us is to prove criminal intent to defraud for a criminal act, and, civilly, to show actual knowledge of a false claim itself.

Mr. BILIRAKIS. Mr. Mangano, my concern in that regard is that because of an honest mistake, not the types that you are referring to, a provider's reputation might be soiled, as a result. Can you address that?

Mr. MANGANO. Well, you know, one of the things that we have as a standard operating procedure, if we have somebody under investigation, we make no public statements about that. So no one in the outside world is going to know about that person through any press release that we are going to put out in our office. So they are protected that way.

When we serve search warrants, we try and do it with a great deal of respect for the practice, so we often will go in on a Saturday morning or ask the physician to stay at night after his hours are over so that we go in so that we don't interrupt any business there. At a hospital, it is the same thing. We try and do it in as unobtrusive way as we possibly can so we don't influence the practice that they have.

Mr. BILIRAKIS. All right. Dr. Becker, any comment?

Mr. BECKER. Organized medicine certainly supports the efforts to eliminate fraud and abuse from the system. We certainly would not condone in any way fraud in the system. What we are concerned about, of course, are inadvertent areas, which really fall probably not in the jurisdiction of the OIG, which looks at fraud, but really we are concerned about the aggressive methods used by the carrier under HCFA's observation about when physicians are alleged to have made overpayments, and where it has become very burdensome for practices to deal with those investigations.

Mr. BILIRAKIS. Well, do you know personally of any instances where a physician falls in the category of a billing mistake or something of that nature but nothing as onerous as kickbacks, where a physician has been accused and whose reputation was soiled? I realize that is a subjective issue.

Mr. BECKER. Sure.

Mr. BILIRAKIS. Oh, you do?

Mr. BECKER. Interestingly enough, when I first came to Clearwater, and this is about 12 years ago now, the person who brought me to town underwent an audit about 2 years after I was there. He originally had an allegation of an overpayment of $120,000. He is a busy physician who does a lot of work, including a lot of work for Medicare, because Largo, Florida has about 50 percent Medicare population.

Mr. BILIRAKIS. Is he still doing work under Medicare?

Mr. BECKER. Still doing great work.

Mr. BILIRAKIS. He is? All right. Good.

Mr. BECKER. He is a good physician; he is a smart guy, and provides excellent care to Medicare beneficiaries.

It was an alleged overpayment of $120,000. Obviously, not very many people have $120,000 in the bank. He had to take a bank loan out to pay that overpayment. He went to his fair hearing, which took months to arrange. He got the vast majority of that back. I believe he got about $120,000 of $140,000 back. So the vast majority he correctly billed initially, and that was proven during his fair hearing.

But in the meantime, it cost him certainly the interest that he had to borrow a bank loan on. It cost him lawyer fees, because he had to hire health care lawyers to help him support his case at the fair hearing. And it certainly was an incredible intrusion and inconvenience to his practice.

Mr. BILIRAKIS. Was the community area aware of all this having taken place?

Mr. BECKER. At that time, the community area was not aware. Now, obviously, there is one of the examples that I gave earlier in my testimony of where—and I am guessing that must be a new policy for the carrier to actually contact the patients. In the practice I was involved in, they did not contact the patients in that particular case. But they have in subsequent cases, which, like I said, I think may be a newer policy.

Mr. BILIRAKIS. I realize Dr. Becker's statement might be an isolated case, but are there—do you know of doctors who have been accused, who ultimately were not found to be guilty, whose reputations maybe were soiled wrongly? I don't want to come across as opposing the efforts on waste, fraud, and abuse. After all, it was this subcommittee, which a couple years ago kept emphasizing the need to do something about this. I am concerned that these things be done in a correct manner, and I am not saying that they haven't been, but we get an awful lot of comments from a lot of providers to that effect.

Mr. BECKER. The only case I am aware of is Dr. Taylor's case where in fact the Medicare carrier did contact his patients prior to his fair hearing. And so certainly there are incidents where due process is the second consideration after penalties are imposed.

Mr. BILIRAKIS. Dr. Miller, my time is up, but can you respond to maybe the Dr. Taylor situation?

Mr. MILLER. Yes. Yes, I can. We agree that—just a couple of points first. When there is an overpayment, by law, Medicare has to take it back. That is by law. It is correct that all steps of the process, when the overpayment is taken, when there is an appeal, and the adjudication of that appeal, that because the beneficiary also has money involved in this, they should be informed. In this instance, I believe that the case that he is talking about this was not a good example. This is not how it should have happened.

How it should happen is at each step of the process, the beneficiary should be informed of what is going on. So on appeal, when most of the money came back in this instance, the beneficiary should have also been notified of that. And there is a clarification of policy that is going out to make that clear to carriers.

Mr. BILIRAKIS. That is going out? It is in the process of going out?

Mr. MILLER. I can't remember whether it is going out or already out.

Mr. BILIRAKIS. Or already has.

Mr. MILLER. But that is a specific issue that we became aware and that we are——

Mr. BILIRAKIS. Thank you. Mr. Deutsch to inquire?

Mr. DEUTSCH. Thank you, Mr. Chairman. Mr. Mangano, Dr. Becker makes a statement that I would like you to comment on. He says in his testimony, I will quote, "Doctors are intelligent people, but we are not attorneys; we are physicians. Doctors should not fear that a computer keystroke error will miscode a diagnosis, which will trigger an audit that can be statistically extrapolated to a liability in the hundreds of thousands of dollars. Many doctors have been bankrupted by this system. We need due process for overpayment allegations; we need a system everyone can understand; we need training from our HCFA carriers for correct coding and documentation."

Mr. Mangano, what are your thoughts on this? And what do you believe is accurate here? And what, if anything, in this statement could benefit from a bit more context?

Mr. MANGANO. I believe everything in that statement is accurate. Nobody should ever be prosecuted for innocent billing errors. The worst that should happen in that case is if the errors have occurred, they do an overpayment back to the Medicare Program. Physicians, as with all other health care providers, need to have the kind of educational and training materials to understand the program as best as they possibly can. So there isn't anything in that statement that I would disagree with.

Mr. DEUTSCH. Can I ask two things about that? What about the responsibility of HCFA to provide that training for physicians?

Mr. MANGANO. I believe it is their responsibility. I have noticed over, say, the last 4 years a significant increase in the amount of training that HCFA has been providing. In fact, we have been on some of the panels when they have met with physician groups nationally. I do know there is a lot of materials going out from HCFA to its contractors, the advancement of some of the web sites that they have, as well as where the beneficiary can also contact Medicare directly and ask questions about Medicare.

There is information on nursing homes. They have got a system—we really are pretty impressed—if you have someone who is about ready to go into a nursing home, you can call up the Medicare web site and find out information about how that nursing home stacks up. There is a lot of really good things going on. That doesn't mean that more isn't needed, and clearly much more is needed.

Mr. DEUTSCH. On the training side, though, if you can, if you can sort of comment on any resource issues, in terms of HCFA itself having the resources to provide that type of training, specifically for physicians.

Mr. MANGANO. I am glad I am not an appropriator——

Mr. DEUTSCH. Right, I understand.

Mr. MANGANO. [continuing] but as a private citizen, HCFA does not have the resources to carry out this program in the way that I think you want it to be carried out or the health care profes-

sionals in this country want it to be carried out. We heard earlier in testimony the amount of money that HCFA has in terms of its overhead costs of 2 to 3 percent. That is really running this program on the cheap. Mr. Friedman, at the end of the table, talked about 15 to 20 percent being more adequate for their private-side business.

So I think the Congress, at some point, and the Administration are going to have to come to the point where if you want this program to operate properly, if you want people to get the training they need, if you want them to pay all the bills that are supposed to be paid, get all the information out, turn the legislation into regulations that are understandable, you have to pay for it.

Mr. DEUTSCH. Let me—and, again, because I want to get at least one more question, if you can try to be a little bit concise with the answer to this and specific if you can, and if you can't, if you can provide us afterwards with the information. Again, the statement talks about physicians being bankrupt because of keystroke errors and a liability of hundreds of thousands of dollars. How many physicians would you say would be in that category over the last 12 months across the entire country?

Mr. MANGANO. With relationship to our office, there shouldn't be any.

Mr. DEUTSCH. No, but how many were?

Mr. MANGANO. I would have to ask that of HCFA, because HCFA's contractors do an enormous number of—well, I won't say enormous—do many audits across the country. I really don't have that number.

Mr. DEUTSCH. Dr. Miller, would you want to respond to that, just to give a ballpark type number?

Mr. MILLER. Okay. I think what you are referring to are physicians being audited.

Mr. DEUTSCH. Or audited with the results of what we just said and with the information that is effectively a human error that was a mistake that led to that result.

Mr. MILLER. What I can tell you is three-tenths of a percent of physicians are in audit in any given point in time. That is about 1,900 physicians out of the 650,000. If I can also say one other thing about this. Program integrity is not my area, but I have been briefed for the purposes of this hearing. The way this works is progressive corrective action, and there is sort of three steps in it. If there is a small, one-time error, it is education and recouping the money. If there is a systematic problem, say, 75 percent of bills are coming in and being denied, then there may be that the physician is put on 100 percent review process to look at the claims. And then, finally, it is only in the most egregious cases, providing services that aren't covered or patients that aren't present, that get referred to the Inspector General.

Mr. DEUTSCH. Thank you.

Mr. BILIRAKIS. I thank the gentleman. Mr. Deal to inquire.

Mr. DEAL. Thank you, Mr. Chairman. Recently, my 94-year-old mother received a notice from one of her physicians that she was no longer accepting Medicare patients. Chairman Bilirakis has recently just introduced an article from USA Today with regard to this issue of certain parts of the country, in particular, suffering

physicians withdrawing from Medicare—as Medicare providers. I suppose, Dr. Miller, I would ask you is this perception that we are losing medical providers because of the complexity and the fear of being prosecuted or being harassed, is that real? And if it is, what, if anything, is HCFA doing about it?

Mr. MILLER. I don't believe that there is a widespread problem where physicians are defecting from the Medicare Program. I believe that there are physicians who do feel that there are burdens, and it is too burdensome to deal with the Medicare Program. We are aware of the situation in Colorado.

What Medicare is doing and what HCFA is doing, and much of this is laid out in the testimony, but for just 2 seconds or so, the kinds of things that we are doing: First and most importantly, we are listening to physicians, and there are several ways that we are doing that. I have mentioned the Practicing Physicians Advisory Council; I have mentioned the Physicians' Regulatory Issues Team. There are conference calls with the medical specialties, I believe, on a monthly basis. There are public meetings that we go to. There are accumulations of frequently asked questions so that we can say, "This is what they are confused by. We need to put out information to clarify this."

Then there is the issue of communicating information. We are trying with the carriers to standardize our communications so that there is not confusion across the carriers. So when we have a new bulletin, we often put the bulletin out to the carrier and say, "This is the guidance. Put it out unchanged to providers so that every provider gets it the same from every carrier."

We are doing things like that. We have national publications. There was another question along the lines here of medical school. We have a publication for interns and residents that says, "This is Medicare. This is what you can bill for. This is how you bill for it." So, again, we can get a standardized message out to the physician. We have toll-free lines that we now have so that physicians can ask questions. We have the web-based learning resources that Mike referred to. These are the kinds of things that we are working on.

Mr. DEAL. Dr. Becker, what is your impression of what is happening in the physician provider community?

Mr. BECKER. Well, I am in Florida, which is fairly—a little different than the rest of the country. Fifty percent of my practice if Medicare, and 50 percent of most physicians' practices in Florida is Medicare, sometimes a much higher percentage. It would be difficult for anybody in Florida to pull out of the Medicare Program without considerably sacrificing how busy you were going to be. So in Florida, it is not happening very much. But I think it is a much bigger problem around other areas of the country where there is a less high percentage of Medicare patients in people's practices.

Mr. DEAL. And in lower reimbursement rate areas, that complicates it even further, I would presume.

Mr. BECKER. I am sure it makes a difference. If you can get a higher compensation from a private insurance company, then it gives you less incentive to see a Medicare patient, for sure.

Mr. DEAL. Could I ask what is done to coordinate the reporting processes of those who are civilly and criminally prosecuted? Is

there any coordination with licensing boards and their States with—in other words, does anybody ever lose their medical license for defrauding Medicare?

Mr. MANGANO. If you are convicted of a criminal statute, you are automatically excluded from participation in any Federal health care program by our office. We put together lists, and they are available on the web sites, as well as people who want to contact us through our other information sources, to find out whether a physician or any other health care provider has been excluded, and we provide that free of charge.

Mr. DEAL. Do you provide it to the State licensing board of the state?

Mr. MANGANO. That is correct. We also provide it to HCFA, who sends it out to their contractors as well as to the State Medicaid agencies.

Now, if you are—if we have a successful civil action against you, in many of those cases, we have an opportunity to have a permissive exclusion. We only take that exclusion in the worst cases. We allow people to stay in business usually when we have a civil action against them. If they are willing to make some changes in the way they practice medicine, in many of those cases, what we do is require what we call a corporate integrity agreement. This is usually for large companies, in which we ask them to put into place training and self-audits of their billings to make sure that they stay good corporate citizens in the future.

Mr. DEAL. Thank you. I believe, Mr. Chairman, Dr. Miller raised his hand. I don't know whether you have time for him to respond.

Mr. BILIRAKIS. Quickly, if you would, Dr. Miller.

Mr. MILLER. I was just going to say that that is also coordinated with the carriers. When somebody is excluded, that information is given to a carrier, and carriers are aware that those providers are excluded.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. BILIRAKIS. All right. The Chair will recognize Mr. Deutsch for his second——

Mr. DEUTSCH. Thank you, Mr. Chairman. I appreciate being accommodated.

Ms. Bradley, in your testimony, you make the following remarks: "While MGMA agrees with both the current and previous administrations that additional HCFA funding is warranted, the efficiencies resulting from improving HCFA's organization and communication responsiveness will vastly improve the system without creating additional costs." What specific changes do you believe we can make right now regarding HCFA's organization and communication responsiveness that would make a substantive difference but would not involve adding additional resources to the agency?

Mr. BRADLEY. I believe that if claims can be processed efficiently without having to wait months and months and months, it won't tie up our staff, it won't tie up the staff at the carrier. We can save monies that way. I believe also that if you continue to offer free educational materials or if you will at least offer free educational materials and educate the provider community, we try to do what is right, we try to do a good job. We need clear communication and clear direction from HCFA and our carriers to do that.

The laws, however, need to be clear. Oftentimes there is a Federal law, and then there is HCFA. There is a State law, and they are hard to know which ones we should be following, what is in the manuals different from a Federal law. So we are caught in the middle, and as I said, we want to do what is right. So if we could have manuals, for instance, that agree with Federal law, that would save the system money.

Mr. DEUTSCH. Okay. Aren't most of the claims quickly processed under the Medicare system, some automatically through a wire transfer process at this point in time?

Mr. BRADLEY. I would say standard electronic claims, we are paid in a prompt manner by Medicare, that is correct.

Mr. DEUTSCH. Let me just follow-up on the two things you mentioned, and this sort of ties into my previous question. I don't think anyone here would disagree with your statement that there needs to be better communication with HCFA and physicians. I don't think there is anyone at all who wants physicians to not follow the procedure, to make inaccurate mistakes. I guess part of it, though, at least there might be a little bit of a difference amongst the panel up here in whether HCFA has the resources to do that. And I guess at least that aspect that you are describing, I don't personally see how HCFA can do it under present resources. I think that they should be doing more of it. I think it would have a cost-benefit effect absolutely. But I don't see them presently being able to do that under their existing structure. So I would agree with you completely about that.

The other issue, though, and, again, I guess part of our job in terms of our oversight responsibility on HCFA is specifically to look at that time element. I mean could you give some elaboration to that time element problem in terms of the processing of the more problematic claims that they have, I mean in terms of personal experience or others' experiences that you can relate to us?

Mr. BRADLEY. Yes. The time element spent in my office as well as spent with trying to——

Mr. DEUTSCH. Well, but also the reimbursement time element, in terms of the processing issues on claims that are not being reimbursed electronically.

Mr. BRADLEY. Claims that are not being reimbursed electronically take longer. Problematic claims can take at least 6 months.

Mr. DEUTSCH. Okay. And what does that mean as a practical problem for you or other offices?

Mr. BRADLEY. It is a practical problem for me, because lots of times I don't get any responses to my letters. I have to have staff continually following the claims. We have to keep calling on the telephone. All this time we would prefer to be spending with our patients who might need our help, who often need our help, for instance, in helping process their secondary claims. We have a lot of patients who come into our office asking for assistance in that manner, for instance.

Mr. DEUTSCH. And let me get one final question: How does the claim processing time under Medicare compare to the claim processing time under the strictly private side of the carrier or the same carrier, for that matter?

Mr. BRADLEY. That is a difficult question to answer. They both have their strengths and weaknesses. I would say that Medicare probably has payments received as quickly as the private payers for a standard routine claim.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Dr. Norwood, inquire?

Mr. NORWOOD. Dr. Wood, you stated in your testimony that there was a need to get groups within HCFA to work together. Would you expound on that for me just a little bit?

Mr. WOOD. Gladly. The Health Care Financing Administration is working on a new set of documentation guidelines to help it in paying claims for physician office visits, hospital visits, emergency room visits, and the like. In that process, it will be critical to engage a large number of providers in a phase of pilot testing. The difficulty, however, is that the program integrity folks are insisting that there cannot be any sort of a pilot where providers would be held harmless or given some sort of protection as that pilot is developed.

It would be anticipated in the pilot that there should be some areas where we would be learning, and there would be differences of opinion about what an appropriate code would be. And so despite all of the intense effort of the group that works directly with physicians in that regard, that would be the health plan provider section that Dr. Miller is leading, they then encounter some difficulties with other parts of the agency. And that is a particular circumstance where there will need to be some significant leadership from the higher levels of the agency to make a decision about how we are going to go forward.

Mr. NORWOOD. PPAC has made a number of suggestions to HCFA and a number of complaints to HCFA, in terms of them not working as well with PPAC. Now, have those concerns been addressed or do we still—where are we with that?

Mr. WOOD. Well, from my position at PPAC, where I have had the privilege to sit for the last year, there has been progress made. I know that some of you are aware of Dr. Kuffner's letter, Dr. Kuffner being the previous Chair of PPAC. And I do believe that PPAC is making progress. In particular, some of the work that has been done with the advance beneficiary notices that Dr. Miller referenced earlier, very positive. It has happened very rapidly, although it has taken a while to get it to the point where something has happened. The documentation guidelines, I think, are another positive sign that HCFA is intending to work with physicians in a prospective manner; that is, trying to work together and putting these guidelines together before the fact, before they are published and before they are implemented.

This will be, I think, the litmus test. If PPAC's recommendations regarding a pilot project or some sort of a demonstration project under the authority of the Secretary cannot be implemented by the agency, then I believe that PPAC's position as an effective advisory committee will have been significantly weakened, and its future then would be in doubt.

Mr. NORWOOD. Well, it certainly is if they just totally ignore any of your recommendations as if you—Dr. Miller, you said overpayment, by law, you have to ask for it back.

Mr. MILLER. That is correct.

Mr. NORWOOD. When that happens, the provider then can appeal that case?

Mr. MILLER. Yes.

Mr. NORWOOD. To whom do they appeal?

Mr. MILLER. I am not sure I can describe this process in the detail that you may want.

Mr. NORWOOD. Briefly.

Mr. MILLER. I believe the appeal goes to the carrier first. And then if there is not resolution there, it then begins to go to an administrative law judge.

Mr. NORWOOD. Well, who determined that it was an overpayment?

Mr. MILLER. HCFA.

Mr. NORWOOD. HCFA?

Mr. MILLER. The carrier.

Mr. NORWOOD. The carrier.

Mr. MILLER. By HCFA and the carrier.

Mr. NORWOOD. Right. You two determined that it was an overpayment.

Mr. MILLER. That is correct.

Mr. NORWOOD. Then the provider can appeal that case.

Mr. MILLER. That is correct.

Mr. NORWOOD. What happens when they appeal that case, and they are found innocent, and it is not an overpayment?

Mr. MILLER. The money is returned to the provider.

Mr. NORWOOD. Right. Now did the same people say it was an overpayment who later, on appeal, said, no, it is not an overpayment?

Mr. MILLER. No, I believe it is—I am not sure I know the answer to that question. I believe if it is appealed beyond the carrier, it is a different group of people.

Mr. NORWOOD. So it is the carrier who denies the payment, because it is an—or who says that it is an overpayment?

Mr. MILLER. That is correct, based on the rules and procedures that HCFA and the carrier have developed together.

Mr. NORWOOD. And then when you appeal, it goes back to HCFA, and you say, "Whoops, wait a minute. That wasn't an overpayment."

Mr. MILLER. No. I think the appeal goes to the carrier first, and then if the appeal goes beyond the carrier, it goes to a different group. Actually, can I ask a question?

Mr. NORWOOD. Of course.

Mr. MILLER. Okay. Thank you.

Mr. BILIRAKIS. Where does that overpayment go?

Mr. NORWOOD. Well, they demand that the physician send the money back.

Mr. BILIRAKIS. Yes. But when the physician sends the overpayment, the so-called overpayment money, who do they send it to, the carrier or to HCFA?

Mr. MILLER. Okay. Let me first get the answer to the first question. It was roughly right but not quite. The appeal occurs within the carrier. There is a different group within the carrier that handles appeals. If it is not resolved there, as I said, then it moves to

an administrative law judge. If it not resolved there, then it moves to a Department appeals board, which is an HHS-wide group that deals with the appeals.

Mr. NORWOOD. Well, what happens to the poor guy sitting down there who has just been told to send the $100,000 check back, patients are written that he is a bad guy, and 2 years later it is found that he didn't do anything wrong; he has just been trashed real well?

Mr. MILLER. That issue——

Mr. NORWOOD. What happens?

Mr. MILLER. I am sorry; go ahead.

Mr. NORWOOD. Well, my question is, what do we do to do the right thing at that point, other than say, "Uh-oh, sorry."

Mr. MILLER. We addressed this question, or at least part of this question, I think, you may have been out of the room when it happened. I acknowledged that particularly the information being sent to the beneficiary and indicating that there was an overpayment on the part of the physician is necessary, I believe, because both the Medicare Program and the beneficiary have money that have gone to the provider. And so we feel it is our responsibility to tell the beneficiary there may be an issue here. What has to be done better is to inform the beneficiary at each step of the process, "This was in question, it is now no longer in question." And there is guidance to do that.

Mr. NORWOOD. Why couldn't we just get it right? Why have to go say that this is an overpayment, go back through appeals, and all that gobbledygook to find out you were wrong to start with? Why couldn't we get it right to start with and not do such harm to people?

Mr. MILLER. I think there are two answers to that, and obviously there is not—these issues do arise. Most claims transactions are done correctly, the overwhelming majority of them. Medicare relative to the private sector has the highest percentages of electronic claims and processes claims between 14 and 30 days by law. Most claims are paid correctly on time.

The second thing is, my understanding is only 3 percent of denials at the carrier level are appealed. So I think your point is taken, we should get them all right, but there a billion transactions a year; some of them will be wrong.

Mr. NORWOOD. You have to have a system that doesn't destroy the lives of people. You say that only 38 people were prosecuted last year, which I can't even do the percentage it is so low. Only 38 were bad actors. Well, we want the bad actors put away too. So does Dr. Becker and Dr. Wood. Everybody does. But in the process of putting away 38 bad people, how many lives do you destroy in that process, meaning physician practices who are taking care of their patients? And if you believe it is just Dr. Wood, Dr. Becker, Ms. Bradley, I can line you up providers from here to Atlanta who will come tell stories just like this.

Now, what you say is, "Oh, the percentages are small." What I say is, it is American lives that you are messing with out there, people that have spent all of their life trying to be prepared to take care of patients. That is the problem with this big, gigantic system we have. You just absolutely run roughshod over—maybe you do it

well, you only get 2 percent. But if you are one of those 2 percent, this is major, major stuff.

Dr. Wood, and I will——

Mr. BILIRAKIS. Your time has expired, but without objection——

Mr. NORWOOD. Dr. Wood wanted to——

Mr. BILIRAKIS. Yes, I saw him motioning. Go ahead, sir.

Mr. WOOD. I can describe for you the process by which a provider may appeal a denial from the carrier. The first level is what is called an informal review, which is handled within the carrier, usually by people that work close to the group within the carrier that denied the claim originally. Second level is a fair hearing, which may be either by telephone or in person, and is supposed to be handled by an impartial hearing officer who is knowledgeable about the Medicare Program and who does not work for the carrier.

Now, the rules from there are somewhat limiting, in the sense that if a provider is in a circumstance that he or she disagrees with the ruling at the fair hearing, there are no other appeal rights if the amount in controversy does not exceed $500. So the physician then is left not to appeal to a higher level. If you have only one claim, it will be hard to get to $500. It will take a lot of claims for especially office services, which may be very small, especially if you are appealing the difference between one or two levels of evaluation in management services.

Now that being said, that actually is one of the reasons that many people simply don't bother to appeal, because the process is very time consuming. It takes a lot of time and ultimately the physician has to come back to the fair hearing, meaning that the physician takes time out of the practice to participate in the fair hearing. And the yield for them may simply be too low in a busy practice.

Mr. NORWOOD. Well, the more of those claims under $500 that nobody can appeal or has time to anyway, how much of that is the dollars we are talking about saving because of our great program of waste, fraud, and abuse?

Mr. WOOD. Well, I think you are actually very prescient in that question, because I believe that a large amount of the reduction in, quote, "erroneous spending," is because of changes in billing to avoid the difficulties that happen.

Mr. BILIRAKIS. Let me get back to the money that you require the physician—the overpayment, where does that go? I want to follow the money. Where does it go? Does it go to the carrier, and is it held by the carrier, or does it go to HCFA?

Mr. MILLER. I believe it is returned to the Medicare Program and held by the Treasury, I believe.

Mr. BILIRAKIS. Well, that is—is that right?

Mr. MILLER. Yes.

Mr. BILIRAKIS. So it doesn't go to the carrier.

Mr. MILLER. No. I believe it comes back to the Medicare Program and is held by the Treasury.

Mr. BILIRAKIS. One other point here. You said by law a number of times, that in the case that you referred to, and Dr. Taylor's case, et cetera, that the beneficiaries have to be notified. And you said—well, did you not? I mean, if there is an overpayment——

Mr. MILLER. By law, we have to take the money back.

Mr. BILIRAKIS. Yes. And then what? Notify the beneficiaries?

Mr. MILLER. I was not saying that by law we had to do that. What I was saying is, is that the beneficiary, particularly in a physician's case, 80 percent from the program, 20 percent comes from the beneficiary, the notice is to the beneficiary that they, too, may have money involved in this. That is why the beneficiary——

Mr. BILIRAKIS. You mean their 20 percent?

Mr. MILLER. Correct. Also, you asked about——

Mr. BILIRAKIS. Boy, that sure does—you know, we are talking about the image and that sort of thing. I mean that is it right there. It gets out into the community, like Dr. Taylor's case.

Mr. MILLER. And as I said, the policy that we have moved to as a result of these kinds of situations are that we inform the beneficiary at each step of the appeals process so that the beneficiary knows when something has been overturned.

The $500 that is being referred to is, in law, in terms of what the appeal level that you can go above, and my understanding is, is that you can accumulate claims to hit the $500 target.

Mr. BILIRAKIS. Mark, a lot of damage can be done in that case of notifying the beneficiaries. I don't know. We have got to talk about that. Okay.

Mr. NORWOOD. Can I have one more little——

Mr. BILIRAKIS. Only if it is a short one. I have got a 2:45 meeting.

Mr. NORWOOD. I will sit there if you want me to. Let me see, which one of you said no one should be prosecuted for honest mistakes? I think it was you. And what you mean, I presume, by prosecuted, they shouldn't prosecuted, meaning in court. They shouldn't be investigated. Did you mean that too?

Mr. MANGANO. No one should ever be prosecuted for an innocent billing error. The problem with it is that when you said investigated or audited, if there were aberrancies in billing, if there were strange things that were occurring in the billing process, what would normally happen is the contractor would take a look at it first and only would refer it to us if they suspected it went beyond billing——

Mr. NORWOOD. Well, the contractor can audit and investigate——

Mr. MANGANO. Yes, yes.

Mr. NORWOOD. [continuing] and you seem to say, "We don't want that to happen. Guys, that is terrible." The solution to that, then, of course, is education. And I will conclude, because the chairman is going to run me out there—the only reason I am going to conclude—I will conclude with asking you to at least admit today that all of this should not be put on the back of the provider. It is not all just the provider needs to be educated. It is equally as much you need to find better processes. You need to have fewer, simpler rules and regulations that a normal doctor can see their patients and deal with you too. Now, will you just tell me that the solution isn't all just educating the doctors?

Mr. BILIRAKIS. This hearing has to end sometime.

Mr. NORWOOD. Can he answer that? If they will just agree.

Mr. BILIRAKIS. It goes on and on. Dr. Miller?

Mr. NORWOOD. Just somebody tell me something besides laying it on the doc.

Mr. MILLER. That is correct. We are, and I have given several examples today where we have tried to improve our processes. You are right. We have to improve our processes.

Mr. NORWOOD. Mr. Mangano, I would love to hear from you.

Mr. MANGANO. I would agree with Mr. Miller.

Mr. NORWOOD. Let the record show you do agree that——

Mr. MANGANO. I agree that everybody that the process needs to work better.

Mr. BILIRAKIS. Well, thanks so much. I think it has been a good, educational hearing. And we will be sending you written questions, requesting written answers. Please respond to those as quickly as you can.

I might add that Dr. Norwood is leading a working group on putting the patients first and HCFA modernization, trying to help HCFA. That is what this is about, trying to help HCFA do what I know they want to do, and that is a more efficient, fair job.

I would ask all of you: please don't hesitate to volunteer any advice, information, or any suggestions to us.

Thank you very much. The hearing is ended.

[Whereupon, at 2:01 p.m., the joint subcommittees were adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR HOMECARE

The American Association for Homecare (AAHomecare) appreciates the opportunity to submit this statement for the written record to the U.S. House of Representatives Energy and Commerce Subcommittee on Health and Subcommittee on Oversight and Investigations. AAHomecare is a national association that resulted from the merger of three smaller national home health associations; the Home Care Section of the Health Industry Distributors Association (HIDA Homecare), the Home Health Services and Staffing Association (HHSSA) and the National Association for Medical Equipment Services (NAMES). AAHomecare is the only association representing homecare providers of all types including not for profit, proprietary, facility based, freestanding, and government owned home health agencies and medical equipment providers.

The members of AAHomecare would like to express their gratitude to the Subcommittees for initiating an in-depth review and analysis of the Medicare program and specifically the restructuring of the Health Care Financing Administration (HCFA). This is an important first step toward addressing inefficiencies existent within the current structure and prescribing concrete solutions to promulgate more effective policy.

As Congress begins to explore possible approaches to HCFA reform, AAHomecare has identified six broad areas that it believes should be included in any HCFA restructuring proposal.

The six broad areas include:

- **Eliminating Unnecessary Regulatory Cost/Administrative Simplification:** The first step in any effort to improve the efficiency of HCFA and providers would be to review all regulations to determine their necessity for homecare services. Regulations that are redundant or simply not needed should be eliminated.
- **Consistent Interpretation:** Consistent interpretations of regulatory requirements by HCFA and Medicare contractors are extremely important. Variations cause confusion among all parties and make it very difficult to adhere to the rules and regulations. Inconsistent interpretations are also costly to the program, providers and patients. A system that would ensure consistency of the interpretations and clear communication of those interpretations needs to be developed. Further any changes should be implemented prospectively rather than retroactively.
- **Timely Appeals Process:** Much of the time and energy of providers includes lengthy appeals processes to determine proper determinations. The appeals process increases costs, energy and time for both providers and the Medicare

contractors. The delay in payment associated with prolonged appeals also increases the cost of doing business with Medicare and will continue to reduce the number of providers willing to serve Medicare beneficiaries. An approach to expedite the appeals process and make public appellate determinations would be helpful.

- **Education/Communication:** As new regulatory requirements are implemented for healthcare providers, ongoing communication between providers, government officials, and consumers must exist. All parties should have the opportunity to discuss the impact of additional regulations and new rules should be subject to public notice and comment.
- **Prohibit Delegation of Policy Decisions:** Medicare contractors are often incentivized by economic considerations rather than what is in the best clinical interest of the patient. HCFA should not be permitted to delegate policy decisions to government contractors in an effort to circumvent established procedures intended to obtain input from effected parties. Clinical/coverage decisions should be completed before economic considerations are brought into the discussion of new policy.
- **Recognize Cost of Regulations:** The government should recognize the cumulative financial impact of new regulations on providers and make sure sufficient reimbursement is incorporated into the payment system to permit providers to be in regulatory compliance as they provide services and products for patients.

Set out below are examples of regulatory problems faced by homecare providers.

1. Eliminate Unfair Burdens In Documenting Medical Necessity

One regulatory burden that has caused particular consternation among home medical equipment (HME) providers is the determination of medical necessity. It highlights the need to evaluate the necessity layers of burdensome requirements that HCFA has developed. The certificate of medical necessity (CMN) is a form to document the medical necessity of certain items of medical equipment. It is required by statute, and was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act. The CMN collects information necessary to determine whether the beneficiary meets Medicare coverage criteria for the DMEPOS item. In order to receive payment for a covered item of DMEPOS, a provider's claim (HCFA—Form 1500) must be accompanied by a CMN signed by a treating physician. The original CMN must be maintained by the supplier and must be produced upon the request of the DMERCs, HCFA, or the Office of the Inspector General.

A supplier who submits a properly executed certificate of medical necessity (CMN) has satisfied its legal obligation to document the medical necessity for an item of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS). HCFA should be prohibited from requesting DMEPOS suppliers to provide documentation in support of medical necessity beyond the scope of a properly executed CMN.

HCFA and the DMERCs ignore the original intent of Congress to designate the CMN as a tool to determine medical necessity. The DMERCs routinely require DMEPOS suppliers to submit documentation of medical necessity *in addition* to the CMN. The requests for additional documentation are unpredictable and often require information that fails to be specified in current medical policy for the item. Additionally, DMERC auditors often request additional documentation for hundreds of claims simultaneously, creating an unreasonable administrative burden for suppliers. The DMERCs also request documentation supporting medical necessity from hospital and physician progress notes although suppliers do not have access to a patient's confidential medical records. Further, DMEPOS suppliers can be assessed overpayments when they fail to produce portions of these records.

DMEPOS suppliers are even subject to overpayment demands when they have obtained the appropriate medical documentation but the physician's notes contained therein are deemed inadequate for corroboration, even though the physician, by acting as signatory, expressly certifies that the information on the certificate of medical necessity is "true, accurate and complete" and acknowledges that any "falsification, omission, or concealment of material fact" may subject him (the physician) to civil or criminal liability. DMERC auditors also assess overpayments for technical errors on CMNs even though these technical errors have no bearing on the documentation of medical necessity for the item.

The Association would recommend that HCFA use the CMN for its original intent in assuring eligibility for the Medicare beneficiary, and eliminate the unnecessary and unworkable requirements for additional documentation.

2. Remove Non-Medicare and Non-Medicaid Patients from Participation in OASIS

A second example of administrative requirements that need to be simplified is the case-mix adjuster known as the Outcomes and Assessment Information Set (OASIS) for home health services. Medicare requires home health agencies to collect OASIS survey data from Medicare and Medicaid beneficiaries. AAHomecare understands the need for this uniform standard to measure homecare patient population outcomes data. However, the Association fails to understand the underlying HCFA rationale in determining that OASIS data must be extended to include non-Medicare/Medicaid patients.

As currently structured, OASIS is overly burdensome in any context. HCFA maintains that comprehensive OASIS data is needed to thoroughly implement the prospective payment system (PPS) for home health agencies. In actuality, approximately twenty questions are needed to accurately reflect the payment category under PPS not the over eighty questions required by HCFA. While AAHomecare strongly supports the need for appropriate and accurate information to ensure quality care under PPS, this is an example of the need to review the OASIS tool to determine the specific questions that are relevant and necessary in providing quality care to the beneficiaries.

AAHomecare is especially concerned about the expansion of the OASIS data collection to private pay patients and the homecare consumers who are not receiving payment from either Medicare or Medicaid. This adds an additional burden to home health agencies to collect personal information on all patients for submission to the government. Equally important, the Association is concerned that the data collected may be extrapolated by HCFA officials to make payment or policy changes in the future. Medicare and Medicaid patients have specific eligibility requirements that are not required of private pay patients. Likewise, private pay patients may receive additional services that are not benefits under the Medicare program. Comparing data from these groups of patients is like comparing apples to oranges.

The length and overuse of the OASIS assessment tool has served as a key factor resulting in the marked reduction of nurses interested in entering the field of home health. Additionally, many nurses already working in the industry are choosing to leave as a result of the procedural burden being placed on them due to increased OASIS requirements. These nurses cite they have become too far removed from direct patient care and focus a majority of their time on compliance with administrative matters. For example, nurses state that the OASIS questionnaire for a patient takes between 20 to 45 minutes while in the patient's home. The homecare industry is now faced with significant losses of qualified nurses who had valued the direct patient care in the home health environment and are now overwhelmed with paperwork.

The Association recommends that OASIS tool be streamlined and applied only to Medicare and Medicaid recipients.

3. Revise/Eliminate the "In the Home" and "Homebound" Definitions

For durable medical equipment providers, patient eligibility is limited to items deemed to be medically necessary for the patient to independently perform the four activities of daily living within the four walls of their home. Items that enable the beneficiary to move about in the community are not covered creating an inherent conflict among the government's policies. The "in the home" is not required by statute, and conflicts with policies aimed at promoting independence, productivity and integration of people with disabilities. This is especially true since Congress has recently passed legislative initiatives to expand a disabled person's opportunities. The legislative initiatives include: the Americans with Disabilities Act (ADA), the Work Incentives Improvement Act (TTW/WIIA) and the Individual with Disabilities Education Act (IDEA). These three initiatives were the direct result of Congress empowering people with disabilities to seek employment while maintaining their benefits such as Medicaid and Medicare services.

For home health agencies, one of the eligibility requirements for Medicare home health services requires the Medicare beneficiary to be "homebound." Last year, Congress broadened the definition of "homebound" by permitting the home health beneficiary to attend religious services and adult day care facilities. Although the broadening of the definition coincided with the other Congressional legislative initiatives, it also increased the providers responsibility to determine the patient's eligibility. The home health agency must determine more closely if the patient leaves his/her home for the purposes of religious services or adult day care or another event.

To the best of its ability, a provider may determine that a patient meets "in the home" or "homebound" requirements but the Medicare contractor may determine differently. The result may be lost reimbursement to the homecare provider who is

working with an arbitrary definition or the provider may face endless appeals processes to prove the appropriateness. Either process has negative implications to the provider who had determined, to the best of its ability, that the patient met the definition.

The Association urges Congress to direct HCFA to eliminate arbitrary eligibility guidelines which incorporate the current "in the home" and "homebound" definitions and develop policies which are consistent with today's social policies and Congressional intent.

4. Clarify Use of the Home Health Advanced Beneficiary Notices

The Home Health Advance Beneficiary Notice (HHABN) is given to Medicare patients when a home health agency believes that services prescribed by a patient's physician will not qualify for coverage under the Medicare home health benefit (65 *Fed. Reg.* 24217). AAHomecare supports the use of these standardized notices as a mechanism to accurately inform patients of their Medicare rights. However, the Association has significant reservations concerning the applicability of the Home Health Advanced Beneficiary Notice (HHABN) as it relates to patients covered under both Medicare and Medicaid reimbursement guidelines.

In certain states, Medicaid agencies have embarked on a Medicare maximization policy. This process is known as "third party liability" (TPL) and essentially positions a home health agency as intermediary between Medicare and Medicaid. Although there are significant issues surrounding the HHABN, this is an excellent example of providers caught in the appeals process because of inconsistent and conflicting regulatory regimes.

In these instances and prior to processing reimbursement claims, the state Medicaid agency will request that a home health contractor, providing service to a dually-eligible patient who has been denied Medicare coverage for a prescribed service resubmit paperwork for coverage review. Thus, in order to be paid for service provided to a dually eligible individual, a home health agency must submit patient paperwork twice before being granted Medicaid reimbursement. In many instances, agencies have been forced to hire a full-time staff person just to address these Medicaid resubmission requests.

Although the provider was originally correct in the billing, the third party liability permits the Medicaid and Medicare program to go through extensive appeals to have a final judgement. As this process continues, the burden is placed on the home health agency to provide the patient's complete file and supporting documentation. At every juncture through the process, the home health agency may be requested to provide additional substantiating documentation.

The Medicare and Medicaid programs should determine a settlement on cases that impact the home health agencies retroactively. As the process moves forward, the HHABN should be properly clarified and used as a tool to determine proper eligibility for possible dually-eligible beneficiaries.

The Association recommends clarifying the use of HHABN to allow for a determination by Medicare on the patient's eligibility. The Association further believes that the Medicare and Medicaid programs should resolve the retroactive cases through a sampling process to end the on-going problem.

4. Eliminate Inconsistencies In Guidelines Issued By DMERCs

Home Medical Equipment (HME) providers supply medically necessary equipment and auxiliary services that enable beneficiaries to adequately meet their rehabilitative and/or therapeutic goals. Pursuant to a physician's order, HME providers deliver medical equipment and supplies to a consumer's home, set up this equipment, educate and train the consumer and caregiver in its use, provide required maintenance service, and assemble and submit the considerable paperwork needed for third party reimbursement. HME providers also coordinate with physicians and other home care providers thereby performing an integral role in home health case management.

The Medicare durable medical equipment, prosthetic, orthotic and supply (DMEPOS) benefit is administered through four specialized regional carriers known as Durable Medical Equipment Regional Carriers (DMERCs). AAHomecare's HME members routinely express their frustration with the inconsistency of the guidelines issued by the four DMERCs and the unpredictable manner in which national policy changes are announced and implemented by these regional coordinators. Changes are often put into effect without any consideration of the potentially significant operational impact these changes will have on providers.

AAHomecare believes that many of the regulatory problems associated with the Medicare DMEPOS benefit could easily be solved through increased and improved education and communication efforts.

Specifically, AAHomecare recommends that HCFA:

- Communicate with DMEPOS providers and provider groups prior to implementing changes in coverage policy or claims processing requirements.
- Seek comments from the HME industry with respect to the operational impact of proposed changes.
- Standardize DMERCs documentation requirements.
- Consider conducting pilot programs to ascertain the impact of operational changes on DMEPOS community prior to nationwide implementation.
- Provide increased opportunity for regulatory education to the DMEPOS community.

Conclusion:

AAHomecare looks forward to working with the subcommittees, HCFA officials, the Medicare contractors, consumers, and other providers to seek a collaborative and more streamlined approach to the delivery of Medicare services. The Association believes that many of the regulatory problems associated with the Medicare program could easily be solved through increased and improved communication and educational efforts.

PREPARED STATEMENT OF MARY GREALY, PRESIDENT, HEALTHCARE LEADERSHIP COUNCIL

The Healthcare Leadership Council applauds the Chairmen and Ranking Members of the Subcommittees on Health and Oversight and Investigations for holding this hearing and reinforcing the need for ongoing improvement in the quality of care for Medicare beneficiaries.

We at the Healthcare Leadership Council believe that a Medicare system with the highest quality of care will be dedicating its time to patient care, not to the administration of regulations. And such a system will be free of the inflated costs that are associated with inflexibility and burdensome micro-management.

Unfortunately, this is not the case in today's Medicare. Under Medicare's current structure, the federal government has been unable to manage Medicare efficiently. The program is highly regulatory and inflexible, with over a hundred thousand pages of regulations, rules, manuals, instructions, letters, alerts, notices, etcetera. Carriers and intermediaries apply rules differently in different locations. And there are often inconsistencies among these many rules. This inefficiency within Medicare adversely affects providers and beneficiaries on many fronts.

Complexity stifles innovation. Medicare cheats beneficiaries from being able to receive the best care achievable when its regulations set standards that may be used by some providers as "ceilings of care." Medicare's extensive coverage process for new items and services can leave beneficiaries behind the curve on advancements in health technology. The administrative process used for modifying benefits and for determining whether certain medical treatments or procedures merit coverage under Medicare is extraordinarily complex, lengthy, and sometimes irrational—resulting in the delay or denial of lifesaving treatments.

One case in point is Hepatitis B liver transplants. Scientific evidence had shown for some time that the outcomes for Hepatitis B liver transplants were comparable to the outcomes of liver transplants made necessary by other primary indications. However, Medicare did not begin covering these transplants until very recently. In 1999, before Medicare began covering Hepatitis B liver transplants, a survey by the American Liver Foundation found that 99 private insurance companies, as well as the Department of Defense, reimbursed for Hepatitis B transplants. The survey also showed that most of the largest liver transplant centers indicated that Medicare was the only carrier that did not reimburse for these transplants.

Those Medicare standards of care that *are* prescribed in regulation are often inflexible and often nonsensical. Efforts to protect the program from fraud have led to tedious rules that reduce the quality of a patient's interface with the medical system. For instance, Medicare will not reimburse for physician visits and/or diagnostic tests that occur more than once per day per patient. As a result, patient care may be compromised, patients are inconvenienced, providers are unable to run confirming or clarifying diagnostic tests, and the course of care is disrupted.

Burdensome coding and documentation. Providers, as well as beneficiaries, must wrestle with the ever-expanding Medicare jigsaw puzzle. Medicare's many complex coding and documentation rules make completing claim forms and ensuring appropriate coding extremely burdensome and time-consuming. For example, drugs must be coded with a Medicare-specific code, and the provider must adjust billed quantities to comply with the code description. Private health plans, on the other hand,

use national drug codes assigned to all drugs approved by the FDA. Furthermore, providers must consult not one source to ensure that they are billing and coding correctly, but multiple manuals, letters, bulletins, and updates. Even after poring through all of these references, providers have learned that there is no guarantee they are proceeding with documentation properly. To make things more difficult, when providers seek clarification of billing and coding requirements from HCFA, carriers and fiscal intermediaries, they often receive different answers.

Medicare's documentation requirements also lead to redundant and inefficient documentation practices. For example, physicians are required to write all notes regarding patient assessment, regardless of whether a registered nurse under his or her supervision wrote identical notes at an earlier point in the day that concur with the physician's view.

In addition, Medicare has inconsistent coverage policies based on the specific site of care. As another example, a rule proposed in 1997—yet still not finalized—details physician supervision requirements for numerous office procedures. The regulation actually dictates during which procedures a physician must supervise from within the examining room and which procedures the physician can supervise from within the "office suite" but not necessarily within the examining room. Such site of care standards are unnecessary inconsistencies that take discretion away from professionals, reduce the quality of care for beneficiaries, and simply lengthen the long check list of rules that providers must remain wary of when treating beneficiaries.

Time and financial resources wasted. Complex and burdensome regulations sap time and financial resources that could be used more productively in providing patient care or developing innovations to improve patient care. A recent survey of the Association of American Physicians and Surgeons revealed that 22 percent of physician and office staff time is devoted to compliance with Medicare regulations. It also found that the processing costs associated with Medicare claims are 26 percent higher than the costs associated with private claims. In addition, Medicare's very lengthy appeals process can result in long waits for needed care or for payments for services rendered long ago. When Medicare carriers deny claims, there are several tiers of review, the highest of which—review by an Administrative Law Judge—can take up to four years to complete. In the meantime, either the beneficiary is denied this care or a provider is denied payment.

Members of the Committee, four years ago Congress took great strides to overhaul the IRS and, in acknowledgment of the increasing size and complexity of the tax code, make the agency and the process more taxpayer-friendly. The hearings brought to the attention of Congress not only the size of the Internal Revenue Code, but the difficulty of navigating through it and the even greater difficulty of getting help from the IRS when navigating through it results in questions or problems.

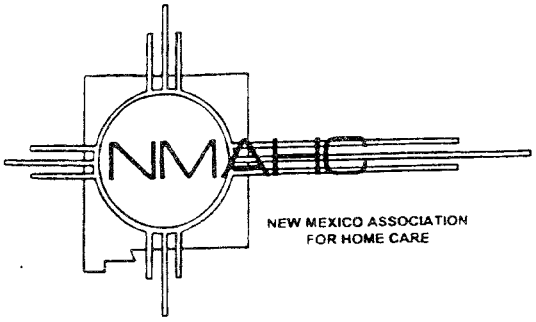
Health care providers should be so fortunate as to have a billing and coding system that resembles the much-maligned U.S. tax system. At least taxpayers know that there is *one* book that details all the rules for paying taxes. That book is about nine thousand pages long. Instead, health care providers have over a hundred thousand pages to pore through—pages that spread throughout multiple redundant and confusing sources and that are constantly changing, yet often outdated.

The hearings on the IRS also revealed the cost of collecting taxes. Many members were astounded and impressed by the amount of money that is actually spent collecting taxes—astounded and impressed that there were taxes that actually cost more to collect than were brought in at the end of the day. Similarly, we ask that you consider the impact that the costs—in time and money—of paperwork, regulations and delays have on patients, providers and the quality of care in the Medicare system. These complex and burdensome regulatory requirements sap time and financial resources that could be used more productively in providing patient care or developing innovations to improve patient care.

In terms of financial resources, a more efficiently run Medicare could perhaps even return to the beneficiary some savings to offset certain medical expenses and other out-of-pocket costs. In the meantime, the inefficiencies and complexities of this program are keeping Medicare beneficiaries stuck in an outmoded and overburdened health care program that could, and needs to, deliver so much more.

HLC is encouraged by the leadership of this Committee and its efforts to work with providers in improving the quality of health care that Medicare beneficiaries receive. We stand ready to assist this committee in any way as you work toward solutions that will allow all Americans to enjoy the benefits of our nation's health care system.

The Healthcare Leadership Council is a coalition of chief executives from America's leading health care companies and institutions, including hospitals, health plans, pharmaceutical and device manufacturers, biotech firms and educational institutions.



April 3, 2000

Congresswoman Heather Wilson
318 Cannon House Office Building
Washington, DC 20515

Dear Representative Wilson,

Attached to this letter, you will find a packet of information that I believe will be very helpful to you in the hearing, April 4, 2001, on the current complexities of the Medicare Program. I received this information from the Visiting Nurse Associations of America (VNAA). In the packet is a letter to the Department of Health and Human Services Secretary, Tommy Thompson, from Carolyn Markey, President and CEO of the VNAA. In addition, there is a list of the Federal requirements for a Start-of-Care (SOC) visit and the related costs to the home care agency.

In the letter to Secretary Thompson, Ms Markey states that "existing federal regulations and associated paperwork requirements are financially crippling VNAs and driving clinical staff away from the home health care profession at an alarming rate". Home health agencies in New Mexico would be in total agreement with that statement and are experiencing the same difficulties with retaining staff. I am hearing over and over again that nurses have left the home care agency "because of the burdensome paperwork". They continually complain about "not having enough time to care for the patient due to the paperwork requirements".

Many of the home care agencies in New Mexico are small and serve rural communities. It is especially problematic for the small rural agency when dealing with complicated paperwork requirements and limited resources.

The New Mexico Association for Home Care is very supportive of the recommendations from the VNAA. I thank you for carrying this message to the subcommittees. I look forward to working with you on this very important issue of addressing the regulatory burden on health care providers and I hope to give you another "real" experience by scheduling you to make an admission visit with a New Mexico nurse.

Please call me at 505-889-4556 if you have additional questions or e-mail me at joieg@nahc.org. Thank you, again for your interest and all your help. You truly do make a difference in the lives of New Mexicans.

Sincerely,

Joie Glenn, RN MBA CAE
Executive Director

March 21, 2001

The Honorable Tommy Thompson
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The Visiting Nurse Associations of America (VNAA) would like to thank you for your interest in alleviating the current federal regulatory burdens on health care providers. VNAA is the national membership association for non-profit, charitable and community-based home health agencies, known as "Visiting Nurse Agencies (VNAs)."

The mission of VNAs is to promote independent living by providing the necessary health and personal care services to enable an individual to remain in his or her home regardless of medical condition or ability to pay. Because most VNAs were established decades (if not more than a century) ago and are directed by voluntary boards of local community leaders, they are deeply rooted in their communities. Most (if not all) VNAs are part of a community network that ensures that the neediest individuals receive proper nutrition, immunizations, nursing and rehabilitative care when appropriate, and other social services.

Existing federal regulations and associated paperwork requirements are financially crippling VNAs and driving clinical staff away from the home health care profession at an alarming rate. Vacancy rates for home health positions in some areas of the country are as high as 30%. Clinicians are handling too many patients, filling out too many federally-required forms, and are burning out from their jobs. VNAs are particularly affected by the nursing and home health aide shortages because they are less able to offer competitive salaries and benefits and compensate for the unpaid regulatory tasks.

VNAA urges you to reduce the current federal regulatory paperwork requirements for home health care in order for VNAs and other home health agencies to maintain a sufficient number of clinical staff to care for patients. Many VNAs must turn away patient referrals from hospitals and physicians on a daily basis because they do not have available nurses and/or home health aides on staff. It simply does not make sense to require home health nurses to collect extensive data from patients and fill out multiple forms when

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there are patients who cannot transfer out of institutional health care settings because of the shortage of home health nurses.

Two actions that VNAA urges you to take immediately are:

- **Make optional the current HCFA requirement for home health agencies (HHAs) to assess non-Medicare/Medicaid patients using the Outcomes Assessment and Information Set (OASIS) patient assessment tool; and**

- **Decrease the number of required OASIS assessments during an episode of patient care if multiple assessments triggered by a hospitalization or another circumstance produces redundant and uninformative clinical information, and decrease the number of questions per assessment to capture only the essential clinical information.**

OASIS is the most time consuming and costly federal home health regulatory requirement. According to VNAA data, the average time that clinicians must spend filling out, reviewing and documenting federal paperwork during and following one patient start-of-care (SOC) visit is 3.2 hours at an average cost of $158 (please see last page attachment for federal requirements). The actual amount of time that a nurse provides medical care during the SOC visit is 45 minutes, or 30% of the average 2.5 hours of a nurse's time during the admission visit. VNAA estimates that the OASIS requirement alone costs a HHA an additional $105 per episode when an average 2.1 OASIS assessments/episode are performed. HCFA currently reimburses HHAs $9.32 per episode for additional OASIS costs. Such reimbursement will drop to $4.32 per episode beginning FY 2002.

According to the U.S. General Accounting Office (GAO)'s January 2001 report entitled, "Medicare Home Health Care: OASIS Data Use, Cost, and Privacy Implications," the average additional time to comply with the OASIS requirement for a start-of-care assessment is 61 minutes more than HCFA's estimate. This does not include the time to perform OASIS during the discharge visit, following a significant change in the patient's condition, or during a possible re-certification visit, which are all required by HCFA.

HHAs are also required to electronically transmit OASIS data collected from Medicare/Medicaid patients to the state survey agency or HCFA OASIS state contractor, and maintain the privacy of their OASIS data. The transmission of non-Medicare/Medicaid data will be required in the spring 2001. Only patients who are under the age of 18, or are receiving maternity or personal (non-skilled) care only, are excluded from the OASIS survey requirement.

Rationale for VNAA's Recommendations:

- VNAA believes that the OASIS assessment requirement has been a primary reason why nurses are leaving the home health profession at an increasing rate. "OASIS was too burdensome" and "Nursing isn't what it used to be" are

predominant responses from nurses regarding why they're leaving their jobs. The 45 pages of admission paperwork include approximately 22 pages on OASIS

- Collecting OASIS data from non-Medicare/Medicaid patients duplicates many state and private payor requirements and adds significantly to costs -- approximately $182.70 for 2.1 OASIS assessments per 60-day episode of patient care, according to VNAA data. Of this $182.70 per episode, approximately $105 is estimated to be the additional cost that OASIS has added to the cost of the previous clinical assessment. HCFA currently reimburses at $9.82 per episode of patient care for "additional" OASIS costs, and reimbursement will decrease to $4.32 beginning October 1, 2001.

- Third-party private insurance does not cover the additional cost for the OASIS assessment because private insurance companies most often have their own required assessment forms and quality checks.

- Making optional the collection of OASIS data from non-Medicare/Medicaid patients would not compromise HCFA's assurance of quality of care for this patient population, nor would it compromise the accuracy of the PPS case-mix adjuster, as HCFA contends. HCFA says that it needs "outcomes" data from both patient populations to ensure that HHAs are providing the same level of care to both populations.

  VNAA believes that comparing outcomes data between these two patient populations is analogous to comparing apples and oranges. In general, the non-Medicare/Medicaid patient population is younger and healthier and not "homebound" as are the Medicare and dually-eligible Medicare/Medicaid patients. As a result, the non-Medicare/Medicaid patients typically receive fewer visits per episode of care and end the episode with a home health or medical social work visit that does not require an OASIS assessment. Comparing the admission OASIS for this group with the last OASIS assessment for the Medicare/Medicaid group would not be a valid comparison of outcomes.

  In addition, the ability to "improve" a patient's condition during an episode of care significantly varies between the patient populations because of age and health acuity issues. Finally, the data that HCFA is collecting from Medicare/Medicaid patients should be more than sufficient to develop an accurate PPS case-mix adjuster. Adding non-Medicare/Medicaid data would skew the existing data to a lower utilization level, which could result in insufficient PPS reimbursement rates.

- Patients are often distressed by the amount of time it takes to answer OASIS questions and by the invasion of their privacy. The OASIS assessment is often more time-consuming than the medical care itself.

- Electronically transmitting OASIS data raises concerns about patient confidentiality. While HCFA is attempting to ensure confidentiality of reports posted on the internet, there is the fear that such reports cannot be safeguarded with 100% certainty.

- In 2003, HHAs will be required to collect OASIS data from ALL patients -- those receiving skilled nursing/therapy services and those receiving only personal care services (e.g., assistance with bathing). Collecting OASIS data from patients receiving only personal care services will dilute Medicare and Medicaid data by adding multiple variables that are not related. For example, many individuals who receive only personal care services have chronic but stable conditions and only need assistance with activities of daily living (e.g., bathing, dressing). Measuring health outcomes from this population will be different than measuring health outcomes of patients with conditions that can significantly improve over a period of time.

- Nurses' job satisfaction has significantly deteriorated because many feel that their jobs primarily consist of paperwork rather than healing people, the latter being the reason why they entered the nursing profession.

Thank you for your consideration of our requests. We would sincerely appreciate the opportunity to discuss these issues with you or your staff. Kathy Thompson on my staff would be pleased to work with your staff on these issues and to schedule a meeting in Washington when convenient to your schedule. Kathy may be reached by telephone at 202/737-3707. In addition, I would be happy to answer any questions that you may have and may be reached at 617/523-4042.

Sincerely,

Carolyn Markey

Carolyn Markey
President and CEO

Federal Requirements for Start-of-Care (SOC) Visit

During an admission visit to a patient's home, a nurse must complete or obtain signatures for the following federally required forms* and explain to the patient all of the following federally required information:

- Patient Acknowledgement, Advance Directives, and Patient's Right of Self-Determination (consent for admission and treatment)*
- Start-of-Care OASIS Assessment (23 page form)*
- Medicare Secondary Payer Form*
- Medication Profile*
- 15-Minute Increment Visit Report*
- Advance Beneficiary Notice (if applicable)*
- Medical Supply Form for PPS*
- Patient Bill of Rights
- Home Safety Guidelines/Checklist
- Emergency Preparedness Plan
- OASIS Privacy Act Statement
- Privacy Act Statement regarding health care records
- Information on interpreter or special communication device arrangements if the provider is a recipient of federal grant money or other federal financial assistance.

Average Number of Pages: 45

Average Time to Complete (in patient's home (2.5 hrs.) and in home health agency (.7 hrs.)): 3.2 hours

Average Cost to Complete (labor and non-labor costs): $158

Average OASIS cost/SOC visit: $87

Average "OASIS-Added" Cost to Patient Assessment Form: $50

Average "OASIS-Added" Cost to 60-Day Episode for 2.1 Assessments: $105

HCFA Reimbursement for OASIS costs/episode: **(FY 2001)** $9.82
(FY 2002) $4.62

AFFIDAVIT OF HUGH DURRENCE, R.PH, M.D.

STATE OF SOUTH CAROLINA §
§
COUNTY OF CHARLESTON §

BEFORE ME, the undersigned authority, on this day personally appeared Dr. Hugh Durrence, known to me to be the person who is submitting his Affidavit before the joint hearing of the Health Sub Committee and the Oversight and Investigation Sub Committee of the House Energy and Commerce Committee, and to be the person whose name is subscribed to the foregoing testimony in support of the Committees' analysis of the Health Care Financing Administration's relationship with their carriers, contractors and providers, and after duly sworn by me, deposes and says:

1. I established PHC Home Health in 1990.

2. The South Carolina Department of Health and Environmental Control ("DHEC") licensed PHC Home Health to provide home health services.

3. The DHEC periodically inspects PHC Home Health to ensure that PHC complies with the Standards for Licensing Home Health Agencies under S.C. Regulation 61-77.

4. The Health Care Financing Administration ("HCFA") certified PHC Home Health to participate in the Medicare program.

5. The HCFA, through the DHEC, as the State Survey Agency ("SA"), periodically surveys PHC Home Health to ensure that PHC complies with the Medicare Conditions of Participation ("COP") under 42 C. F. R. 484, et. seq.

6. The HCFA assigned PHC Home Health to submit Medicare home health beneficiary claims for payment to the regional home health intermediary ("RHHI"), Palmetto Government Benefits Administrators, LLC ("PGBA").

7. PGBA is a subsidiary of the insurance company, Blue Cross and Blue Shield of South Carolina.

8. PHC Home Health periodically submits Medicare home health beneficiary claims to PGBA for payment.

9. Generally, PGBA acting as the RHHI, pays the claims PHC Home Health submits for home health services provided to qualified Medicare beneficiaries.

10. Additionally, the RHHI, through the medical review process, "Additional Development Request ("ADR"), periodically reviews a regulatory prescribed number of randomly chosen home health beneficiary claims submitted by PHC Home Health before they pay the claim.

11. The RHHI audits the cost reports that PHC submits to the HCFA.

12. Finally, the RHHI can conduct random site audits according to the audit matrix developed by the relevant HCFA regional office ("RO").

13. On or about April 16, 1998, the former Congressman Mark Sanford, a local television reporter, and a camera crewmember accompanied PHC Home Health personnel to the home of Mr. John Fox.

14. In relevant part, PHC Home Health provided Medicare home health services to Mr. Fox.

15. The purpose of the visit to Mr. Fox was to show the public how the Medicare Interim Payment System ("IPS") was affecting a Medicare home health beneficiary.

16. The local television station subsequently gave a televised report of the visit with Mr. Fox.

17. On or about June 22, 1998, PGBA suddenly stopped paying claims PHC Home

Health submitted to them for home heath services given to Mr. John Fox.

18. PGBA did not notify PHC Home Health through the customary ADR process before they suspended payments of Mr. Fox's claims.

19. On or about July 28, 1998, Mrs. Peatsey Hollings, wife of the Honorable Senator Ernest (Fritz) Hollings, a local television reporter, and a camera crewmember accompanied PHC Home Health personnel to the home of Mr. John Fox.

20. The local television station subsequently televised the visit with Mr. Fox and showed, among other things, Mrs. Hollings speaking about the adverse effect that the IPS would have on home health patients.

21. On or about August 17, 1998, the Charleston Post & Courier published an article that discussed IPS' impact on home health beneficiaries. The article quoted my view of the IPS' effect on home health beneficiaries.

22. Both the television broadcast and the newspaper article were accessible to PGBA employees at the time of the dissemination.

23. On or about September 3, 1998, about seventeen calendar and ten business days after the newspaper published the article that quoted my view of the IPS's effect, PGBA notified PHC Home Health by telephone that they intended to come to Charleston and audit the PHC Medicare certified home health agency.

24. On or about September 14, 1998, about ten calendar and six business days after PGBA called saying that they intended to audit the home health agency, PGBA auditors arrived at PHC Home Health.

25. Generally, according to PGBA's policy, they notify the provider by letter at least two weeks before they arrive to conduct the audit.

26. After four days of auditing the Medicare certified home health agency, the PGBA auditors notified PHC Home Health personnel that they had not found anything wrong during the audit, and that they would give an exit conference when they returned from their lunch.

27. Upon returning from their lunch, the auditors notified PHC Home Health personnel that they had talked to a PGBA supervisor, and that they would return to conduct a "full audit."

28. Subsequently, PGBA disallowed several costs that PHC had included in the 1996 cost report.

29. Among others, PGBA denied the cost for an ICD-CM Code Book because the auditors did not know that the home health agency used the book to get the medical diagnosis and procedure codes that the home health agency must put on the HCFA Form-485 (Plan of Care) and the Universal Bill Form-92.

30. Additionally, PGBA denied the cost of plastic forks used by home health agency staff to eat a lunch meal that PHC Home Health served to them during a staff education event; the auditor believed that the cost was for "Lady Diana souvenir forks." Lady Diana was the brand name of the plastic forks.

31. Although the auditors gave other reasons, the most frequently used justification for disallowing certain costs was, "that the cost was not related to patient care."

32. Generally, according to the HCFA's policy, the RHHI gives an exit conference before the auditors leave the provider.

33. PGBA did not give PHC Home Health the customary exit conference before they left PHC Home Health after they completed the second "full audit."

34. On or about December 1998, PGBA sent PHC Home Health a remittance advice ("RA") that included among other things, an unexplained payment for $31,000.

35. Subsequently, PGBA alleged that they had improperly overpaid PHC Home Health and that PHC Home Health had inappropriately kept the overpayment.

36. Although PHC Home Health and Senator Hollings' Office asked PGBA several times to provide the documentation related to the alleged improper overpayment, PGBA never produced the related documents. Eventually, PGBA provided an explanation that, if accurate, shows a lack of internal controls regarding the use of taxpayer funds. (SEE ATTACHED).

37. On or about January 22, 1999, four months after PGBA auditors left PHC Home Health from the second "full audit," PGBA issued PHC Home Health an improper Notice of Provider Reimbursement ("NPR").

38. On or about June 22, 1999, PGBA issued PHC Home Health an amended NPR.

39. On or about February 9, 1999, five months after PGBA auditors left PHC Home Health from the second "full audit," PGBA auditors gave PHC Home Health an exit conference, notwithstanding that they gave the exit conference only after PHC Home Health traveled to Washington, D.C. and asked for help from Senator Hollings' staff.

40. During the exit conference, PHC Home Health personnel asked the PGBA auditors why they had chosen to conduct a site audit of the Medicare certified home health agency.

41. Although the auditors said that they had chosen the Medicare certified home health agency through a "random process," they would never define the audit matrix.

42. Subsequently, a United States Senator and the Executive Director of the South

Carolina Medical Association also asked PGBA why they had chosen to conduct a site audit of PHC Home Health.

43. Responding to their inquiry, PGBA gave them two different reasons for choosing to audit PHC Home Health.

44. On or about September 27, 1999, PGBA's Anti Fraud Unit requested Mr. John Fox's medical records for services provided by PHC Home Health between May 1, 1998 and July 31, 1998.

45. PGBA alleged that they requested Mr. Fox's records because Ms. Fox had complained to PGBA.

46. Subsequently, PHC Home Health learned that the period Ms. Fox questioned was in September 1999, not May 1998, and that another provider gave the services in question to Mr. Fox.

47. In another instance, PGBA's Program Integrity Unit denied and recouped payment for a series of medical social work visits PHC Home Health gave to a beneficiary.

48. Here, PGBA alleged that PHC Home Health failed to submit the visit reports that supported PHC Home Health made the social work visits.

49. On appeal, PGBA admitted that they had the visit reports in question, but that PHC Home Health had placed the visit reports "out of sequence" for review.

50. PHC Home Health submitted that a prescribed sequence for submission of medical records did not exist.

51. On or about the Wednesday before Thanksgiving of 1999, an inspector from DHEC arrived at PHC Home Health and conducted a license inspection that they could not relate to a license inspection that was due, or a Medicare recertification survey.

52. Subsequently, the inspector decided that PHC Home Health violated two rules under S.C. Regulation Number 61-77.

53. The first violation alleged by the inspector related to whether PHC Home Health had administered a Tuberculosis screening test to a nurse, notwithstanding that the DHEC admitted the rule itself was not clear.

54. The second violation alleged by the inspector related to whether they required a PHC Home Health supervisor to sign an employee evaluation, notwithstanding that PHC Home Health's policy did not require a supervisor to sign the evaluation, nor does DHEC's or HCFA's policies require such a signature.

55. Notwithstanding that absent a supervisor's signature on the employee's evaluation did not violate any state regulation, the inspector held that PHC Home Health endangered the health and safety of patients when the supervisor failed to sign the evaluation.

56. Although the DHEC subsequently agreed that the supervisor's signature on the evaluation was not necessary, if PHC Home Health had not brought the matter before the DHEC, the inspector's error could have subjected PHC Home Health to an "Extended Survey" under the federal COP for suspected threat to the health and safety of patients.

57. Since the televised programs and newspaper article discussed above, PGBA randomly selected my durable medical equipment company for review under an initiative issued by the Office of the Inspector General ("OIG), and reviewed my medical practice under another initiative.

58. Additionally, PGBA continued to randomly choose PHC Home Health claims for medical review.

59. For one reconsidered claim, PGBA refused to pay $17.49 for supplies because

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PHC Home Health did not include an "itemized supply list" with the reconsideration request, notwithstanding that the reconsideration standard does not require an itemized supply list.

60. Still in another claim, PGBA alleged that PHC did not have doctors' orders to provide at least three nurse visits.

61. Notwithstanding that PHC Home Health did have the orders from the doctor for the visits in question, PGBA denied the visits.

62. Moreover, PGBA recklessly advised PHC Home Health to ask PGBA to reopen the claim.

63. Because of PGBA's reckless advice, the beneficiary lost the regulatory window to submit a proper reconsideration.

64. On or about December 2000, PGBA agreed to mediation and settlement of the 1996 audit disallowance.

65. Subsequently, PGBA notified the PHC Home Health attorney who was handling the matter, that PGBA had lost important documents that PHC Home Health had submitted about two years before to support the costs PGBA disputed as not related to patient care.

66. At considerable cost to PHC Home Health, the documents were submitted again to PGBA.

67. Since I spoke publicly against the IPS, PGBA has randomly chosen my companies at least five different times for some type of scrutiny.

68. Apart from the alleged overpayment from the financial audit of 1996, neither the HCFA, its contractors, the DHEC, nor the OIG has found that any of my companies violated any laws, rules, or regulations during any of their "random" inspections.

69. Nonetheless, I have spent large sums of money defending myself and my companies.

70. These unnecessary reviews interrupt operations, diminish cash flow and, consequently, patient care suffers.

71. PGBA's behavior concerning PHC Home Health is one example of how PGBA abuses its power under the Medicare law.

72. Finally, I submit to the Chairperson conducting this hearing that PGBA's behavior concerning PHC Home Health shows, that the HCFA has lost control and oversight of this RHHI.

FURTHER AFFIANT SAYS NOT

Hugh D. Durrence, MD
Affiant

Signature of Affiant

SUBSCRIBED AND SWORN to before me this 3rd day of April 2001

Laura A. Wood
Notary Public, State of South Carolina
My Commission Expires
June 20, 2006

The following paragraph is from letter submitted by:

Mr. Ronald Smith, Manager, Financial Management Branch
Division of Financial Management and Program Initiatives
Health Care Financing Administration - Region IV
Dated: March 15, 2000

December 4, 1998 Payment to PHC

Prior to the meeting with PHC in the Regional Office on December 3, 1999, we discovered that a payment for a cost report underpayment of $31,534 had been sent to PHC in error. Subsequent to the meeting in the Regional Office, PHC questioned the circumstances surrounding the payment. We also had concerns about why the payment was made and made it one of our review objectives at PGBA.

In our review of the audit workpapers we found a copy of a Notice of Program Reimbursement ("NPR") dated December 4, 1998 for the December 31, 1996 cost reporting period. In discussions with PGBA managers and supervisors we confirmed that the $31,534 payment to PHC was for the December 4, 1998 NPR which was scheduled to be sent to PHC. However, PGBA held the NPR at the last minute before the deadline, but the scheduled payment was not stopped. The December 4, 1998 NPR contained an audit adjustment posting error that had turned an overpayment into an underpayment. We have instructed PGBA to take immediate corrective actions to prevent situations like this in the future. PGBA has established controls to try to prevent recurrences in the future. However, PGBA must reopen the cost report to recover the improper payment.

PATIENTS FIRST: A 21ST CENTURY PROMISE TO ENSURE QUALITY AND AFFORDABLE HEALTH COVERAGE

THURSDAY, MAY 10, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH, JOINT WITH THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman, Subcommittee on Health) and Hon. James C. Greenwood (chairman, Subcommittee on Oversight and Investigations) presiding.

Members present, Subcommittee on Health: Representatives Bilirakis, Upton, Greenwood, Deal, Burr, Whitfield, Bryant, Pitts, Brown, Capps, Deutsch, Eshoo, Stupak, and Green.

Members present, Subcommittee on Oversight and Investigations: Representatives Greenwood, Bilirakis, Stearns, Burr, Whitfield, Bass, Deutsch, Stupak, and DeGette.

Staff present, Subcommittee on Health: Tom Giles, majority counsel; Kristi Gillis, legislative clerk; Amy Droskoski, minority professional staff member; and Bridgett Taylor, minority professional staff member.

Staff present, Subcommittee on Oversight and Investigations: Joe Greenman, majority professional staff; and Chris Knauer, minority professional staff member.

Mr. BILIRAKIS. Good morning. I now call to order this third joint hearing in the 107th Congress, of the Health Subcommittee and the Oversight and Investigations Subcommittee. This the third hearing of our series entitled Patients First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage.

Patients First is an initiative launched by the Energy and Commerce Committee to modernize and reform the Health Care Financing Administration. To improve the quality of patient care, we are conducting a top-to-bottom review of HCFA's structure, operations and regulations.

Today's hearing will be especially useful to our process because we are honored to have such a distinguished and impressive panel. I would like to welcome to our hearing four former Administrators of the Health Care Financing Administration. Dr. Bill Roper, Dr. Gail Wilensky, Dr. Bruce Vladeck, and Nancy-Ann DeParle have all had the daunting task of running HCFA—and I emphasize

"daunting," and dealing with Congress. I hope that today we will be able to have a candid discussion with them about what works at the Agency and what can be improved.

Our examination of HCFA will also be guided by the input that we receive from stakeholders, most notably, the true stakeholders, the beneficiaries and providers. To help us understand their concerns, we have created surveys—or "questionnaires"—to collect comments, concerns and suggestions.

I would like to enter into the record a sample copy of each of these surveys. I would note that the text of these surveys can be reviewed on the Internet at the following address which is up there on the board—http://hcfasurvey.house.gov.

Mr. BROWN. Well done.

Mr. BILIRAKIS. We have undertaken an ambitious project to reform HCFA and put patients first. Over the next several months, we will work to ensure patients receive quality affordable health care through Federal programs, and with the help of our expert witnesses today, as well as the beneficiaries, providers, and other stakeholders, I am confident that we will succeed in our efforts to put patients first. And I yield to Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. As we think about how to strengthen Medicare, Medicad and S-CHIP and help HCFA negotiate the challenges they have, we have a rare opportunity to hear from four of the Nation's most highly respected health policy experts, who also happen to be former Administrators of the Health Care Financing Administration.

I would add that my health care policy person, Ellie Tahoney, graduated—got a Master's Degree from Dr. Roper's program in North Carolina, and she is very well trained. And Dr. Roper, until today, was the only of the four that I was not acquainted with, so welcome to him and the other three of you. It is a thrill to have you here, and looks to be an exciting day.

HCFA-administered health insurance programs—Medicare, Medicaid and S-CHIP serve 80 million Americans. Those are just the direct beneficiaries. When you factor in the positive impact on families and communities, as well as the critical funding stream for safety-net and other providers, these programs benefit every one of us.

A great deal is at stake when we contemplate HCFA reform. It doesn't mean we should shy away from changes when those changes make sense. For example, it makes sense to adequately fund HCFA. That would be a major change. As it stands now, we expect HCFA to run on a hope and a prayer. Not only is the Agency chronically under-funded, but we have no qualms about increasing its workload without increasing its resources. Then we whine in this Congress when HCFA fails to meet statutorily imposed deadlines for resource-intensive systems changes.

Last year, we gave $11 billion to Medicare managed care plans. They insure 16 percent of the Medicare population. HCFA insures the rest. We didn't give HCFA a dime.

Over a 3-year period, HMOs have dropped 1.7 million seniors from coverage. They have cut back on the very benefits that attracted seniors to their plans in the first place. They claim to be

over-regulated, but we have no idea how they spend the money we give them.

And this year we are focusing on HCFA reform, not Medicare+Choice reform. Don't get me wrong, it is certainly worthwhile to make direct improvements in HCFA, but we should keep our concerns in perspective.

In terms of HCFA reform, it also makes sense to address concerns raised by Medicare providers. There are clearly some kinks in the policies and procedures under which HCFA, its contractors and its providers operate. We should coordinate with HCFA to make sure the necessary statutory, regulatory or administrative changes are made to straighten these problems out. But should HCFA undergo a massive reorganization? It would certainly keep HCFA busy, as if the Agency weren't busy enough, you know, it would be an excellent way to burn up extra administrative dollars, if there were any. But does it make sense? No. Reform should mean giving HCFA the tools and the flexibility it needs to continuously improve its operations. It should not mean restructuring the program, which implies either an arbitrary and costly reorganization or, far worse, a 36-year step backwards into the private insurance market.

In the latest issue of the Harvard Health Policy Review, Bruce Vladeck and Harry Kane wrote opposing articles on Medicare. Well, my views were certainly more aligned with Dr. Vladeck's. His article is entitled "Medicare Works," while Dr. Kane's was entitled "The Medicare Menace."

There is a sentence in Dr. Kane's article that I want to share with you, discussing a private sector alternative to traditional Medicare, Dr. Kane wrote: "The dynamics of a market can still thrive, but that will always mean there will be market frictions," he said. And he went on and said, "Some people will not do nearly as well as others in obtaining all the medical services they want and need." Dr. Kane is obviously comfortable with that, I am not. Enough said about Medicare privatization.

Should Medicaid be removed from HCFA? If we want to make HCFA work better, we need to give HCFA more resources, we need to release our statutory stranglehold on them, and we need to work with them to address provider concerns. We do not need to arbitrarily create a new home for one of the three health insurance programs which HCFA administers.

I will stop there, Mr. Chairman. I am looking forward to getting the perspective of our four distinguished witnesses.

Mr. GREENWOOD. (Presiding) Thank you. This is a joint hearing between the Health Subcommittee and the Oversight and Investigations Subcommittee, and lest anyone think that Chairman Bilirakis and I are being overly formal by trading seats off and on, I need to swear in the witnesses, so that is why I moved to the Chairman's seat.

Let me thank the four witnesses. This is a real special occasion for us to be able to draw on your collective knowledge and experience at HCFA to help us with our mission.

I think there are two ways that we could go wrong. One of them is to do anything arbitrarily or make change for the sake of making change. None of us wants to do that. And certainly none of us is

critical of anyone at HCFA, past Administrators, current employees. I think everyone universally agrees that we have been blessed with great Administrators. We have been blessed with a whole slew of people at HCFA, all of whom are very, very dedicated and very competent, but this is a vehicle that was built in 1977, I think, and that has been asked to carry a lot more weight over the years, and it does us well, for the sake of the beneficiaries, to think through whether, given today's management ideas, today's realities, today's information systems, whether there are ways to improve the system.

I think we should go into this process without any prejudices, without any presuppositions about what we should or shouldn't do, but rather do some real innovative, blue-sky thinking, thinking about paradigms and how it is best to serve these clients of ours in the 21st Century. And I would yield to Mr. Green for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing, the third in a series on the problems facing the Health Care Financing Administration. I especially am eager to hear from our panel of witnesses since they have been working on these issues for two decades. And like my colleague, Sherrod Brown, having dealt with HCFA Administrators in our 8 years in Congress, 9 years now, this is the third hearing we have had on this issue, and we have already heard from providers, contractors, insurers and others that have to work with the Agency day in and day out. We have heard their frustrations, their concerns, the problems they see with the Agency.

What we have heard from panelists at each hearing is that HCFA is over-burdened and under-funded. The Agency is responsible for administrating Medicare, Medicaid, State Children's Health Insurance Programs, as well as the health-related provisions of the Health Insurance Portability and Accountability Act. Funding these programs is challenging enough, but Congress makes the job harder for HCFA by constantly moving the goalpost.

Congress' micromanagement of the Agency is a constant problem for HCFA, forcing them to implement pages and pages of new policies. The Balanced Budget Act alone created 350 new Medicare and Medicaid policies. But before some of these changes could be fully implemented, Congress revised the BBA in 1999 and again last year. Despite all these changes, Congress has failed to provide HCFA with the additional resources it needs to manage the increased workload.

The fiscal year 1995, before passage of HIPAA, before creation of the Children's Health Insurance Plan, before passage of the Balanced Budget Act, HCFA's administrative budget was $2.2 billion. Yet, 5 years later in 2000, however, HCFA was appropriated less money, $2.1 billion.

HCFA is the largest provider of health care in the country, and probably in the world, yet we in Congress ask the Agency year after year to operate on a shoestring budget. As Dr. Roper states in his testimony, this low administration budget should not be a source of pride, it should be a source of embarrassment.

HCFA and Congress must work together to maximize its efficiency, to modernize its operations to better serve the beneficiaries

and providers, and to reach our mutual goals of providing our elderly and disabled populations high quality health care.

I have read each of the witnesses' testimony. I am interested in hearing about the ideas they share on how we can improve this Agency. I am especially interested in proposals to resolve some of the issues through the Administration. I am afraid if we wait for Congress to do this, it will take much longer than necessary, and we may not like what we end up getting.

Mr. Chairman, I thank you for the time, and yield back.

Mr. GREENWOOD. Thank the gentleman. Mr. Deal, for an opening statement.

Mr. DEAL. Pass.

Mr. GREENWOOD. Mr. Deal passes. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. I will be brief, and thanks for holding this hearing. This has been an ongoing concern, and these hearings emphasize the need for action and attention to HCFA.

As I am sure the previous Administrators in front of us today are well aware, HCFA-bashing is a popular pastime up here on the Hill. I and everyone else in this room today would like to change that.

In reading the testimony, each of the previous Administrators agree on a need for reform. So do I, and so do many beneficiaries and providers in my district. The layers upon layers of bureaucracy within HCFA is one area of concern. Another is the lack of funding. Still another—and this list could go on and on—is the sheer volume of mandates given to HCFA by all of us here in Congress.

I have said this before and I will say it again—although I don't believe in throwing money at HCFA as the solution to all their problems, it certainly cannot continue running with administrative costs of less than 2 percent. What this slim budget translates into is a lack of adequate computer system and information technology, a lack of adequate training for staff, and a rather high turnover of HCFA Administrators.

I believe HCFA reform is an area that crosses party lines, and this is proven by the similarities contained in the testimony of our four witnesses, witnesses that know better than anyone else exactly what problems affect the proper running of HCFA.

I look forward to hearing each of their suggestions on how best to make HCFA workable again. I will be in and out, Mr. Chairman, because I have a couple of other things, but I am looking forward to the witnesses, and it is good to see so many old friends back here. Thank you.

Mr. GREENWOOD. Thank the gentleman. Ms. Eshoo.

Ms. ESHOO. Good morning, Mr. Chairman, and thank you. Good morning to the distinguished panel. For sometime now, I have been concerned that bureaucratic barriers at HCFA are inhibiting beneficiary access to new technologies, and I think the people that are going to testify today know this because they have heard from me on it.

According to a Lewin Group study, it often takes as long as 5 years for a product to make its way through the HCFA maze, yet it only takes 18 months to get FDA approval. It doesn't make sense to me that the Federal Government can determine whether a prod-

uct is safe and effective in 18 months, but takes 5 years to decide whether we will pay for it or not.

As you know, Mr. Chairman, my Congressional District enjoys the largest concentration of biotech companies in the country. While this is a great source of pride to me, there is also a burden that comes with it, and many of them are created, I think, by the problems that are at HCFA.

We've spent an inordinate amount of time and resources calling and writing the Agency about coverage delays, failures to reimburse, and illogical coding decisions. Rather than micromanaging the Agency, we should really address the structural problems that produce the inefficiencies.

Last year, I led the effort in this committee to include in the BBA give-backs package two provisions aimed at streamlining the coverage process at HCFA. I am pleased that we were successful in that, however, it wasn't enough and more work has to be done.

So, I am committed to taking a comprehensive approach to streamlining HCFA in much the same way that we did with FDA in 1997. Prior to FDAMA, FDA had many of the same problems that HCFA currently suffers from. By modernizing the Agency in a very comprehensive way, we were able to dramatically improve approval times. I am proud of that work, and I think that we need to apply the same model to HCFA.

We also have to combine these efforts in streamlining the Agency with additional resources. At 2 percent, HCFA has one of the slimmest administrative budgets of any Federal Agency. So, as Congress continues to add new responsibilities to the Agency, we have to make sure that the resources are there. Otherwise, whatever our reforms are, we are not really going to be able to be very proud of them because they won't be able to handle them. They won't be able to implement them.

So, I am looking forward to working with all the members of this committee and the Agency in making this happen, and I look forward, of course, to hearing from the distinguished panel. As Bart Stupak said, we have some good friends that are going to be testifying today. Thank you.

Mr. GREENWOOD. Thank the gentlelady. The gentleman from Michigan, Mr. Upton, for an opening statement.

Mr. UPTON. Thank you, Mr. Chairman. I appreciate today's hearing. I know that we are here today, and the HCFA staff on the front lines, administrating the Medicare program, to share the same goal and commitment—ensuring continued access to high quality health care services for our seniors and disabled beneficiaries, while guarding the integrity of the program and the taxpayers' investment both now and in the future.

I am delighted to hear about the witnesses. I want to put my full statement into the record. I know that we want this program to run efficiently, and to do so, by hearing from the former Administrators, I think that we will have some good ideas in terms of where we need to go and what adequate level of resources they need to do the job that we want them to do. And I yield back the balance of my time so that we can listen to their testimony. Thank you.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairmen, thank you for calling today's hearing. I think it is an excellent idea to ask for the perspective of our four distinguished witnesses. They've been in what is one of the hottest seats in our government and can give first-hand insights on how the Medicare program can be more efficiently managed in the short-term and the long-term to address the mounting frustration we are hearing from Medicare beneficiaries and health professionals alike. I want to personally thank our witnesses for their willingness to be here today and give us the benefit of their experience.

I know that we here today and the HCFA staff on the frontlines of administering the Medicare program share the same goal and commitment—ensuring continued access to high-quality health care services for our seniors and disabled beneficiaries while guarding the integrity of the program and the taxpayers' investment in it both now and in the future. Congress and HCFA should be partners in this effort—not adversaries. We have tended to rake the agency over the coals for its errors, failures, and problems, and that is part of our oversight function. But I don't think we've been as willing to be open to hearing from HCFA about what it is the agency needs to perform more effectively and efficiently and to go to bat for those changes. We need to change this.

For starters, we should go to bat for the funding HCFA needs to administer the program efficiently and effectively. I think a cosigned letter from us to our colleagues on the Labor/HHS/Education Appropriations Subcommittee reflecting what we will learn today about agency's needs would be a good place to start.

Our witnesses will give us differing visions for the future of HCFA today, but they are very consistent in their recommendations for reasonable, common-sense steps we can take now, over the short-term, to help the agency function better from the perspective of beneficiaries and health care professionals.

First, I think a lot of the dissatisfaction we are hearing from our constituents, beneficiaries and providers alike, stems from the contractor system that's been with us, relatively unchanged, since the Medicare program's inception. Does it really make sense to have 50 separate contractors, or is this a recipe for miscommunication. Does it really make sense to have a law on the books that prohibits HCFA from competitively bidding for contractors? What an effective tool that could be for improving contractor performance, particularly if part of the evaluation for contractor renewal is beneficiary an provider satisfaction.

Second, instead of having 50 different contractors making coverage calls on new technologies, wouldn't it make sense to beef up and streamline HCFA's national coverage policy process and give them the authority to pay what they need to attract the expertise they need?

These are just two areas in which some common-sense reform would go a long way. I'll focus on several others later this morning as we have a dialogue with our witnesses.

Again, let's think in terms of forging the partnership we need to achieve our mutual goals of ensuring beneficiaries' access to high-quality care now and in the future.

Mr. GREENWOOD. The Chair thanks the gentleman. Without objection, his written statement will be entered into the record. The Chair recognizes the gentlelady from California, Ms. Capps.

Mrs. CAPPS. I thank you, Mr. Chairman, for holding this hearing, and I am impressed with our witness panel today, with the expertise that will be at the table.

I am pleased we are looking at the Agency that manages Medicare and hearing from those who know it best. As we listen to their testimony and question them on possible reforms, I hope we will remember the following: That Medicare is the most successful government health program in history. It has ensured the availability of health care for millions of older Americans who had previously no options.

I have heard, as I am sure we all have, lots of loose talk about reforming and privatizing Medicare. The idea of turning this program over to the private sector is a bad one. The marketplace can

be a wonderful place of efficiency, but it is also ruthless in its drive for profit, and we must not allow health care decisions for our seniors to be strictly business decisions, and we can see that danger clearly in some of the excesses of managed care.

Government works best when it is harnessing the incredible potential of the private sector, but softening some of its harsher edges. To be sure, there may be room for more businesslike efficiency in HCFA, and I am open to making those very changes. For instance, we do need to modernize and streamline the coding and coverage processes, especially for new devices, treatments and technology. I echo my colleague, Anna Eshoo, in stating that I wish we could modernize HCFA the same way that the Food and Drug Administration—that we have been able to do that with them, but it would be a terrible injustice to our seniors to open Medicare, unshielded, to the cruelties of the business world. Medicare is a sacred program to many of today's seniors. They count on it, and need to be able to do so in the future.

We as a society have made a pledge to them that they will have health care, and we need to follow through on this pledge. We should also take a moment to recognize how hard a task it is that Congress has assigned HCFA. I personally want to thank our four former Administrators here for the years of service that you have given to this Agency. Balancing Medicare is an enormous challenge and a delicate balancing act. While we don't want to compromise patient care with excessive regulation, we also need to make sure that the Agency preserves a high level of program integrity and works to prevent fraud, waste and abuse.

Often, this committee has sent contradictory messages to HCFA about our priorities. We tell them to come down hard on fraud, waste and abuse, and then the next day we are screaming at them because they are being too aggressive. It is hardly fair to put them through that and not clearly state our goals and, also, to clearly examine the relationship between our goals and the funding resources that we give the Agency to operate.

I look forward to working with you on this, Mr. Chairman. I hope that we can address these issues in a fair-minded and a bipartisan way. Thank you.

Mr. GREENWOOD. The Chair thanks the gentlelady, and recognizes the gentleman from Florida, Mr. Stearns, for an opening statement.

Mr. STEARNS. Thank you, Mr. Chairman, and good morning. This is a conundrum, trying to figure out insight into this Health Care Financing Administration, HCFA. I don't think any of us feel comfortable that we know all the answers here. Lots of times we criticize the Agency, but it is so important, so it is nice also to find out ways we can improve it.

Interestingly enough, I had a constituent in my district who was on Social Security Disability, and he turned 65 and he wanted to convert to Medicare, and it was almost an impossibility given all the paperwork. And as we sit here today, my constituent has still been unable to convert his Social Security Disability into Medicare. And we have helped him. He has received forms. We filled them out. And what is troubling is that he has been unable to use his secondary insurance which he purchased at a total cost of $1200,

to help him. So we have been hassling this back and forth for over a year, so I am interested to hear the testimony of the witnesses.

Also, I would like to comment a little bit on Dr. Roper and Dr. Wilensky's testimony, in which they reaffirmed their support of reforming Medicare using the Federal Employee Health Benefits Program as a model. I welcome their suggestions here. I fully concur with what they spoke about, with all the changes we have today in the program, and the complexity of it, obviously we need an overhaul. How we do this, we don't know, but maybe to use as a paradigm, the FEHBP is a good idea. This is a program that has worked, it has had low inflation up to this date, and I think if we provided that same kind of program for the seniors, it would also provide them access to new drugs and devices without a government-run program, but a private sector program with competition.

So, I look forward to hearing from our witnesses, and I thank both Chairmen for having this hearing.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentlelady from Colorado, Ms. DeGette, for an opening statement.

Ms. DEGETTE. Mr. Chairman, I have a very excellent opening statement which I would ask unanimous consent to submit for the record.

Mr. GREENWOOD. No, we insist that you read it. Without objection, the gentlelady's opening statement will be entered into the record, and the Chair recognizes the gentleman from New Hampshire, Mr. Bass, for an opening statement.

Mr. BASS. Thank you, Mr. Chairman, and I just want to associate myself with the remarks of my colleagues behind me, and thank both you and Mr. Bilirakis for holding this series of hearings which are not only timely and instructive, but also very relevant to what will undoubtedly be one of the one or two most important issues that this committee will address during this Congress—the reform or review of the Medicare system in general and, within that category, the provision of—or the issue of providing a prescription drug benefit for seniors.

It is important to understand how this important and substantial program is administered, what its problems are, and what options we have available to us. So, I thank you for holding this series of hearings, and look forward to hearing from our witnesses. Yield back.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Chairman Bilirakis and Chairman Greenwood, thank you for holding this important hearing. This is the third in a series of hearings this Committee is holding on the reform and modernization of Federal health care programs.

At this morning's hearing, we are honored to have assembled before us the previous four Administrators of the Heath Care Financing Administration. I can think of no better group of distinguished people to bring before this Committee to talk about the issues facing HCFA.

I hope today to continue a process we began earlier this session, beginning with our March 1st hearing on this topic, where Republicans and Democrats work together to improve the lives of people participating in these programs.

The objective of these hearings is clear: We want to ensure that America's seniors will have access to the best health care technology that our country has to offer. This will help Medicare patients live longer and healthier lives.

HCFA has come under heavy criticism in recent years from both sides of the aisle. We are not here today, nor are these hearings designed, to bash HCFA. We want to hear your perspectives as Administrators who ran this program about what you learned and what your thoughts are as you hear all of the criticisms levied against this agency. Are they justified? How should the agency be changed? Is it a cultural thing? What are the resource needs of the Agency?

Dr. Vladeck, in your paper "Making Medicare Work," your first set of findings are that "beneficiaries need better customer service;" "beneficiaries face unintended financial liabilities;" and "beneficiaries are subjected to too much and confusing paperwork." That is concerning. Often times we hear these concerns as they relate to providers. I am interested in your insights into these areas and your suggested reforms to address them.

Dr. Wilensky, I am interested in fleshing out the fundamental tensions you see existing at HCFA and seeing what we can do to improve that dynamic. Ms. DeParle, I certainly appreciate your comments that we all need a breather from more changes to the Medicare program. We made major changes in the Balanced Budget Act of 1997, and I think it's time we all assessed where HCFA is with implementing those provisions and the impact that the work load had on your agency and your staff.

Dr. Roper, you served the earliest of any of the four here today and therefore are the most removed from HCFA's current operations. Yet as far back as 1986 when you started your tenure under President Reagan, you say that HCFA was "the favorite four letter word of people in the health care industry." How do the issues we are confronting today differ from those you faced fifteen years ago?

Clearly, there will always be some tension between HCFA as the agency paying the bills, and the providers, who are the ones getting paid. But when beneficiaries are affected and when people familiar with the Agency say the culture is as bad now as it has ever been in recent memory, we need to step back and ask how did we get here, and how can we make it better. We owe at least that to the beneficiaries and their families.

Chairman Bilirakis and Chairman Greenwood, thank you again for holding this hearing. I look forward to hearing from the witnesses.

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

I'm pleased that all of you are here today. I've had the opportunity to work with each one of you over the years as you served as Administrators of the Health Care Financing Administration. I think each of you personify the extremely high level of ability and commitment that we have had in the persons serving at the leadership level of the Agency.

It has been my experience—and I think each of you would echo this, that in fact at all levels of HCFA, there are many, many public servants who have shown unusual dedication and commitment. They have done their jobs under extremely difficult conditions: a rapid expansion of workload and no corresponding increase in resources—both in terms of dollars and staff positions.

Further, they have operated during a period when we in the Congress have made many complex changes in Medicare, when we have frequently failed to resist micromanaging the agency, and when we have exhorted the agency on the one hand to stop any incorrect payments—we call it fraud and abuse—but criticized you when the steps taken to achieve that goal have caused legitimate unhappiness in the provider community.

I want to make just a few points. One, clearly we need to do more to give the agency the resources it needs. It is inexcusable that fewer people work in HCFA now than were there than when Dr. Roper was there a dozen years ago.

Two, we need to resist the idea that somehow we in Congress have a magic bullet in terms of how to reorganize the agency that will somehow solve these problems. Just setting up a Board, or chopping off vital pieces of HCFA, or rearranging the boxes, not only won't solve the problem indeed it may make it worse. Further we here in the Congress are not in the best position to really know the implications of what we may try to do. So I think we have to be very careful here.

Finally, I want to stress that I find the idea of moving Medicaid out of the agency—and treating it even more like the forgotten stepchild that we'd just as soon was someone else's responsibility—is a serious mistake.

Medicare and Medicaid are both vital health care insurance programs—and I emphasize that word insurance—that are depended on by millions and millions of Americans. Medicaid now serves nearly 40 million people—at least as many as

Medicare. It is approaching Medicare in expenditures. It deals with the same population of providers. And we have worked to establish the same standards for those providers, including nursing homes, to name one particularly important example.

The populations themselves overlap. In fact, I would argue that Medicare only works for low-income elderly and disabled people because Medicaid is there to supplement it—paying premiums, coinsurance, providing long-term care, prescription drugs, and other additional services.

It is a mistake to turn our backs on years of progress and return to viewing Medicaid as a welfare program, or as a grant program to states or organizations, as opposed to a program of insurance coverage for beneficiaries.

Both Medicare and Medicaid are critical programs for the American people. Both are vital to the health care system. Providers depend on them. Aged, blind, disabled people, and low-income families and children, depend on them. We need to work together to make them work better for us all.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

I am pleased to have such a distinguished panel assembled today. Together, you have managed the Health Care Financing Administration (HCFA) through more than a third of its existence. With that much wisdom you are well suited to make recommendations to improve the agency. I look forward to hearing your different perspectives on the challenges facing HCFA and how we can help the agency best meet them in the future.

One of the challenges facing the agency is the administrative budget. HCFA has been entrusted with enormous responsibilities and duties but given a meager allotment to perform them. It is a credit to you all that HCFA has done so much with so little. How much does HCFA need to effectively and efficiently meet its mandated goals?

Another key challenge is balancing the different roles that the agency is often asked to play, as a regulator, as a purchaser, and as a protector of those who depend on HCFA to guarantee quality health insurance coverage. From my perspective, HCFA's number one priority is to protect the millions of people who depend on its programs for their health insurance. Part of that means ensuring that providers continue to participate in the program, making the rules understandable, and paying claims in a timely manner. Part of that also means being a prudent guardian of public money and working to eliminate fraud and abuse. These goals require careful, thoughtful, and open consideration by the agency. How can the Congress help with this balancing act?

Often we in Congress hear the call for "reform" of the agency—either from frustrated providers or from those with an ideological bone to pick about the role of government in their lives. I don't hear seniors calling for reform of HCFA—I hear them asking for assistance with prescription drugs. I don't hear children, the elderly, or the disabled calling for more flexibility in Medicaid—I hear them asking for the government to protect the coverage they have. Therefore, what I am most interested in hearing about today is the role of HCFA for beneficiaries—the seniors, the disabled, children, families, and others who depend on the programs HCFA runs. With a doubling of the Medicare population expected in the next two decades and the desire to continue to expand health insurance coverage through successful programs like Medicaid and the Children's Health Insurance Program, HCFA will be asked to protect an increasing number of Americans, both young and old. What needs to be done to make HCFA work better for beneficiaries?

One of the ideas I have heard floating around is that we should separate the Medicaid program from HCFA and allow the agency to focus solely on Medicare. While Medicare is a very important program, I am concerned about what this approach might do. Medicaid, like Medicare, is an insurance program which serves vulnerable populations. Many of the same functions are performed for both programs and separating the two would merely mean a duplication of bureaucracy. Further, I cannot support any proposal that would place less importance on the 40 million elderly, disabled, women, and children in Medicaid than those protected by Medicare. We cannot allow either program to "wither on the vine" or to suffer from "benign neglect."

I thank the Chairman for holding what I believe will be a most informative hearing. What the agency and its programs need at this time is a firm commitment from Congress that will enable it to do a first rate job of protecting and serving the millions of Americans that depend on the health care they receive through the agency's programs. Part of that is funding. Part of that is giving the agency the tools it needs to perform its multitude of responsibilities. And part of that is for us to foster a good

working relationship between the agency, Congress, providers, and beneficiaries to achieve our mutual goals. Today's hearing should help.

Mr. BILIRAKIS. The Chair thanks the gentleman, and now calls for the witnesses: Dr. William Roper, who is the Dean of the School of Public Health, University of North Carolina at Chapel Hill; Dr. Gail Wilensky, John M. Olin Senior Fellow at Project HOPE and Chair of MedPAC; Dr. Bruce Vladeck, Senior Vice President for Policy, Institute for Medicare Practice, Mount Sinai School of Medicine, and Nancy-Ann Min DeParle, Former Administrator of Health Care Financing Administration, all for Administrators. As you are aware, this is a joint hearing with the Oversight and Investigations Subcommittee and the Health Subcommittee, and you understand that when we do this, we have a practice of taking testimony under oath. Do you have any objection to testifying under oath?

Mr. ROPER. No.

Ms. WILENSKY. No.

Mr. VLADECK. No.

Ms. DEPARLE. No.

Mr. GREENWOOD. According to the rules of the committee, you are entitled to be advised by counsel. Do you care to be advised by counsel?

Mr. ROPER. No.

Ms. WILENSKY. No.

Mr. VLADECK. No.

Ms. DEPARLE. No.

[Witnesses sworn.]

Mr. GREENWOOD. We are going to ask that each of you give a 10-minute statement. We are doubling the normal allotment of time because we are so eager to hear your testimony, and we will start with Dr. Roper.

TESTIMONY OF WILLIAM L. ROPER, DEAN, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL; GAIL R. WILENSKY, JOHN M. OLIN SENIOR FELLOW, PROJECT HOPE, CHAIR, MEDPAC; BRUCE C. VLADECK, SENIOR VICE PRESIDENT FOR POLICY, INSTITUTE FOR MEDICARE PRACTICE, MOUNT SINAI SCHOOL OF MEDICINE; AND NANCY-ANN DePARLE, FORMER ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. ROPER. Good morning, Mr. Chairman. It is an honor and a privilege to appear before you. I am Bill Roper. I am Dean of the School of Public Health at The University of North Carolina. I was HCFA Administrator starting in 1986—actually, I started 15 years ago this week. I served from 1986 to 1989, and it is a pleasure to come back to talk with you and my colleagues about this important program.

Following my time at HCFA, I was also Director of the CDC, the Federal Public Health Agency in Atlanta, and served in the private sector as a senior executive with a managed health care company, so I think I have seen other aspects of the world that HCFA touches and is touched by.

When I was at HCFA, I often jokingly remarked that HCFA was the favorite four-letter word of providers in the health care industry, but I think that those tensions, those concerns have surely

been heightened in the years to come. There are significant improvements to be made in HCFA and we are going to be talking about those today, but I would begin by saying the fundamental problems we face are primarily problems of the Medicare program itself, not primarily of the Agency that administers it.

Having been head of both HCFA and the CDC, I used to say as well that HCFA is a "black hat agency" whereas the CDC is a "white hat agency"—that is, on most days, most people think good thoughts about the Centers for Disease Control and Prevention. On the other hand, on a good day HCFA makes only half the people mad at it.

The essence of what HCFA does is saying "no" to people, lots of people—the Congress, beneficiaries, providers, and so on—and when you say no, you make people mad, and that is what I think we all need to understand as we talk about this.

Many of the problems attributed to HCFA are not of its own making. It exists and functions in a conflicted environment where the Congress will often pass legislation with noble, even lofty, goals, but that have internal challenges—for example, the challenge for fiscal responsibility while at the same time not saying no to beneficiaries when they believe they need health care services, pushing for quality in health care services while at the same time not upsetting doctors and other providers. Those are surely challenges. I would say, in general, it is difficult to be both customer-friendly and to be a regulator.

There are some specifics, though, that I would like to talk about, and I will do that quickly. The Medicare program itself is sadly out-of-date, it needs to be modernized. It has failed, and continues to fail, to take advantage of the innovations that we have had in the private sector and, as was said earlier, I am on record elsewhere as saying it ought to be much more like the Federal Employee Health Benefits Program.

In general, beyond that point, new skills and expertise are needed in the Agency's workforce. New tools and data systems are needed to enable informed purchasing decisions and informed assessments of quality and other important tasks. HCFA needs to have explicit approaches to hiring staff with private sector skills, and needs to realistically evaluate its resource needs. It needs to be functioned more as a continuous quality improvement agency and, as such, needs to be given much more freedom to implement pilot studies or to test efforts to guide improvements in services.

In the past, no one has ever accused HCFA of being too nimble, and that need to innovate is at the forefront of this problem. At present, we need a new approach to trying out ideas on a short-turnaround time. Perhaps feasibility waivers could be granted where something doesn't have to be researched to death to demonstrate whether it works or not, but you can try something for even a short period of time and, if it works, spread it more broadly and, if it doesn't, abandon it and go on to something else.

As I and others have previously said, it is important to emphasize the need for more resources for HCFA itself. When I hear people brag about how little Medicare spends on administration, I cringe. That should be a source of embarrassment, not of pride.

The Agency is under-staffed both in numbers and in the mix of skills, and it is seriously hampered by inadequate systems. There are actually fewer staff in HCFA today than when I became Administrator 15 years ago, despite a tripling of the outlays. The inadequacy of resources shows in the quality of the output.

Now nearly 25 years old, HCFA needs to be updated, however, I believe a large-scale reorganization is not necessarily the way to do it. As well-intentioned as it was, and it was, HCFA's recent reorganization produced much chaos. It created mass confusion in many respects. Accountability has been diffused throughout the Agency at the regional and central levels. Individuals outside the Agency are confused about who is accountable for particular issues, and uniform implementation of procedures and processes is largely absent. A confusing organization might ease HCFA's essential dialog with the private sector, which is already unsympathetic with HCFA and, even more so, unsympathetic to the chaotic structure.

Rarely are problems solved by moving boxes around on the organizational chart. I believe it is time to re-evaluate Medicare's contractor system, the fiscal intermediaries and carriers. We still have too many intermediaries and carriers to be efficient. I believe there are 50 today—30 Part A, 20 Part B. We could dramatically reduce the number of contractors and improve the management of the program, while being more efficient.

I would suggest the most significant problem Medicare and HCFA faces is that is stuck firmly in a fee-for-service mentality and modality. Integrated health delivery systems are much more appropriate and responsive to the needs of seniors, certainly far more promising than the Yellow Pages fee-for-service approach of organizing care for seniors with serious, complex, chronic illnesses.

I believe private plans, including managed care and indemnity plans, should compete with the traditional program on the basis of quality and cost but, unfortunately, the current Medicare+Choice program brings together an inhospitable environment with complex legislation and unrealistic rules that have made the Government in a managed care setting undesirable to the private sector.

The attitude among many private companies is that doing business with the Federal Government in health care is a sure way to lose your shirt. When I was HCFA Administrator, I got many questions about "can we depend on you, the Government, to be a reliable business partner over time." I would have to say that a fair reading of the last 15 years is, the Government is not a reliable business partner, and we have to fix that if we expect this program to grow.

One of the ideas that has gained some currency recently is to remove the administration of the managed care portion of Medicare from the fee-for-service part. I believe, on balance, that both should remain within HCFA, but it surely makes sense to develop a new, separate unit whose full-time assignment is Medicare+Choice because HCFA staff are still largely fee-for-service oriented. The new unit would need individuals from the private sector with specific expertise in managed care, and perhaps there ought to be designated a new Deputy Administrator for Medicare+Choice, or an Associate Administrator for it.

I would also like to comment on another matter that has received a fair amount of attention recently, the possible creation of a Medicare Board. I believe the Secretary and the Administrator of HCFA are the President's appointees charged with responsibility for health care financing within the laws enacted by Congress. The creation of a National Medicare Board or similar organization would only serve to make more diffuse the systems of management, of responsibility, and of accountability that are necessary for the Agency to be effective in its work. As some have pointed out, the notion of a unitary executive—the President, the Secretary, the Administrator—is one that I think we would be better served if we follow in general rather than having independent boards and commissions.

Finally, HCFA needs an administrative structure that promotes internal accountability and responsibility, and that is understood by all of HCFA's partners, public and private. It needs to modernize and enhance its existing workforce with new and different skills. It needs adequate personnel and systems resources that reflect the enormous responsibilities it faces. It needs new legislative and regulatory flexibility that allow it to engage in different, innovative arrangements. And, finally, and most importantly, I believe, HCFA needs to be able to work in an environment of reasonable expectations from the public, the Administration and the Congress.

I thank the committee for the opportunity to be with you today.

[The prepared statement of William L. Roper follows:]

PREPARED STATEMENT OF WILLIAM L. ROPER, DEAN, SCHOOL OF PUBLIC HEALTHTHE UNIVERSITY OF NORTH CAROLINA

Good morning Mr. Chairman and members of the Committee. I am William L. Roper, Dean of the School of Public Health at The University of North Carolina at Chapel Hill.

Before I assumed my current post at UNC Chapel Hill, I was senior vice president for Prudential HealthCare where I was responsible for medical management and other services supporting Prudential's health plans nationwide, including what are now Medicare+Choice plans. In this role I observed first-hand the Health Care Financing Administration's regulatory processes and the challenges they can create.

Before my tenure at Prudential, I was Deputy Assistant to the President for Domestic Policy, and then Director of the Centers for Disease Control and Prevention under President Bush. Earlier, I served as Administrator of the Health Care Financing Administration (HCFA) under President Reagan (1986-89). At HCFA, I was responsible for managing Medicare and Medicaid through a period of significant change in these programs. I am pleased to be here today and to participate with the other former HCFA Administrators.

When I was at HCFA, I would jokingly remark that HCFA was the favorite four-letter word of people in the health care industry. Today, those dissatisfied with HCFA include not only the industry, but also large numbers of beneficiaries, the media, the population in general, and in particular the Congress. It often seems that HCFA is second only to the IRS as a target for criticism. Certainly, there are significant improvements to be made at HCFA, and I will elaborate on these as I see them. Let us be clear, however, that the fundamental problems I will be speaking about today are primarily problems of the Medicare program itself, not just the agency that administers it. Having been head of both HCFA and the Centers for Disease Control and Prevention (CDC), I believe one is a "black hat" agency and one is a "white hat" one. You can reorganize HCFA all you want, and put all the bells and whistles in its reporting channels you want, but the agency will always have saying "no" as what characterizes it.

GENERAL CONTEXT

In addition, many of the problems attributed to HCFA are actually not of its own making. HCFA functions in a political environment where the Congress will often pass legislation with very noble but unrealistic or perhaps even conflicting objectives

and expectations. The resulting legislation may be unclear or unrealistic, but HCFA has to figure out a way to implement it.

Consider the challenge faced by a well-meaning Congress that is committed to fiscal responsibility, but must also balance the needs of constituents, who will not sit still for denied hospital admissions. Another example would be that all Americans want to receive the highest quality of care possible, but many are uncomfortable with some of the regulation, oversight or data acquisition activities that might be needed to achieve that end.

I am by no means a proponent of additional government regulation. On the other hand, to fulfill the objectives of many statutory provisions there is often the need for more intervention or oversight than you and the American people welcome. We need to recognize that HCFA is quite often doing a difficult job in its effort to walk the fine line between maintaining a focus on the good things you want to come from the legislation you enact, and actually achieving those objectives in a reasonable way. It is difficult at times to be both customer friendly and a regulator.

Clearly, there are strong opinions about each of these issues, and HCFA must contend with them all. We should all have a realistic vision of HCFA and its potential within a politicized environment.

There are, however, a number of specific problems and issues that I would like to address today.

NEED FOR INNOVATION

The Medicare program is sadly out of date; it needs to be modernized. It has failed—and continues to fail—to take advantage of innovation in the private sector.

I am on record as strongly supporting a reform of Medicare, making it much more like the Federal Employee Health Benefits Program.

In particular, change is much too slow under the burden of excessively prescriptive legislation, which sometimes places impossible burdens on the Agency. This includes dealing with innovation in medical technologies, which can take years to gain approval for coverage under Medicare, as well as innovation in management approaches, increased emphasis on modern skills, and appropriate technology for an increasingly complex health care financing market.

Although some improvements are being made, such as changes in HCFA's customer service, e.g., the Medicare Helpline, technological improvements are needed in HCFA's day-to-day implementation of Medicare. It is not enough to strive to be customer friendly—HCFA must view itself differently and become more forward-thinking in its world view. For example, new skills and expertise are needed in the agency's work force so that it can deal more effectively with complex approaches to health insurance. New tools and data systems are needed to enable informed purchasing decisions and assessments about quality of care.

In some ways, the agency and all of its customers need to recognize that these are the activities for the future. For example, a worthy idea today is paying more for higher quality. To pursue that approach, HCFA needs to assure that it has all of the necessary tools and skills at hand to assess quality in ways that would allow differential payment.

These changes surely include re-training. They also mean that HCFA needs to have explicit approaches to hiring staff with private sector skills, and needs to realistically evaluate resource needs in terms of number of staff, and quality and quantity of technological tools and data systems.

In addition, while much of the world has successfully moved to use the tools of continuous quality improvement, HCFA is mired in old practices and is unable to move quickly to test and implement new approaches. I suggest that HCFA should be given much more freedom to implement pilot studies or test efforts to guide a movement to more efficient service. Simply put, no one has ever accused HCFA of being too "nimble."

Up until now, HCFA's way of trying out new ideas has been using the waiver authority under Section 1115. That approach has evolved into doing things under the clinical trials mindset: plan, execute for several years, carefully evaluate. The cycle time is years. HCFA needs a new approach to trying out ideas on as short a turn around as does a well-run managed care company. These might be called "feasibility waivers" or something without the word "waivers" in it where HCFA tries out a new way of paying providers or contracting for services.

THE NEED FOR NEW RESOURCES

As I and others have previously said, it is important to emphasize the need for more resources for HCFA itself. When I hear people brag about how little Medicare

spends on administration, I cringe. That should be a source of embarrassment, not pride.

The agency is understaffed (both in numbers and in the mix of skills) and it is seriously hampered by inadequate systems. There are actually fewer staff in HCFA today then when I became administrator 15 years ago, despite a tripling of the outlays. The inadequacy of the resources shows in the quality of the output.

STRUCTURAL REORGANIZATION

Certainly, it is appropriate to look at HCFA at this time and to consider reforming the Medicare program. Now nearly 25 years old, HCFA needs to be updated. However, a large-scale reorganization is not necessarily the way to do it. As well intentioned as it was, HCFA's recent re-organization produced little effect but chaos. It was so extensive—involving moving so many people and boxes on the organizational chart—that it created mass confusion. I know that Bruce worked very hard to get the best advice possible before launching the new structure; however, experience shows that it did not work.

Accountability has been diffused throughout the agency at the regional and central levels, individuals outside the agency are confused about who is accountable for particular issues, and uniform implementation of procedures and processes is largely absent. A confusing organization muddies HCFA's essential dialogue with the private sector, which is already unsympathetic to HCFA and even more so to the chaotic structure. The private sector rightfully expects corporate-type efficiency in their interaction with the agency. Rarely are problems solved by "moving the boxes around" on an

organizational chart. There are a number of examples of problems that I and others think are attributable to the recent reorganization of HCFA. I will be happy to discuss these in the question and answer period that will follow shortly.

REEVALUATE MEDICARE'S CONTRACTORS

I believe it is time to reevaluate Medicare's contractor system—the fiscal intermediaries and carriers. There has been a reduction in the number of contractors over what formerly was the case .

I fear we still have too many intermediaries and carriers to be efficient. And further, the large variations across them is not in the best interests of beneficiaries or providers. With today's information and communications technology, we could dramatically reduce the numbers of contractors, and improve the management of the program while being more efficient.

MEDICARE MANAGED CARE

I would suggest that the most significant problem of Medicare—and thereby of HCFA—is that it is stuck firmly in a fee for service mentality and modality. Despite efforts on the part of the Agency, the managed care option for Medicare has not achieved its great promise. In my opinion, integrated health delivery systems are much more appropriate and responsive to the needs of seniors, certainly far more promising than the "yellow pages" fee-for-service approach of organizing care for seniors with complex, chronic illnesses. Nonetheless, a hostile environment and ambivalence toward an integrated, or managed care, approach, doomed its implementation. In fact, the way it was created was directly linked to its downfall, as it resulted in so many onerous regulations on health plans.

My thoughts about giving Medicare beneficiaries choices are long-standing. In 1987, I wrote an article for the *Wall Street Journal* editorial page on this subject entitled, "Medicare's Private Option." My message was simple: keep traditional Medicare intact, but increase choices available to Medicare beneficiaries by expanding the role of private sector health plans. At that time I wrote—and still believe today—that private plans, including managed care and indemnity plans, should compete with the traditional program on the basis of quality and cost. I oppose forcing older Americans to leave traditional Medicare in favor of private health plans. What I support is giving them choice. Do not take away the current Medicare system—just give beneficiaries more choices.

When I served at HCFA, we believed that well-managed private health plans offered an attractive alternative to traditional Medicare coverage. We were committed to giving private health plans a fair opportunity to compete and letting beneficiaries decide what option would work best for them. Under this vision for Medicare reform, we at HCFA advocated a Private Health Plan Option, or PHPO, based on five goals:

(1) Ensuring appropriate access to quality care;

(2) Increasing incentives for efficiency;
(3) Reducing government's role in deciding how much to pay for individual health care services;
(4) Reducing government's role in micromanaging medical practice; and
(5) Expanding the range of choices available to both Medicare beneficiaries and health care providers.

However, what has happened is that an inhospitable environment has combined with complex legislation and unrealistic rules to make working with the government in a managed care setting undesirable to the private sector.

For example, reimbursement rates can change every year. This kind of uncertainty is unacceptable to most businesses, who would prefer a longer-term arrangement. In fact, the attitude among many private companies is that doing business with the federal government is a sure way to lose your shirt. I suggest that a concerted effort to change this attitude through a change in business approach is warranted.

For example, setting rates every two to three years would create stability in the eyes of the private sector, and increase desirability of participating in the Medicare managed care program, thus increasing choice for seniors and competition to participate. The end result would be that HCFA could be more discerning in their choice of contractors, and operate more efficiently overall. I would suggest that you compare the current Medicare+Choice program, which has not succeeded, to the FEBHP, where managed care plans participate successfully alongside fee for service plans and where real choice is thus available.

One of the ideas that has gained some currency is to remove the administration of the managed care portion of Medicare from the fee-for-service part. I believe on balance that both should remain within HCFA, but that it makes sense to develop a new, separate unit whose full-time assignment is Medicare+Choice. This is important in part because HCFA staff are still largely fee for service oriented. The new unit would need individuals from the private sector with specific expertise in managed care programs.

A MEDICARE BOARD

I would like to comment on another matter that has received a fair amount of attention recently—the creation of a Medicare Board. HCFA has a difficult job—perhaps as difficult as any in government. Over the 35 plus years since the creation of Medicare and Medicaid, HHS and the Congress have worked to address program design and needs. The Secretary of HHS and the Administrator of HCFA are the President's appointees charged with responsibility for HCFA, within the laws enacted by the Congress. The creation of a National Medicare Board, or similar organizations will only serve to make more diffuse the systems of management, responsibility, and accountability that are necessary for the agency to be effective in its work.

SUMMARY

In summary, then, I would argue that several things must be in place if HCFA is to succeed in fulfilling its job as the agency entrusted with responsible management and leadership of the Medicare program.

- bHCFA needs an administrative structure that promotes internal accountability and responsibility, and then translates that accountability and responsibility into a structure that is understood by all of the HCFA partners—both public and private.
- HCFA needs to modernize and enhance its existing workforce with new and different skills that focus on the full range of program responsibilities including prudent purchasing, quality assurance, and innovative health insurance arrangements. HCFA needs to be receptive to change as the world around it changes.
- HCFA needs adequate personnel and system resources that are reflect the enormous responsibilities involved in a $200 plus billion program.
- HCFA needs new legislative and regulatory flexibility that would enable the agency to engage in different innovative arrangements with health plans and others.
- And finally, HCFA needs to be able to work in an environment of reasonable expectations from the public, the Administration, and the Congress.

It has been a pleasure to participate today with the other former HCFA Administrators. I would also like to thank the Committee for creating this forum and for bringing us together to discuss the many important issues facing HCFA. I would be pleased to answer any questions you might have. Thank you.

Mr. GREENWOOD. Thank you very much for your testimony. As witnesses are undoubtedly aware, there is a vote in progress right now, and I don't think the members who are here want to miss the opportunity to hear from the "Mount Rushmore" of HCFA here that we have assembled. So we are going to recess for about 10 minutes.

[Brief recess.]

Mr. BILIRAKIS. Well, let us just go ahead and get started. Dr. Wilensky, John M. Olin Senior Fellow with Project HOPE, the Chair of MedPAC, located here in Bethesda, Maryland.

Dr. Wilensky, please proceed.

TESTIMONY OF GAIL R. WILENSKY

Ms. WILENSKY. Thank you, Mr. Chairman. I was the HCFA Administrator from 1990 to 1992. As you indicated, I have been the Chair of the Medicare Payment Advisory Commission since 1997. It has given me an opportunity to see some of the effects of the current statute and regulations in terms of administering the Medicare program.

I am primarily going to give my remarks, though, as a result of the experiences I had as HCFA Administrator and as a health policy analyst.

There is no question that HCFA faces a fundamental tension. The members have noted that, and Bill Roper has already. That tension reflects the competing focus on establishing a user-friendly Medicare program, assuring that seniors can get access to high-quality care and being financially prudent with taxpayers' money. And I think it is important that we recognize that there is this fundamental tension that HCFA faces.

Nonetheless, it appears now that there is so much frustration, particularly being reported by providers, confusion over billing procedures, fears of making false claims, that there is reason to be concerned that seniors will have difficulty getting access to the high-quality care that Medicare has always provided, if there isn't a way to make this a more user-friendly program both for seniors and particularly for providers.

In its March 2000 report, MedPAC reported some evidence, although that evidence has not been continuing, of down-coding—that is, providers billing for services that were less complex than they had actually provided. You should not countenance abusive behavior, and the Congress has been appropriately concerned about up-coding in other types of Medicare fraud and abuse. But I believe that the Government should be equally concerned about evidence of down-coding. This is troublesome, and it can't, in the long-run, be good for the Medicare program or for the seniors that it serves.

There are a variety of places where we have frustration, but as I talk to physicians and hospital administrators, home care agency administrators, nursing home administrators, it seems that the greatest sense of frustration revolves around the contractors' performance, the so-called "fiscal intermediaries and carriers."

When I was there, that same level of hostility and frustration revolved around the PROs, the Peer Review Organizations, and I am going to make a suggestion for some changes that reflect some of the reforms that went on in the early and mid 1990's, that I think

have helped reduce the tension between the provider community and the PROs.

In general, to reduce frustration, we need to make sure that providers have better education, and seniors as well; that there are clear billing procedures and protocols; and that there are less frequent and more regularized periods when changes are made. We need to make sure that HCFA is funded appropriately. Thus far, Dr. Roper has said so, I am quite certain that the other two HCFA Administrators will echo that concern.

And, finally, you need to have a change in attitude by the contractors. Right now, the default position—that is the presumption unless proven otherwise—is that the bills are submitted in an incorrect way, and that program integrity requires reliance on documentation. Because there is limited funding in addition, there is an attempt to use a series of different automated strategies to deny claims. It is an attempt to not get into a position of pay-and-chase—that is, pay the bills and then only after-the-fact, if there is a problem, to go after those particular providers.

A different default position would have a very different attitude—to presume that bills that are properly submitted and that can go through the screens are, in fact, proper, and then to search for patterns of abuse, using statistical analysis. This is very similar to the change that occurred with the PROs in the early to mid 1990's—that is, before that time a PRO would pick up a record on an after-the-fact basis and try to decide if there was an untoward event, whether or not that meant something. But, in fact, it was very difficult, in a retrospective case-by-case review, to see whether it was, in fact, a problem. There has been over the early to mid 1990's a change in how the PROs respond in looking for patterns of care that are problems and focusing on patterns of outcomes, and it is precisely that change in position and default that I think would change the attitude and change the behavior of the contractors.

We also need to be very mindful of the burden that is imposed on the providers by the various assessment and data collection efforts, and to be sure that we are collecting data that is needed only for purposes of payment or for purposes of quality monitoring. When you look at the minimum dataset that has been put together by HCFA, which I have, it is overwhelming at the amount of time and the complexity that these data collection efforts are asking the providers and the administrators to make in filling out these claims, time that would otherwise be devoted to patient care activities.

I believe that it would be helpful, although the timing is a concern, to reorganize HCFA so that it focused on running a modernized traditional Medicare program. I think that the current combination of Medicare+Choice with traditional Medicare is not a stable and viable long-term option. This is clearly the subject of another hearing as to why the current construction is not one that I believe is a stable combination.

I am on record as saying that I believe that a Federal Employees Health Care Model is a good model for the future, where traditional Medicare remains an important part of the Medicare pro-

gram, but there are a variety of other private programs that are offered alongside traditional Medicare.

If this type of a reform is introduced, the question is whether or not the traditional HCFA program ought to be in the same administrative agency. Although I think there are arguments that can be made on both sides, I would prefer to see it in another part of HHS, or possibly in an expanded part of OPM, the Office of Personnel Management, which is where the actual Federal Employees Healthcare Plan is run. It is a hard call because there are some discontinuities that could result by having these programs split but, on balance, I think that the expertise is not in HCFA and that the focus in HCFA is on running a traditional Medicare program, and that is where it should be. HIPAA ought to go the same place where this administration occurs. So, if you do go with the Federal Employees Healthcare Model, you have to make this decision about inside HCFA or in another agency. I don't think the Medicare Board is a proper source of accountability.

I also believe that the clinical and QA functions that are now in HCFA could go to the CDC or the FDA, and at least the moms and kids part of Medicaid could be combined with the Children's Health Insurance Program and made a part of the agency that runs TANF. I don't feel that this is the only kind of reform that would work, but it is an attempt to try to allow HCFA to focus on that which ought to be its main responsibility—that is, running traditional Medicare. That is a very major obligation, and one that takes a lot of focus.

The timing of making such a change is very important, and it is possible that we have already past the point in early administration where it makes the most sense to do this type of reorganization. And being mindful of the fact that any type of reorganization, even one that takes discrete pieces of HCFA and attempts to move them elsewhere, runs the risk of having further disruption.

So, in thinking about the reorganization, you need to consider the types of reform that you want to put in place. You ought to probably phase in these changes, and you need to think about the timing very carefully. But I believe that this type of reallocation of function so that HCFA is focusing on running the very best modern of what we now call a traditional Medicare program would help seniors get the kind of quality care we want to see in the long-term.

For me, the bottom line is that there is currently a serious mismatch between the responsibilities that the Congress and the Administration have given HCFA, and the resources that are made available to HCFA.

HCFA needs to function better. It needs to reduce the burdens on providers. But, equally important, the Congress needs to give HCFA more flexibility and more funding, and stop the kind of micromanagement that all four of us have experienced.

And while we are at it, HCFA could also use a new name. Going around the country and trying to explain to people what the Health Care Financing Administration meant was one more burden on the Administrator that Administrators don't need. Thank you very much, Mr. Chairman.

[The prepared statement of Gail R. Wilensky follows:]

PREPARED STATEMENT OF GAIL R. WILENSKY, PH.D. JOHN M. OLIN SENIOR FELLOW, PROJECT HOPE

Mr. Chairman and members of the subcommittee: Thank you for inviting me to appear before you. My name is Gail Wilensky. I am a John M. Olin Senior Fellow at Project HOPE, an international health education foundation and also a former Administrator of the Health Care Financing Administration. My testimony today reflects my experiences as a HCFA Administrator as well as my views as a health economist.

I am here today to discuss ways to improve the way HCFA functions. The objective of the changes I am recommending is to improve the way the Medicare program functions and to reduce some of the regulatory burdens on providers without abdicating the fiduciary responsibility of HCFA to be prudent stewards of the Medicare trust funds. I would also like to discuss possible ways to reallocate some of the functions that historically have been assigned to HCFA. Such a reallocation could make the agency function more effectively by allowing HCFA to concentrate its energies on running Medicare. I believe such a reallocation of functions would be desirable, irrespective of other reforms to the Medicare program but would be particularly important with some of the reforms under consideration. I recognize, however, that the timing of a reorganization would need to be carefully considered, in order to minimize the potential for further disrupting the functioning of HCFA.

Fundamental Tensions Faced by HCFA

HCFA faces certain fundamental tensions with its goals of establishing a user-friendly Medicare program and assuring that seniors can get access to high quality health care while also being financially prudent with the taxpayers' monies. The frustration being reported by many physicians and other health care providers because of the confusion about billing procedures and fears of being charged by HCFA and/or the Inspector General with submitting false claims is, in part, a reflection of these tensions. Some of the tensions are inherent in a program as large and complicated as the current Medicare program but if left unchecked, can mean an important diversion of time and energy away from patient care and ultimately, become a threat to the future availability of high quality care.

Last year, MedPAC reported evidence of some "down-coding" in both the hospital and physician settings. Although there is not continuing evidence of down-coding, the finding was consistent with reports by various providers regarding their uncertainty about how to bill Medicare appropriately and their concerns about being charged with making false claims against the Medicare program. Government officials should not countenance abusive behavior by providers, but it should be equally worrisome to the Government that providers may be deliberately under-billing Medicare in an attempt to stay clear of HCFA or the IG. Such behavior will not be to the long-term benefit of Medicare or the seniors it serves.

Strategies to Improve Functioning and Reduce Provider Frustration

Among the many complaints raised by providers, uncertainty about proper billing and coding and discrepancies in treatment by various contractors (called fiscal intermediaries and carriers) seem to be at the top of most lists. Better education sessions, clearer billing procedures and protocols, less frequent and more regularized periods for changing billing procedures would represent important steps in reducing these legitimate frustrations. As is true for many aspects of HCFA reform, some of these changes will require greater flexibility from the Congress than has usually been granted to HCFA.

Most of these changes can be carried out administratively, but expanding the types of organizations that can be contractors will require a change in legislation. And ultimately, a better functioning system of contractors will require better funding of the contractors as well. The mis-match between the administrative responsibilities and the resources for administering Medicare has been noted by each of the former Administrators. A former senior career HCFA employee summed it up best when she said, the problem with the contractors is that they've been asked to do "too much, too fast in a system that's been overtaxed and under-funded."

Some of the problems associated with the contractors go beyond uncertainties about proper billing and inadequate responsiveness to queries raised by providers. These problems are associated with the very divergent way Medicare, as a national program, is administered around the country. The tension between the goal of national uniformity for a Federal program like Medicare and the importance of allowing for some local discretion to reflect the different ways medicine is practiced around the country has been a part of Medicare since the program began. The granting of limited discretion to local contractors with regards to coverage and payment was a part of the original Medicare legislation. This discretion makes Medi-

care less conservative with regard to the coverage of new treatments and technology than would occur with a program requiring national uniformity.

While local discretion in payment and coverage may be the cause of some provider frustration, the more significant source of frustration comes from discrepancies in the program integrity portion of Medicare. Theses tensions occur because of the discrepancies in policies and behavior between HCFA central-office, the ten regional offices and the more than fifty private contractors that carry out the actual payment, claims processing and audit operations for Medicare. Unlike discrepancies in coverage, which are actually quite limited, these discrepancies primarily involve differences in the amount, duration and scope of covered benefits. They produce little gain and a lot of provider confusion and frustration.

The importance of the program integrity activities has clearly increased, partly as a result of recommendations from the OIG audit on financial management and partly as a result of the Health Insurance Portability and Accountability Act (HIPAA) and the Balanced Budget Act (BBA). Both HIPAA and BBA focused attention on fraud and abuse and provided increased resources for program integrity. But the increased emphasis on program integrity didn't have to have produced the level of frustration that has resulted. This frustration is more a reflection of the prevailing attitude towards Medicare providers, namely that they are not to be trusted and that the way to prevent improprieties is to review first and pay later. With each contractor having its own notions of proper payment and utilization, it is not surprising that substantial inconsistencies have resulted and with them, substantial frustration.

The default position of the current environment presumes billing may be incorrect or inappropriate. In such an environment, program integrity requires heavy reliance on documentation. This presumption combined with limited funding for contractors has led contractors to develop a series of automated strategies that deny claims. This has limited the amount of editing that needs to be done after-the-fact and also reduces the need to "pay and chase." But it has also led to an explosion of medical review polices, policies that differ from contractor to contractor and with it, a heavy reliance on documentation.

A different strategy, reflecting a different attitude and default position, would be to pay properly submitted bills and search for patterns of abuse based on statistical analyses. This change in focus would mirror a change that began taking place with the Professional Review Organizations (PRO's) in the early to mid 1990's. Prior to that time, activities by the PRO's focused on a case-by-case, retrospective review of medical records. The problem was that when a "bad" or undesirable outcome occurred, it was very difficult to tell whether it was a single, idiosyncratic occurrence or whether it indicated a problem worthy of pursuit. This behavior limited the effectiveness of the PRO's and made them intensely disliked by the physicians.

As part of a more general emphasis on quality improvement, PRO's began to focus on patterns of care and patterns of outcomes, rather than individual case review. Physicians and institutions that have patterns of care and patterns of outcomes that differ from their peers are more readily identifiable as potential problems and can be dealt with more directly. A move to this type of model would have the statistical-analyst contractors become the focus of program integrity rather than the medical directors and carriers and have the medical directors refocused on quality improvement efforts.

Another way to reduce provider frustration is for HCFA to be more mindful of the time and burden imposed on providers by various assessment and data collection efforts. The Beneficiary Improvement and Protection Act (BIPA) required the development of patient assessment instruments that use common data elements. This requirement provides HCFA with an opportunity to focus on the development of instruments that emphasize brevity and simplicity, collecting only those data elements needed for payment or quality monitoring. It is not obvious this requirement has driven past efforts. As an example, the MDS (Minimum Data Set), developed to guide care planning for nursing home resident care planning, has more than 350 items to be filled out. Instruments of this nature may not only compromise data accuracy and take valuable time away from patient care, but are also likely to increase provider frustration.

In a similar vein, concern has been raised in MedPAC's March 2001 report about use of the Minimum Data Set for Post-Acute Care (MDS-PAC) as the basis for collecting data for quality monitoring and payment purposes across all post-acute care settings. While this instrument has the advantage of potentially providing a more coordinated approach across all post-acute care settings, which is clearly a plus, it has the disadvantage of being lengthy and complex. MDS-PAC covers more than 400 items, with at least seven different time frames for patient assessment. Collecting the same information in the same way across settings is important, but focusing on

the precise purposes for which the data will be used and defining the minimum set of information needed to accomplish this goal is equally important.

MedPAC will be issuing a report in December which looks at Medicare burdens on providers and will lay out areas where productive reform could be undertaken and suggest the principles that should underlay such reform. MedPAC's March 2002 report will also include some focus on contractor relations in Medicare.

HCFA's Current Functions

Reviewing HCFA's current responsibilities and reallocating some of these functions to other parts of HHS represents another strategy that may help HCFA focus on efforts to reduce provider burden and frustration.

HCFA's foremost responsibility is administering the Medicare program. Medicare covers 39 million people and is expected to cost around $240 billion in FY2001. The agency employs approximately 4200 individuals in central and regional offices but has contracted indirectly for the services of about 38,000 FTEs through its network of over 50 private contractors who act as its fiscal intermediaries and carriers. These include the people referenced earlier that actually pay the bills and provide financial oversight for the services provided. In addition, HCFA manages the participation of more than 260 plans involved in the Medicare+Choice program. This makes HCFA bigger than most cabinet level departments in terms of both money and personnel.

The proper oversight and administration of Medicare is a full-time job for any agency. The problem is that HCFA is also responsible for providing oversight to the Medicaid program, conducting surveys and certification of certain types of health facilities, approving the Children's Health Insurance Program (CHIP) proposals submitted by the states, enforcing federal health insurance portability laws and some fraud and abuse prevention activities. These activities require a wide variety of talents, skills and experience and present a management problem for even the most talented administrator. HCFA's problems will only get worse as the baby-boomers start to retire and the number of people on Medicare increases dramatically, making the world's largest insurance company, HCFA, even more difficult to manage.

Administrative Issues Supporting a Reformed Medicare with Prescription Drugs

Even in the absence of any type of Medicare reform, including the adoption of a prescription drug program, a case can be made for restructuring HCFA so that it can focus on running the Medicare program more effectively. If Medicare is changed in any substantial way, the administrative issues become even more important. Among the issues that should be addressed are the functions that should be included in a reorganized HCFA. How should HCFA be restructured so that it can effectively manage a modernized fee-for-service Medicare program? What type of administrative structure makes sense for the private plans that participate in Medicare, either as Medicare+Choice or potentially as separate prescription drug programs? What role will PBM's have in a reformed Medicare program and how will they be administered?

A first logical step, at least in principle, should be to move all or most non-Medicare related functions as well as some clinical and quality assurance functions currently in HCFA elsewhere within the Department of Health and Human Services. The functions relating to conditions of participation and quality assurance such as the survey and certification of nursing homes, the conditions of participation for hospitals, and the certification of clinical labs should be housed either in CDC or FDA.

The oversight of the Medicaid program is more complicated. Medicaid has always been somewhat the stepchild of HCFA. At least the portion of Medicaid relating to "moms and kids" should be moved elsewhere and given appropriate resources and leadership. The part of Medicaid that covers the aged and disabled is more complicated because of the overlap with Medicare. If this portion of Medicaid is also moved, coordination with Medicare could be provided through interagency agreements. Putting together the "moms and kids" portion of Medicaid with the approval of proposals submitted by states under CHIPs also makes sense. One consideration would be to put these programs together with the Administration for Children, Youth and Families, the agency that runs the welfare program. Another consideration would be to put all of these programs together in a new entity that also included other state health programs like HRSA (Health Resources and Services Administration), and SAMSA (Substance Abuse and Mental Services Administration).

HCFA needs to focus on running a modernized fee-for-service program. A series of changes would be needed to modernize the traditional Medicare program. These include the authority to use selective contracting, centers of excellence, disease management programs, best-practice programs and other changes commonplace in better-run private sector plans. However, the desirability of some of the specific au-

thorities to be granted HCFA will depend in part on the viability of the private sector programs offered to seniors. Selective contracting, for example, may be a desirable option as long as there is an active set private-sector plans but represent undesirable amount of power to grant to government if traditional Medicare is effectively the only Medicare program.

One question is whether HCFA will be given the power to administer a modernized fee-for-service program. Will Congress allow HCFA the flexibility that will be needed to run such a program and will Congress and the Administration provide HCFA with the resources needed to carry out such a task. History is not encouraging on either of these issues.

If HCFA or any governmental agency is to run a modernized fee-for-service program, Congress will need to change its relationship with HCFA and retreat from it very micro-prescriptive directives. Changes in attitude and behavior will also be required from HCFA employees. HCFA has been painfully slow to undertake demonstrations or adopt promising ideas from the private sector. If HCFA is to run a modernized fee-for-service program, the organization will need to be more responsive, more pragmatic and more creative in its behavior than it has been in the past.

The appropriate administrative structure for the private plans that participate in Medicare in part depends on how Congress chooses to further reform Medicare. I believe that the current combination of a Medicare+Choice program, which provides a highly regulated environment, with payments set independent from the traditional program and a traditional Medicare program, is not a stable, long-term option. I am already on record as supporting a reform modeled after the Federal Employees Health Benefits Program. This type of program, particularly if some provisions were made to protect the frailest and most vulnerable seniors, would allow seniors to choose between competing private plans and a modernized fee-for-service Medicare program for the plan that best suits their needs.

I am well aware that the FEHBP model remains controversial among some Members of the subcommittee. However, I think it's important that committee members recognize that many of the most vexing issues that need to be resolved for a premium support program must also be resolved with Medicare as it is currently structured. These issues include risk adjustment, providing understandable and user-friendly information to seniors, assuring that quality care is being delivered, providing safeguards for frail and vulnerable populations and given the strong interest in prescription drug coverage, the design of a prescription drug benefit that doesn't depend on administered pricing to moderate spending.

Some attention has been given to the potential use of a Medicare Board to provide oversight for private plans and to negotiate with private plans as well as to provide the administrative structure for a premium-support type of reform, if that is the direction of reform Congress chooses to take. However, potential problems of accountability of a board plus the difficulties of using a board-structure for an entity that has significant administrative and operational responsibilities make the Board concept a less attractive administrative structure. A better choice would be a separate agency within HHS, such as was proposed last year in H.R. 4680 or an expanded version of the Office of Personnel Management, which negotiates with health plans on behalf of the Federal Employees and resides in the executive office of the President. The most important functions of this new entity would be to review and approve benefit packages, make payment modifications (to reflect risk adjustment, etc.), direct open enrollment periods, provide information about plan choices and either structure competitive bids or be empowered to negotiate premiums. This new entity would also be an obvious place to put HIPAA responsibilities.

I recognize this type of structure would divide the responsibility of administering the overall program between two entities but I believe this is far preferable than lodging both with HCFA. HCFA has little experience in negotiating with outside entities. The functions and role for government in running and monitoring competing private plans are fundamentally different from the experiences and mind-set of HCFA employees. Also, separating these functions would help HCFA focus on administering a more modernized fee-for-service program.

Finally, we need to be clearer about the role PBM's will play in administering the prescription drug program for traditional or modernized Medicare and the type of leadership that will be needed to manage such a program. Almost all of the prescription drug proposals have invoked the concept of PBM's as the appropriate administrative structure to administer an outpatient drug benefit. In large part, this reflects the belief that administered pricing, the main instrument of cost-containment for other parts of traditional Medicare, will not be used for prescription drugs. Since PBM's have had some success historically in moderating spending in the private sector, it has been assumed that they will be able to do so in the public sector as well.

But many unanswered questions remain about how the PBM's will function, how much independent power they will be granted and where the government oversight function of the PBM's will be lodged. Will there be competing PBM's within an area, how will they be chosen, how much power will they have to devise formularies, encourage generics, impose tiered co-payments, will they be allowed to take financial risk, will they be encouraged to take financial risk and so forth. If there is a new administrative agency providing oversight for private health plans, that would be the logical place to provide oversight for the drug benefit as well. In any case, the management of this benefit will require leadership and private sector experience not currently available in HCFA.

Getting From "Here" to "There"

Historically, changes in Medicare reimbursement policy and structure have been phased in over several years. This has helped to cushion the disruption that abrupt changes could cause. It also makes sense to consider phasing-in changes in the structure or organization of a reformed Medicare program that requires substantially different roles for government or substantially different roles for the administrative institutions supporting the program. Any interest in experimenting with various strategies for reform or the administrative structures supporting reform makes it important that we begin the process.

But the Congress needs to be clear that there are risks and potential costs involved with any restructuring of HCFA. The reorganization of HCFA several years ago affected most individuals within the agency and caused significant disruptions in workflow. Reorganizing HCFA would best be done at the beginning of a new administration or at the end of a presidential term. The ideal time for some of the reorganization may already have passed. Reorganizations that move relatively separable parts of the agency will be less disruptive than reorganizations that move large numbers to new positions.

Whatever the decision on reorganizing and restructuring HCFA, Congress needs to recognize that there has been a serious mismatch between the responsibilities given to HCFA and the resources the agency has been granted. HCFA needs to find ways to reduce the burdens being placed on providers and to function better as an administrative agency. Congress needs to be more realistic in terms of the demands it places on the agency and with the support it provides. Both need to happen together; neither is likely to happen alone.

Mr. BILIRAKIS. All four of you smiled at that suggestion. Dr. Vladeck is the Senior Vice President for Policy with the Institute for Medicare Practice of Mount Sinai School of Medicine in New York.

Dr. Vladeck, please proceed, sir.

TESTIMONY OF BRUCE C. VLADECK

Mr. VLADECK. Mr. Chairmen, members of the committee, I am very pleased to be here again back before you today to have the opportunity to participate in this hearing. I am still weighing in my mind the metaphor of "Mount Rushmore" and my comfort level with that, but it is a whole new perspective on a variety of things for me.

As I believe you know, I was Administrator of the Health Care Financing Administration from 1993 through 1997. Prior to that time, I spent 6 years on the Perspective Payment Assessment Commission, one of the predecessors to MedPAC. And, as Mr. Bilirakis well knows, right after I left HCFA, I was appointed as a member of the National Bipartisan Commission on the Future of Medicare, where I had the pleasure of serving with the Chairman, which was one of the few pleasures I would associate with that experience. So, I have been involved in these issues in a number of ways. Of course, I am now employed by a major academic Medical Center which has some sensitivity to Medicare policy issues. As well, the committee staff knows, and they have been very considerate and flexible, I returned just last night from a very long trip abroad,

which explains the absence of an appropriate written statement on my part, and I appreciate the committee's indulgence in its absence.

There was a report that we did at the Institute for Medicare Practice on the future of Medicare that I asked be distributed sort of in lieu of that, and I do want to make—I was going to make just four points very quickly this morning, but in response to Gail's comments and some of the others that have been made recently, I would make a fifth.

I agree entirely on the name issue. I actually thought that Medicare and Medicaid Administration, or "MAMA," would be a much friendlier name for the Agency. And I found when we discussed internally, that every male member of the senior staff was in favor of that renaming, and every female member was opposed. And since we had more women in the senior staff of the Agency than men in the senior staff of the Agency, that was the end of that particular proposal, and also that Administrator's willingness to float any specific proposals for changes in name, but I would certainly applaud any efforts in that regard. Almost anything would be better.

There are four other points that I want to make. First, I used to teach that policy administration and public administration were in some ways fundamentally inseparable, but in some ways as well, they are not, and there are just some basic administrative things that one needs to do anything in terms of people and the right kinds of people, and money, and information systems, and both of my colleagues who have spoken already have spoken to it, and I know that Nancy-Ann would agree.

I want to particularly emphasize the extent to which, in provider communications and provider education, in fact, HCFA is doing substantially less of that than it did a decade ago, purely for budgetary reasons. Almost all of those activities were historically funded through the contractors. As contractor budgets were effectively frozen in the light of increasing volume of claims processing activities and the statutory requirements on timeliness of claims processing, those functions gradually got squeezed out, and the level of service or nonservice being provided to providers and beneficiaries alike is woefully inadequate, we would all agree with that, and that is a pure money issue. In fact, I think, as many private sector organizations have learned over time, while there are issues of management and training and staffing an organization, at some fundamental level you get the level of customer service, however you define your customers that you pay for, and we are not paying for any under the administration of Medicare and Medicaid at the moment, and it shows, but it can be fixed.

The second point I would make is that when one seeks greater flexibility and nimbleness, to use Dr. Roper's phrase, on the one hand, simultaneously, with greater consultation, due process, fairness and openness to a wide variety of views, we have a flat-out contradiction. And this is a contradiction that Members of Congress are familiar with in a number of ways, as well as folks in the executive branch, and so forth, but I think both that we need to recognize it relatively explicitly and that we need to—I think the Con-

gress needs to—take some responsibility about making decisions about it.

We talk about greater authority to do things like disease management or inherent reasonableness, as Dr. Roper described, I would suggest that HCFA, as it has traditionally been overseen by the Congress and traditionally responded to by providers, could never in a million years get away with the kind of flexibility and the kind of privacy of negotiations and the kind of processes that go on between the Office of Personnel Management and the plans that participate in the Federal Employees Health Benefits Plan.

The outrage that one would hear from the provider community and from the plans about secret negotiations, about administrative discretion, about not having adequate consultation, and so forth, would make the kind of negotiations that drive the operations of the FEHBP simply impossible, unless one were prepared to accept that large parts of the Medicare program would be administered informally through a discretionary negotiated process, largely in secret, which we couldn't even do in particular markets for half-a-handful of managed care plans without Congress intervening to reopen those experiments.

Similarly, there is a flat-outright tension between flexibility to respond to the enormous heterogeneity of the health care system in the United States and the increasing pressures to have uniformity and "fairness" in policy from one place to another. Some of the so-called "confusion" or lack of clarity that providers particularly, and manufacturers, complain about in that a policy regional office in California may interpret a policy differently from a regional office in Texas, arises from the fact that those two regional offices are trying to respond to very different local circumstances. This is a very big, very heterogeneous country, with very big, very heterogeneous health care systems, and the more uniformity you have, the more instances you will have in which rules seem particularly inappropriate or out-of-place in particular communities, and that is just a constant tension that is built into having national programs of this kind in a health care system that is so heterogeneous, but we have to be explicit about that.

The third point I would make is, I think HCFA is often criticized for what are really policy failures, and I think someday, if ever, someone writes an objective history of the Medicare+Choice, in fact, they will applaud Nancy-Ann Min DeParle and her colleagues who were then at HCFA for an absolutely extraordinary job of bringing up an extraordinarily complex set of legislative requirements, and a whole new approach to beneficiary education and beneficiary choice, in a remarkably short period of time, under a system of enormously constrained resources.

I think the simple fact is that when we all worked together on the Balanced Budget Act in 1997, we ended up with a payment formula for managed care plans which established a level of payment in 1998 and 1999 which, in most markets, most plans could not effectively provide the benefits that they wanted to provide and avoid losing money. I would specify—I would remind you that the rates that are paid in every county in the United States are established by a statutory formula. I think the Congress, in the Balanced Budget Act, as we all said while we were working on the Balanced

Budget Act, tried to do a number of mutually contradictory things simultaneously in the establishment of those payment formulas, and they didn't work because we were trying to balance too many conflicting objectives at the same time in setting those payment levels.

The history of managed care participation in the Medicare program, for which we now have more than 30 years of history, is that there has never been a protracted period of time in which the involvement of plans increased in terms of the number of plans participating in the program and the number of beneficiaries enrolled in the plans, and the programs saved money. In fact, the two moved in opposite directions. When the program was paying plans at a level that was costing the program money, enrollments went up very substantially, as they did during my tenure. When we changed the formula in the BBA to limit the amount of overpayment to plans, enrollments dropped and plan participation dropped, and we haven't solved that policy problem. That's not an administrative or regulatory problem.

Finally, I would just emphasize, as we think about organizational structures of one sort or another, that Titles 18, 19 and 21 of the Social Security Act are relatively complicated statutes that affect more than 80 million Americans directly, and every American in one way or another, in a variety of important ways, and the expertise and commitment and dedication of the core staff of HCFA is really, in that regard, an extraordinary national resource which is, in some says, very fragile and would be very easy to lose or damage, and I think we need to worry about it over time, just in terms of all of us having a stake in and responsibilities for some very, very important, very complicated programs, about which the level of expertise or the number of individuals who have some sense of institutional memory and know what is actually in the statute, is probably diminishing over time, not increasing over time, as the programs grow in the number of people they cover.

In some ways, of course—and we haven't talked about it at all up to this point in this hearing—the Medicaid program, and the Medicaid statute is even more complicated than the Medicare statute. And there is an awful lot of Federal dollars at stake there, and there is the well-being and health care of even more individuals than are covered under the Medicare program at stake there. And the risk of diffusing or losing the kind of just expertise and specialized knowledge that is contained primarily in the career staff at HCFA, I think, would raise some very significant concerns about their implications on the Federal budget and, in the longer-term, for the well-being of those 80 million beneficiaries.

Again, I very much appreciate the opportunity to appear here today under these circumstances. I congratulate you on asking us. I appreciate your asking us to come here, and I am happy to respond to any questions.

Mr. BILIRAKIS. Thank you very much, Doctor. Ms. Nancy-Ann Min DeParle is the immediate former Administrator of HCFA, who has been pretty busy the last couple of years. She now is the mother of two. I remember, it seems like yesterday when you were going through your first one.

Ms. DEPARLE. It does. It does.

Mr. BILIRAKIS. It seems that way to me, anyhow. Please proceed, Nancy-Ann.

TESTIMONY OF NANCY-ANN DePARLE

Ms. DEPARLE. Thank you, Mr. Chairman, and Chairman Greenwood as well. I, too, appreciate the opportunity to be with you this morning. It brings back some pleasant memories and some difficult memories because I did serve at HCFA during, I think, a very challenging time for all of us, with the enactment of the Balanced Budget Act and the need to get the Balanced Budget Act implemented so we could preserve the solvency of the Medicare Trust Fund. And I think you saw in that period the fullest manifestation of the difficulties that HCFA faces in trying to work with providers and trying to implement laws that are extremely prescriptive, often for good reasons, but also in trying to be responsive to providers and beneficiaries.

I provided a written statement for the record, so I am just going to hit the high points, and many of the points I am making have also been made by others here.

I identified two major problems at HCFA. The first is the one you have heard, I think, from everyone this morning, and from many of you as well, which is that the Agency has faced dramatically growing responsibilities and inadequate resources to handle those responsibilities. And, to me, one number sort of says it all, which is that in 1998, which was the peak year of the Balanced Budget Act—and not only was that a period when we were writing regulations, which is the kind of thing that you normally do to implement statutes, but I daresay that each and every one of you had some specific issue with a provider in your district or your community where you needed some special help, helping them to understand things. So, there was a lot of customer service work that we needed to be doing. And the FTEs in that year were 3942 Full-Time Equivalents whereas in 1980 the FTEs were 4961. So, in a year when I think everyone would agree our responsibilities couldn't have been greater, the things we needed to be doing with the providers and just in managing this transition to all of these changes that we did, you know, couldn't have been greater, and yet we did not have the resources to get it done.

The main example that I have cited is one that you heard also, I think, especially from Dr. Roper, but also from Dr. Vladeck, which is customer service. For example, I think every provider should have a manual that they can look to. If you are a home health agency, there should be a Home Health Manual that you know all the rules are in there that you know apply for Medicare, so that you know what to do as a physician. It turns out that for physicians, it is different in every State, so there would have to be 50 manuals, but whatever. In Michigan, they should have a manual. That doesn't exist, and the Agency was in the process of trying to come up with that—and it should be online, too, by the way—but the Agency was in the process of trying to come up with that when Dr. Vladeck left. We then had to suspend work on it while staff worked on implementing the Balanced Budget Act. And when we went back to it to try to get people back involved in doing the manuals, we saw that most of the work we had done was irrelevant

because, of course, we changed many of the payment systems. We just need more staff to get these things done, to do the kind of customer service that I think you want.

Many of you have also complained about the slowness in answering the mail. You send a lot of letters to us. You get very specific letters from providers in your district that get into esoteric details about the wage index in a particular district, or whatever. It is not something that you can just send to a mail room and say "Do a form response to this." It takes analysis. It takes people spending time on it. And we have had a very difficult time having the kind of staff that we need to just get that done. You can't say you are doing proper customer service, if you are not doing those sorts of things.

I want to mention one more example on the issue of resources because it relates to a point that Ms. Eshoo made, and Ms. DeGette, which is the coverage issue. We took some steps forward in the last couple of years in making that process more open and transparent. And I think if you talk to the medical device community and the biotechnology community, they will say that we did take some steps forward.

Now, any citizen can petition Medicare to make a coverage decision and the Agency is trying to hold itself to timeliness standards, but we simply don't have the kind of staff that we need to make those decisions.

The FDA has hundreds of staff who are devoted to looking at devices and deciding whether they are appropriate and safe and effective, and I am not saying that that is the same judgment that HCFA has to make, but you still have to have clinicians who are able to look at something, to talk to other professionals, to figure out if it works or not, is it appropriate for the Medicare population.

We have a lot of trouble attracting people like that, and we have a lot of trouble finding room for those FTEs in our budget, and that is something that we really need to fix if we are going to have the kind of Medicare program we want to have.

The second problem I identified is also something you heard a lot about this morning, which is not enough flexibility. And, again, it is not—I am sympathetic to why laws are written in such a prescriptive fashion. Part of it is, frankly, just to get scoring under the Budget Enforcement Act rules. It is not just because people enjoy writing prescriptive laws, but when they are written in that prescriptive way, then that means the Agency's regulations need to be prescriptive and, after all, if you are running a program for millions of providers and millions of beneficiaries, you need to have some rules. But then it is very difficult for us when, Mr. Greenwood, you have a specific problem in Pennsylvania, to be as flexible as you might like, to try to adjust, to have some discretion. And as Dr. Vladeck suggested, there would be many who would say that was unfair if we worked individually with providers. We actually did quite a bit of that while I was there, trying to help providers understand different provisions of the Balanced Budget Act, or give them more time—home health agencies, for example—to pay back money under the interim payment system. But it is just very difficult, and there is an inherent tension between those two roles, and I don't know what the answer is. But I think a big part of the

answer is more resources for the Agency to do more customer service and more provider education.

You might not be able to change the fact that there is going to be a tension between prescriptive laws and prescriptive regulations and discretion, but if we could do more customer service, then maybe there wouldn't be so much concern about that in the provider community.

I also had two recommendations, and I am going to add one more that I heard this morning from Dr. Roper. My first recommendation is that we should provide HCFA with more resources. Congress should be very clear about its priorities among the many things that HCFA could be doing, and we should give the new Administrator time to achieve them. And I went into some detail about some of the authorities that I think the Administrator needs to be able to do his job better.

Investing in HCFA now is critical, I think we all agree with that, and I am very hopeful that this committee will be able to do something about that.

Second, I recommend that you try to provide HCFA with additional flexibility to do its work. Dr. Vladeck talked about contractor reform and ways of modernizing that relationship and holding the contractors more accountable. Dr. Wilensky also talked about that. There are proposals that are here that we could certainly talk about that would achieve that, and that is something that is needed.

Finally, I want to associate myself with Dr. Roper's remarks about the need to have reasonable expectations from Congress and the public, and that is another recommendation, if you will. I recently was speaking to a former colleague at the Agency, and this person is not someone who is prone to feeling a lot of pressure. And he said to me, "You know, it is really hard to be here when you feel like you are working so hard and all you hear is that HCFA doesn't do a good job." And the tone of this hearing today has not been that way, and I want to thank you all for that. And I hope that in formulating your recommendations for the future of HCFA, that you bear in mind what a tremendous job the people who work there are trying to do, and that the morale is very difficult right now, it is a very challenging environment, and that whatever steps you take should be constructive and should recognize the public service that those people are providing. Thank you.

[The prepared statement of Nancy-Ann DeParle follows:]

PREPARED STATEMENT OF HON. NANCY-ANN DEPARLE, FORMER ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Chairman Greenwood, Congressman Brown, Congressman Deutsch, and distinguished Subcommittee Members, thank you for the opportunity to offer my perspective on how to strengthen the Health Care Financing Administration (HCFA) so that it can better serve Medicare, Medicaid, and S-CHIP beneficiaries and the American people. I applaud the Committee's leadership in soliciting the views of the four most recent HCFA administrators to provide insight into the challenges we faced in trying to manage the agency and solicit advice about what Congress can do to help.

I served as HCFA Administrator from November 1997 until October 2000, when I left to become a Fellow at the Institute of Politics and the Joint Interfaculty Health Policy Forum at Harvard University. I am now working as a health policy consultant and as a senior advisor at JP Morgan Partners, LLC. Before coming to HCFA, I served for more than four years as the Associate Director for Health & Per-

sonnel at the White House Office of Management & Budget. I have also worked in state government and as a lawyer in the private sector. The time I spent at HCFA was the most rewarding professional experience of my life, and it also was the most challenging.

BACKGROUND

HCFA is filled with talented, dedicated professionals who work hard to carry out agency's responsibilities of providing healthcare to over 74 million Americans. Over the last several years, the agency's workload has increased dramatically and its responsibilities have also expanded to cover new areas. The following examples of the agency's accomplishments over the last few years provide some context for this Committee's deliberations in the hope that, when focusing on HCFA's problems and developing ways to address them, you will also acknowledge the agency's strengths.

• *Legislative Mandates, including the Balanced Budget Act:* Since 1996, HCFA has been responsible for implementing over 700 provisions from 5 major pieces of legislation: welfare reform, the Health Insurance Portability and Accountability Act (HIPAA), the Balanced Budget Act of 1997 (BBA), the Balanced Budget Refinement Act of 1999 (BBRA), and the Benefits Improvement and Protection Act of 2000 (BIPA). I will focus my remarks on the BBA. HCFA staff worked hard to implement the BBA and its some 335 provisions requiring changes, in some cases major changes, to virtually every aspect of the Medicare program, as well as substantial changes in Medicaid. For Medicare fee-for-service, implementation has required designing complex payment systems, writing or negotiating regulations that comply with the Administrative Procedure Act, and providing guidance to the over 50 fee-for-service contractors around the country that pay Medicare claims and interact with hospitals, physicians, home health agencies, and other providers. Many changes also involved extensive changes to Medicare's computer systems. This was a massive undertaking with many deadlines that were difficult to meet and high stakes, because the of the importance that we achieve the BBA's goal of extending the solvency of the Medicare Trust Fund.

• *State Children's Health Insurance Program (S-CHIP):* The BBA also created the new State Children's Health Insurance Company, which HCFA staff worked with the States and other stakeholders to launch in a matter of months. Today, this program provides health insurance to some 3.2 million children whose families cannot afford private coverage but earn too much to qualify for Medicaid.

• *Fiscal Accountability:* At the same time that HCFA staff were working to implement the BBA, we were making major strides in reducing the Medicare payment error rate. In 1997, the Inspector General's first-ever audit of Medicare's books under the Chief Financial Officer's Act had revealed a fee-for-service claims error rate of 14 percent, which translated into $23 billion in erroneous payments in 1996. By the 1999 audit, we had cut that rate in half, and last year we received an unqualified or "clean" opinion from the Inspector General's auditors, signifying that Medicare's accounting records are now in order.

• *Y2K:* Also, HCFA staff were working flat-out for two years to ensure that computer systems were Y2K-ready both internally at HCFA and at all of the over 50 claims processing contractors around the country so that there would be no interruption in services to beneficiaries or payments to providers.

• *Medicare+Choice and Beneficiary Education:* The BBA created the Medicare+Choice program, giving beneficiaries across the country more health care choices. In addition to implementing these sweeping changes, the agency launched the award-winning National Medicare Education Program in 1999. This massive education effort includes 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. 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 compares with the national average satisfaction score of 72, and represents one of the highest gains achieved by a federal agency that works directly with the public.

• *Nursing Home Initiative:* Beginning in 1998, HCFA implemented initiatives to improve the quality of care our most vulnerable citizens receive in nursing homes and ensure that the objectives of the nursing home reforms in OBRA 1987 are being achieved. The General Accounting Office (GAO) has concluded that the agency has made progress in improving the survey and certification process, oversight of the states, and enforcement of the regulatory requirements. in addition, HCFA launched the "Nursing Home Compare" website, which allows beneficiaries and their families to compare nursing homes using a variety of quality indicators by zip code.

• *Coverage:* Under the leadership of the new Chief Clinical Officer, a geriatrician, HCFA revamped the process that the agency uses to determine what Medicare covers to make it open, transparent, evidence-based, and much more timely. As part of this effort, we established the Medicare Coverage Advisory Committee, a group of over 100 experts including clinicians, researchers, device industry and beneficiary representatives who advise the agency on coverage. Most requests are acted upon within 90 days, and the public can track the progress of each request on the internet. HCFA has made more than 20 national coverage decisions using this new process.

• *Management:* We also took steps on a number of fronts to manage the agency better and be more responsive to beneficiaries, providers, and the Congress. For example, we examined the process that we were using to oversee the contractors that process more than one billion Medicare claims a year and serve as HCFA's face to the provider community, and found it embarrassingly weak. We made tough decisions to reallocate resources and strengthen oversight; for example, we imposed customer service standards requiring contractors to answer 97.5 percent or more of telephone calls within 120 seconds, and respond to 95 percent of written inquiries within thirty days. In addition, we made changes in the Center for Health Plans and Providers to consolidate the staff that make policy and oversee the Medicare+Choice plans, in order to cut down on confusion and be more responsive to the health plans.

I am proud of what the agency was able to achieve during the three years I was there, particularly in view of the difficult environment in which we were operating. The BBA reduced Medicare payments to virtually every hospital, physician, nursing home, home health agency, and other health care provider in the country. On top of this, in the wake of revelations by the GAO and the HHS Inspector General about program integrity lapses in the Medicare program, the Clinton Administration initiated a concerted attack on waste, fraud and abuse. Although HCFA was still only auditing a very small percentage of Medicare claims, there is no question we stepped up our efforts to ensure that Medicare funds were not misspent, and several high-profile prosecutions conducted by the Inspector General and the Justice Department highlighted the Administration's focus.

The combination of the BBA and the fraud crackdown created a very negative environment. In some instances, we probably tried too hard to meet deadlines in the BBA and did things that, in retrospect, I would have done much differently. (One example is the BBA's provision requiring home health surety bonds, which was both a BBA requirement and an element of our program integrity efforts). Simply put, the thousands of providers affected by the BBA were very angry, and they let you know it, and you let HCFA know it. While I am all too aware of the difficulties the agency faces, I believe this context is a part—I would argue a big part—of Congress's current unhappiness with HCFA. I hope that the Congress will bear that in mind as it works to make improvements and will take a constructive path to improving services for beneficiaries, providers, and other customers.

WHAT ARE HCFA'S PROBLEMS?

I believe that HCFA's problems are related to a few simple facts. HCFA has growing responsibilities, insufficient resources to do them all, and not enough flexibility to do them well.

• *Growing responsibilities and insufficient resources to handle them.* It is clear from this Committee's own legislative agenda that HCFA's responsibilities have increased dramatically over the past few years. The massive workload of the Medicare and Medicaid changes in the BBA, along with the creation of the new S-CHIP program, and the insurance reforms of HIPAA, have stretched the agency's staff and contractor resources way beyond their limits. Neither the Administration nor the Congress has provided adequate funding for HCFA to meet these new responsibilities, much less carry out its other duties in a responsible way. For example, in 1998, the peak year of BBA implementation, HCFA had 3942 full-time equivalents (FTEs), compared with 4961 in 1980. The 1998 staffing level was inadequate to write and publish the dozens of regulations and notices mandated by the BBA (in the end, HCFA managed to publish 39 regulations and 71 notices), much less to satisfy BBA requirements and carry out the agency's other day-to-day responsibilities.

CUSTOMER SERVICE NEEDS

Current resources are inadequate for HCFA to do its job the way Congress and the agency staff want it to. Improving relationships with beneficiaries, hospitals and physicians means having frequent and regular communications with them (and not just their trade association representatives) through "town hall" meetings, satellite

broadcasts, and other means. And it means having clear requirements and answering questions.

The complexity of the Medicare statute and the need to spend Trust Fund dollars prudently makes clear and specific program requirements and intensive provider education a necessity. At present, the various rules and regulations that providers need to know to stay in compliance with Medicare are scattered through a dozen or more manuals (i.e., carrier manual, intermediary manual, etc.). In 1996, the agency launched an effort to rationalize these manuals so that, for example, home health agencies would have a manual (available both in hard copy and online) that would contain everything they needed to know. A good idea, but this work had to be interrupted so that staff could work on implementing the BBA requirements and Y2K, and as they pointed out, the BBA rendered much of the work they had done on the manual irrelevant and out-of-date. It is simply not possible to do the kind of customer service HCFA needs to do with the level of staffing and resources the agency currently has.

And while the agency is often credited for its low administrative costs (which hover around 1-2 percent of program dollars), it is important to realize that this efficiency sometimes has been achieved at the expense of sound management. For example, we have driven the cost to process a Medicare claim down to about $1 per claim so the contractor budget could be stretched further. We even eliminated the toll-free lines that physicians used to call carriers with questions about Medicare billing in order to accommodate increased spending on other areas, including beneficiary education and outreach. (These toll-free lines have been reinstated.) In short, the contractor budget must be able to accommodate improved customer service and education for both providers and beneficiaries.

One of the things I am not proud of is that during most of the time I was there, we had trouble getting the mail opened and answered in any sort of timely fashion. We spent considerable effort analyzing the problems and making changes to try to improve our process, but the bottom line is that we simply did not have adequate resources to respond to, for example, 50,000 comments on the proposed hospital conditions of participation regulation, and also answer hundreds of pieces of incoming Congressional mail a week in a timely fashion.

STAFF RESOURCES

Further, even if the absolute level of staff were adequate to carry out the agency's responsibilities, HCFA does not have the ability to hire and retain staff with the skills it needs. This is a problem shared by other government agencies, but I believe both the need and the inability to meet the need are worse at HCFA. For example, the agency made major changes in the Medicare national coverage process in mid-1999, which were designed to create a process that is open, transparent, dependable, and evidence-based. We modeled the new coverage process after a similar advisory board process used by the FDA; however, where the FDA has hundreds of clinicians and other scientifically skilled personnel to evaluate new technologies, HCFA has only 30. And it is not just the FDA. Other agencies, such as the Agency for Health Care Research & Quality (AHRQ) have the ability to hire staff for statistics and research at salaries which are above the federal guidelines, but HCFA does not, despite the importance of its mission.

As we all seek to improve customer service and move to being a prudent purchaser of quality health care for beneficiaries as opposed to simply a billpayer, HCFA needs to hire beneficiary counselors, clinicians, and experts from private health plans and providers. The agency has made some progress in hiring staff who have this type of outside experience. However, valuable and qualified staff often leave the agency because salaries are comparatively low and it is demoralizing to try to carry out the agency's responsibilities in an atmosphere of constant criticism and distrust.

Not enough flexibility

Medicare law has become more complex and prescriptive over time in order to achieve savings that can be "scored" by the Congressional Budget Office, as well as Congress' distrust of the agency's decision-making capability. In addition, the Administrative Procedures Act, the Federal Advisory Committee Act, and other statutes governing the way HCFA and other agencies must behave, make it very difficult for HCFA to relate to the public in the way the agency or Congress would like it to. For example, if, in developing a regulation to implement a provision of the BBA, HCFA finds that the payment methodology specified in the law is mistaken and does not reflect Congressional intent—or even that it does reflect Congressional intent, but it will have unintended consequences that no one wants—there is nothing the agency can do. I wish I had a nickel for every time a member

of Congress called me and asked me to "fix" this or that provision because it adversely affected a provider in his or her district. They were almost always incredulous when I advised them that, unfortunately, it was unlikely that I had the authority to do anything.

And if, with respect to this hypothetical BBA provision, the agency wanted to meet on a regular basis with industry representatives as it was drafting the regulation to get their views and work out problems in advance, the agency would be required to charter a Federal Advisory Committee, complete with financial disclosure forms, Federal Register notices, and the like. That process could take 6-8 months at the least, and while I was there, it usually took almost a year because the total number of committees government-wide was limited. Needless to say, this has a chilling effect on communications with providers and the public. Of course, these statutes are intended to protect the public from agencies imposing regulations without authority, making deals with special groups behind closed doors, or making policy without providing affected parties an opportunity to comment. Nevertheless, my experience was that these process rules often impeded, rather than promoted, responsive good government.

A related problem arises when a statute specifies a precise way it wants the agency to do something and then Congress gets frustrated if it does not like the results. For example, the BBA specified in extensive detail the new county-based payment formula for Medicare+Choice plans. When this formula produced payment rates that were lower than what was expected or desired, HCFA was criticized for creating "thousands of payment zones" and then "underpaying" them. A similar situation occurred after the agency spent almost two years in a BBA-required negotiated rulemaking with the ambulance industry, and several members of Congress sought to pressure HCFA to alter the rule because ambulance providers in their states did not like the results of the negotiation. In these situations, the agency cannot win; it is extremely difficult to satisfy all members of Congress, especially if they each have a different interpretation of what a statute directs the agency to do.

RECOMMENDATIONS

I would offer two recommendations to address these problems:

First, provide HCFA with additional resources, be clear about Congress's priorities, and give the new Administrator the authority and the time to achieve them.

The Bush Administration has requested an overall increase in HCFA's budget of almost 5%, with about a 9% increase in the operating budget. The budget proposal is a step in the right direction, but as my statement makes clear, HCFA is so understaffed and under-resourced to carry out its basic responsibilities that this does not go far enough. Congress should put the agency on a track to double its administrative budget over the next five years, with major improvements in information technology, provider education, and customer service initiatives. And, as it has done in at least one other case in creating a so-called "performance-based organization" at the student loan agency within the Department of Education. Congress should be explicit about what it wants the agency to achieve with the additional funding and provide the agency head with authority to waive certain personnel rules so that he can recruit and retain highly qualified staff without artificial FTE or salary constraints and hold them accountable.

Currently, the HCFA administrative budget has to compete with funding for the National Institutes of Health, Head Start, child care and other health and education priorities for limited discretionary appropriations. Congress should consider funding these administrative costs similar to the way that the Peer Review Organizations (PROS) in Medicare are currently funded. Funding for administrative expenses would come from the Medicare Trust Fund, and would not have to compete for limited discretionary appropriations. In order to maintain fiscal discipline, these funds would be subject to OMB approval, and as I have stated, HCFA should be held to certain performance standards

Second, provide HCFA with additional flexibility to do its work.

Because of the way the Medicare law is written, HCFA must rely on private-sector contractors, mostly insurance companies, to do such things as process claims, interact with hospitals, physicians, and other health care providers, make local coverage policy, and many other important tasks. Yet HCFA has its hands tied when it comes to selecting those contractors and, to a great extent, in holding them accountable. Medicare is unique in that the Federal Acquisition Regulations do not apply to its contractors. For the past eight years, HCFA has sent legislative language to the Congress that would change this and broaden the pool of qualified private sector entities to do the job, permit incentive based contracts, and allow con-

solidation to achieve economies of scale. HCFA should also be granted greater flexibility related to the Federal Advisory Committee Act and the Paperwork Reduction Act, as well as greater flexibility in hiring and compensation of outside employees, in exchange for greater accountability. In addition, HCFA should be granted additional authority to implement care management techniques that are standard in today's private sector healthcare marketplace, like disease management and case management for Medicare beneficiaries.

CONCLUSION

Many, including some of my colleagues today, have argued for structural changes and/or reorganizations within HCFA. While it may be tempting to think that reorganizing or placing certain functions elsewhere is the answer, I believe that the two recommendations I have outlined above will address many of the problems that HCFA has. Further, maintaining HCFA as a single point of accountability for all Federal health insurance activities is important to ensure coordination and integration.

We have just weathered a difficult and remarkable period in Medicare's history, and we worked together on a bipartisan basis to ensure that the Medicare Trust Fund would remain solvent in the intermediate term, until about 2029. That is good news, and it provides us with an opportunity that we should not miss, to consider the kinds of long-term reforms that will best promote the kind of Medicare program we want for the future. Investing in HCFA now is essential if we are to be in a position to choose wisely among our options and if we want to ensure that Medicare, Medicaid, and S-CHIP are effectively and compassionately managed.

Mr. BILIRAKIS. Thank you. Well, we will go through a round of questions with a very strict 5 minutes, and then afford the panel an opportunity for a second round. We are going to be able to get to that and release these good people in a reasonable period of time only if we stick to the 5 minutes.

First, you do us honor in being here, and I mean that from the heart, as you have done honor to the American people in having served in that very tough job. What this committee is trying to do—and I know that we don't always work in as bipartisan a fashion as we should—is to help HCFA. HCFA officials are the first to admit that the agency's image with the public and providers is not a good one. We are trying to help HCFA do a better job.

I would also like to announce that the Administrator-Designate, Tom Scully, is here, and he has been here for some time taking notes. Tom, I trust you are learning all that we are.

Mr. VLADECK. I hope that we don't get him to reconsider.

Mr. BILIRAKIS. His face has just turned red. Well, there is really so much to discuss. We have to talk about contractors. I know we visited HCFA sometime ago, and that was part of the emphasis in our discussions there. Apparently, there is a lack of flexibility. I stand corrected and apologize if I am mistaken—but I don't know that over the years that you all have appeared before this committee, or even contacted us, and said, "We need more flexibility regarding the choice of contractors and our ability to monitor them." So, it has been a problem apparently, but I am not sure that we were as aware of it as possible.

We are talking about constrained budgets, and the other side constantly talks about the lack of money, and there is no disagreement there. But, I am not sure that I have heard very much emphasis on the part of HCFA officials testifying to that effect. In fact, I raised the question at one of our prior hearings, and one of the officials came up to me and said, "We tried to get additional money, but OMB shot us down, and therefore we couldn't come in

with a request for additional dollars." So, apparently there hasn't been a proper emphasis as far as that is concerned.

I am pleased to see that the President's budget this year increases the money for HCFA tremendously over the prior fiscal year, the current fiscal year. I think we are all very pleased with that.

How aware are seniors of HCFA, its function, its responsibility, how much it has to do—directly, with the quality of health care? Do you have any opinions in that regard?

Ms. WILENSKY. I think because there is not the equivalent of the Social Security Office, that most people do not understand that there is a Federal agency that is taking on the functions that Social Security does, except that most of the actual day-to-day bill-paying is taken on through these contractors. That was a deliberate decision that was made in the mid-1960's, is rather than set up local or regional offices, that it would be done in a contractual way.

Mr. BILIRAKIS. Is that a good idea, the contractor's concept as against the local offices?

Ms. WILENSKY. It is different. There was not adequate recognition at the time, particularly with the advantage of hindsight, that there are at least two very separate functions. One is a claims processing function, and that there are a lot of different types of organizations that could take on claims processing. They could be either regionalized or they could be centralized. And then there was the local function involved in speaking with both seniors and providers and resolving differences between them. I think those are really local, and that whatever we were to do about changing who could be the bill processors, which is a legislative issue and which HCFA, at least over time, has approached various committees in Congress about trying to have expanded. But to recognize that there are these two functions and that there really is a legitimate local function and that part of it is making sure that the local presence persists in having a discussion about how best to do claims processing in the 21st Century.

Mr. VLADECK. If I could just add a couple of points to that. First, when Medicare was created, it was administered by the Social Security Administration, and you had that pre-existing field office structure, and that was the primary point of contact for beneficiaries. A decision was made when HCFA was created not to reinvent that wheel. And I am told that worked reasonably well until the very significant cutbacks in Social Security Administration staffing that took place in the early 1980's when, of course, the Agency was more willing to let go of Medicare specialists than it was willing to let go of income-related specialists.

But the second thing was that I think that there has always been some ambivalence and confusion on the part of other folks in the executive branch about the extent to which they were prepared to have an identifiable entity within the executive branch that administered the Medicare program because it was something that was so popular—a program that was so popular with the American public that they didn't want to have to share credit in some basic ways. And we have recommended in another setting, another context, that the whole issue of whether it does Medicare any good, or Med-

icaid any good, to be part of the Department of Health and Human Services at all.

I think it ought to be part of thinking about these structural issues. Our rule-of-thumb—and I think it was true under my predecessors from both parties—when there was good news associated with something HCFA was doing, the Secretary made the announcement, and when there was bad news the Administrator made the announcement. And, certainly, the Public Affairs Office in the Department of Health and Human Services always worked under that rule. I think the Budget Offices always worked under that rule as well. And we know from survey data, the average Medicare beneficiary has no idea where in the Federal Government responsibility lies for——

Mr. BILIRAKIS. My time is expired. Dr. Roper, I know you wanted to add something, briefly.

Mr. ROPER. To the narrow issue of was the decision in 1965 to go with contractors a wise one, I think it was at the time. To refresh memories, what happened is, Medicare was set up very much like BlueCross-BlueShield, and you had a contractor for Part A and a contractor for Part B, so basically a hundred contractors, 50 and 50.

What has happened over time is that number has been whittled down a bit year-to-year. But it has been very difficult to eliminate contractors. Basically, what we had to do, each of us, is occasionally find some contractor that was just doing a horrendous job and kick them out of the program, so you went down from 49 to 48 to 47 and whatever.

Mr. BILIRAKIS. We have got to explore that area so much more. Mr. Brown.

Mr. ROPER. And what has not happened, if I could just add—I will be quick—what has not happened is enlarge the pool to go to different new organizations to start afresh in a green field operation to create the kind of contractor that you really want to have for the 21st Century.

Mr. BILIRAKIS. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. I agree with Dr. Wilensky and Dr. Vladeck about the good idea of a name change. To show Chairman Bilirakis and incoming Administrator Scully that I am a uniter, not a divider, I suggest the Ronald Reagan Institute for Big Government Health Care.

Ms. DeParle said something at the conclusion of her testimony about employee morale, and there is an awful lot coming out of Congress, a sort of denigration of public service, and it makes it harder for your employees at HCFA to do their jobs, it makes it harder to attract young people to public service. Part of it is the kinds of things we say in this institution, part of it is the increased workload and the continued mandates that all four of you spelled out. And the one thread that very nonpartisanly ran through what all of you said was the lack of resources. As Dr. Roper, almost the first thing he said, there are fewer employees today than there were when he was there. The flatline budget not even close to accounting for inflation, the mandates we continue to give you.

Talk to us, each of us—and I guess this will probably take all 5 minutes—I would like you to give us—and President Bush has sug-

gested we think a budget increase of 5 percent, although I have also heard other numbers from the budget yesterday—but give us a number, if you would, and how that money should be used in sort of a nutshell, what we ought to be doing, where this budget should go in the next year and in the next couple of years.

Mr. ROPER. I think where the money ought to is in enhancing the expertise that HCFA has by hiring new kinds of people who are familiar with how private health insurance markets work, and new skills and communication. I think a large part of it ought to go into, as others have said, enhancing communications with beneficiaries and with providers.

What the right number is, just to pull a number out of the air, I would say at least a 25-percent increase in the budget. But I would hasten to add, it is simply unrealistic for me, or anybody else—Tom or the Secretary or whatever—to advocate for more money for HCFA at a time when we haven't yet agreed on what it is we want HCFA to do because the right response from the appropriators is going to be, "My gracious, we are not going to pour good money after bad," et cetera. And as long as the mindset is that this is not money well spent, arguing for a very substantial increase, which I am, is going to fall on deaf ears.

Ms. WILENSKY. The best way to get a proper number is to ask the HCFA Administrator specifically what they want to do with that money. My guess is you are talking about somewhere in the neighborhood of 10 or 15 percent, but it is a guess because I haven't tried to task out what needs to be done.

One of the reasons that I have suggested taking off areas that I think are not inherently related to running a good, traditional Medicare program in a modernized way and putting it elsewhere is because I think it would allow the HCFA personnel to focus on what they do best, and to do it within budget. Now, this, of course, would increase some of the cost of some of these other places that would take up some of these functions, and that is why deciding exactly how you structure HCFA and then how much money is needed is important.

But I believe if the law were changed to allow more modernized bill processing groups to come compete instead of the current limited pool who can actually be contractors, that would allow you to do things a little more efficiently.

HCFA has been able to reduce the number of systems that are used substantially more than the number of carriers and fiscal intermediaries, so there will be some savings, but not as many as people might think. But I do believe that if there were ways to try to go out and have the people who do a lot of transactions now, either the credit card people or other types of people, in bidding in terms of some of the claims processing, it could make a positive difference. But I am not talking about a small change, not as large as the one you just heard, but I am not talking about a small change.

Mr. VLADECK. I can't give you an exact number with all the University of North Carolina and University of Michigan trained staff around, I could suggest some parameters. I think there ought to be a full-time, appropriately trained Medicare specialist in every Social Security District Office, and you can count the number and

multiply it by a salary level for that, and probably two in the bigger ones. And I think for perhaps 35- or 40,000 institutional providers in the Medicare program, on a ratio of 1-to-50 perhaps, you ought to have an account executive type customer service function probably within the contractors rather than within the executive branch because the personnel systems of the contractors are more flexible, to be a sort of one-stop phone number that people can have to answer questions, to get problems resolved, and things of that sort.

And you probably need a number of those on the Part B side per State for physicians and some of the smaller, but more numerous categories of providers as well. I think you are talking primarily about half through the executive branch budgets and about half through the contractor budgets. Probably, if you are really going to do this customer service right, a doubling of the number of people, but that would be much less than a doubling of HCFA's administrative budget, the largest single chunk of which goes to running computers to pay claims. More than half of it is just the claims processing function itself now, and you wouldn't need to increase that. And I think Gail is right, you could actually reduce that.

The other thing that you need to do, and it is perhaps in the way of a one-time expenditure than a continuing expenditure, but I think the experience, again, of most of our service industries under the private health insurance industry, and certainly the private health care industry, is if you are going to do high-quality customer service for both providers and beneficiaries, you have to have the information technology platform from which to do it. You can hire all the call center people you want, you can hire all the field reps you want, but unless they can sit down at a terminal which can give them answers to the particular questions that the inquiry is involved in, they are not going to be able to provide very high-quality service.

To a large extent, we need, I think, a getting-over-the-hump kind of investment in making available the kind of information technology for the program that would permit you to save on contractor cost, but would also permit you to do late-20th Century level customer service, at least, within the program.

Ms. DEPARLE. I think I represent the high-water mark because I, perhaps reflecting on my recent experience, more recent experience at the Agency under the Balanced Budget Act, I think that you could easily double the administrative budget of the Agency over the next 5 years and not run any risk of misspending funds. And I think you could devote the additional funds to the areas that we can all agree need to be strengthened, without necessarily having to answer the question of what is Medicare going to look like in the future. The Agency is so under-staffed and so under-resourced that it has to have investments now in information technology, as I think everyone has agreed, in provider education which, frankly, might have prevented some of the fraud and abuse problems that we have had and that we have had to work through together, and customer service initiatives, we have some of the infrastructure for that with the Medicare+Choice, but we need to devote more resources to it, and also coverage. That is an area where

we really need to make some investments, and the current budget level doesn't allow the Agency to do that.

I agree with you that Secretary Thompson's request is a step in the right direction, but I hope the Congress will be able to do even better.

Mr. BILIRAKIS. Thank you. Mr. Greenwood to inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman. Years ago, I read a book called "The Seven Habits of Highly Effective People." Maybe some of you have read it. I don't remember what they were, which probably explains a lot, but the one thing I do remember is that he had a little quadrant, and he had "important things," "less important things," and "urgent things," and "less urgent things," and he talked about how we all spend most of our time in the "urgent" and "important," and a lot of time in the "urgent while not very important," and spend very little time in the "not urgent but important" quadrant, which encompasses planning and sort of thinking through into the future.

And the question I have for you—and thank you again for all your help with this, and I hope we can continue to have your help—is there any of that going on at HCFA? In other words, has it been the case that you have been so busy putting out fires and responding to congressional inquiries and new statutes, that you haven't been able to have a segment of your hierarchy or of your administration just sort of off, insulated from the daily demands and being able to think through how should we structure ourselves into the future, what is changing in the world of technology and the world of health care, so that we can really think into the future? Has HCFA such a function and, if not, should it?

Ms. DEPARLE. I think the Agency has had that function at various times, Mr. Chairman, and you and I talked about this a little bit. I would have to say that over the last 3 years, I think that being at HCFA was an experience of drinking out of a fire hose, and you are not—occasionally, the senior staff would have outside speakers come in and we would have an exercise or we would think about the future. We have a strategic plan and in doing that plan and updating it, we sometimes did that. But it wasn't, frankly, as though we could afford to devote the staff to just thinking outside the box or thinking about the future. And I am sorry that we didn't have the resources to do that, we weren't doing it.

Ms. WILENSKY. My sense is that it became increasingly more difficult for that to happen, as you and I had spoken on this issue. When I was there, the major implementation was to implement the relative value scale and to introduce capital to perspective payment for the hospitals and to worry about Medicaid provider and donation. Those were three major issues, but nothing like the type of implementation burdens that Nancy-Ann had to face and that Bruce got the beginning of in terms of the Balanced Budget Act.

So, it is possible for an agency like HCFA to be able to put some time into place, that was how we had the idea of changing how we looked at the PROs and what it would take, and beginning to think about the Medicare transaction system and the fact that politically it was very difficult to reduce the number of carriers and fiscal intermediaries, but if we could get them to use the same system

we could accomplish some of the savings without as much political pain, but you can't do that if you are drinking out of a fire hose.

So, I think that it is, in part, incumbent on the Congress, particularly during periods when, for whatever legitimate needs, it feels like it must have a lot of legislative change to recognize that that increases the administrative burden of the agency that will be implementing those legislative changes and to respond appropriately, but that has been a very difficult thing to have happen.

Mr. GREENWOOD. Let me pose a related question, and that is another similar area, the whole question of wellness. How can we, again, instead of constantly responding to health crises in individuals, what should the Agency be doing with regard to promoting wellness in the Medicare population, wellness in the children's population, wellness in the Medicaid population, so that health care costs the taxpayers less?

Is HCFA engaged thoughtfully in those processes, and what are your thoughts about what we should do on that score?

Mr. ROPER. Thank you for the question. I happen to chair an organization called Partnership for Prevention that is focused on advancing prevention and wellness and national policy in the private sector and the public sector.

We have made some progress, but not nearly enough in this. The root of the problem we face is that when the statutes were passed in 1965, authorization was made for paying for treating sick people, and the notion of paying for checkups or screening or immunization or whatever, we have, one by one by one, added some of those things through statute to the program, Medicare and also Medicaid, but we need to do more of that.

Frankly, I don't want to divert the conversation, but just to make the point, one of the attractions of prepaid capitated plans is the incentive given for promoting wellness, et cetera.

If I could just add a quick response, I fully agree with the point that we ought to invest more in learning new ways of delivering health services, health policy, et cetera, whether that is done inside HCFA or at the Agency for Health Care Research and Quality. The investment in that kind of research is tiny compared to the huge and important investment we make as a Nation in fundamental biomedical research. There is just no comparison.

Mr. GREENWOOD. Thank you.

Mr. BILIRAKIS. Mr. Deutsch to inquire.

Mr. DEUTSCH. Thank you, Mr. Chairman. And, actually, I was just talking to staff because one of the things all four of you have done as Administrators that has really been very positive is, in fact, some of the initiatives that you started, but I think patting ourselves on the back as well as some of the initiatives on preventative care and, as much as we have done on that, though, I was just asking the numbers, there is still the utilization rate is just still amazingly so poor. And as all of you are aware, I am sure, July 1st we go to a whole new slew of Medicare wellness coverage.

I want to, at least in this round, focus on something that this committee, both the Health Committee and the Oversight Committee, has been dealing with over the last several months, and that is the issue—and we have had anecdotal stories of HCFA being too tough on providers in their efforts to police against fraud,

waste and abuse, in fact, creating really, at least anecdotally, very unfair situations for providers.

I want to focus really actually on Ms. DeParle just because I want to actually read and actually submit for the record a U.S. News and World Report article, and it is somewhat dated, 1998, during your tenure, but as you well recall, our Oversight Committee pulled you in front of it and questioned you about why the Government wasn't doing a better job in fraud issues. And let me just quote—and as I said, I will submit this for the record—this is a quote from that story.

"Gabriel Hernandez is not your typical medical practitioner. He couldn't tell an x-ray from an EKG. His sole preparation for a career in the field was ten lucrative years as a logistics coordinator for the Mendelin Columbia cocaine cartel, a job that gave him plenty of cash, sleek power boats, and 5 years in Federal prison. But shortly after his release in 1993, a crooked accountant tipped Hernandez to the largesse of the Federal Medicare program, and his new career was born. Hernandez set up more than two dozen phony medical clinics in the names of friends and relatives, and applied for a provider number, the code that doctors and companies use when they submit bills to Medicare's computers. Florida's Medicare Office, more than half funded by Federal Medicare, gave him his provider number within 2 weeks. No one bothered to check his clinics, his background, his list of patients. A few days later, an assistant began billing the State via computer for mythical checkups and procedures, and Medicare payment checks began to flow in. In the course of 2 easy years, Hernandez received checks totaling $1.7 million. "The drug business was very dangerous', he said with a charming smile, 'but not health care poor. It was easy money and there was no risk'. Hernandez, authorities said, is only one of a horde of hardened criminals who saw Medicare for what it really was, an unguarded $250 billion a year pile of cash just waiting to be had. Over the past decade, many of the criminally inclined have moved out of the drug trade to start careers in Medicare fraud, where penalties are low and rewards are stratospheric. To realize this windfall, they have set up thousands of phony clinics, medical equipment outlets and laboratories, a vast underworld of health care investigators find particularly difficult to understand, let alone penetrate. Owners are shielded by layers of cutout companies, lowly runners and mules are employed and sometimes blackmailed to move the money. Profits flow through a maze of bank accounts into offshore places like Liechtenstein, the Kirks and Cacaos Islands and Cypress, and often back into drug business. One Russian informer interviewed said Russian groups cleverly serve up defunct companies to investigators, diverting them from going forward. 'We are always chasing something that isn't there anymore', says Bruno Vinero, who heads the New York Section of Department of Health and Human Services Office of Inspector General."

We have heard all this before, but this article was written when you were HCFA Administrator. I think it important to recall the environment we were in just a few years ago to put some of these fraud and abuse complaints into at least some context. So I have three questions for you.

First, can you comment on what your experiences were when you were HCFA Administrators, regarding Congress' appetite in going after fraud, waste and abuse?

Second, do you still believe that Medicare fraud is still a serious problem plaguing the program today, and do you believe the Government is doing enough to combat it?

And, third, do you think that during your tenure and the other Administrators' tenures at HCFA was too aggressive in going after Medicare fraud and abuse?

Ms. DEPARLE. Well, first, you asked about Congress' view about this. As a matter of fact, I arrived at the Agency when Dr. Vladeck was still there, to serve as his Deputy while I was awaiting confirmation, and I believe it was the week that the Inspector General's first ever audit of the Medicare program came out, and it revealed an error rate of 14 percent in claims that were paid inappropriately, which translated into $23 billion in Medicare funds that were misspent for, I guess it was 1996, 1995 or 1996, and that was not a pleasant week at the Agency. Congress was furious about that. We were not happy about it. We needed to get on top of it. We needed to make sure that Medicare wasn't wasting the taxpayers' dollars, and we worked with the Congress—in particular, Mr. Greenwood's committee was very interested in this issue—and the Congress did give the Agency more resources and, in particular, gave more resources to the Inspector General and to the Justice Department, through the Health Insurance Portability and Accountability Act, to use on program integrity.

In 2 years, we were able to cut that error rate in half. I do think that it is unfortunate that a lot of what occurred left providers with the feeling that the Agency, or the Government, thought they were all crooks. And I think it is important to make a distinction between the prosecutions that occurred and the investigations that occurred, and the appropriate role of HCFA.

My view is that, in general, program integrity should not be a law enforcement function, it is a function of HCFA. HCFA should be the steward of the Medicare Trust Fund. HCFA should make sure that funds are spent appropriately, but to do that we need an appropriate amount of resources. We need to be able to do provider education.

We did launch, in fact, a project down in Florida doing provider education down there to help physicians and others understand how to bill Medicare. We started doing some things like site visits before we let new equipment suppliers into the Medicare program. But all those things cost money. So, we need to continue to be vigilant, I think, there. I am not really prepared to say whether the exact number is sufficient at this point, but in everything else, Medicare is a growing program and we need to continue to be vigilant.

Mr. BILIRAKIS. The gentleman's time is expired. Mr. Deal.

Mr. DEAL. Thank you, Mr. Chairman. I want to thank all of you for your testimony and, Dr. Vladeck, I want to express appreciation to you in the way you have laid out your written testimony here. One of the things that this committee has tried to determine over a period of time is the kind of things that need to be changed and whether they can be changed administratively within the Agency,

or whether they require the action of Congress statutorily to make those changes, and I appreciate the outline that you have given us, and you have indicated those areas that are administrative and those areas that are statutory, and I think that will be helpful to us as we proceed through this, and I thank you for that.

One of the areas, of course, that all of you have alluded to is the lack of adequate funding for administrative purposes. One of the complaints we, of course, continue to hear is that the reason that HCFA is ineffective in many regards is that the staff is too large, that it takes too much time to make changes, that flexibility, or the lack thereof, is in large part because changes have to be vetted through so many subcommittees and so many various divisions within the Agency, and I have a concern that if we simply increase that, that we are going to slow down the entire process and, even though we may want to give flexibility, we may, in fact, do exactly the opposite. Would you care to address that subject?

Mr. VLADECK. Well, I would make a specific proposal. I would—and, again, this goes back to my concern about the relationship between HCFA and the Department of Health and Human Services—but I would suggest that the Congress might mandate that for every increment of x-percent in the size of the HCFA staff relative to rulemaking processes or other regulatory roles, that the number of employees of the Department of Health and Human Services who don't work for HCFA, whose job it is to oversee and harass HCFA be reduced proportionately. And we still have a very strong and under the new Administration, I believe, an even strengthened Office of Management and Budget that has the responsibility on behalf of the whole executive branch for making sure that individual agencies and individual parts of the executive branch are responsive to the needs of consumers and the general public in the regulatory process, that they are not too bureaucratic and so forth.

What we have done within the executive branch over the last decade or so is add several more layers of review so as bureaucratic as HCFA may be, we have multiplied that by entities outside HCFA, all of which have oversight on a piece of HCFA's role. So, I think you could address some of those issues.

Again, I would urge the committee at the appropriate time to seriously consider the question of the relationship between the Agency and the Department of Health and Human Services more generally. I know that Secretary Thompson—for the first time in quite some time, we have a Secretary who has shown a great deal of interest in some of these administrative questions, and maybe this is not a good time to talk about that, but I think the relationship—if you think about levels of review and levels of bureaucracy, once HCFA is done with a regulation or a payment formula or so forth, the number of steps after the Administrator signs a document, before it appears in the Federal Register, before it appears in a HCFA Notice and so on and so forth, has multiplied enormously over the last decade or so, and I would say you ought to focus on reducing that while not building it up within the Agency itself.

Mr. DEAL. And I assume that would tie in, as you indicated, to your suggestion that it be made an independent agency and separate it?

Mr. VLADECK. That is right.

Ms. WILENSKY. I think it is with the appropriate mindset of an Administrator of understanding the need to have regulations out in a timely way, there are always organizational changes or requirements for accountability that can be introduced within the Agency so that when you have conflicts arise when people are putting together regulations, as inevitably happens, there is a clear manner for resolving conflicts, and to the extent that that can happen, you can keep the process flowing in a reasonably timely way.

I appreciate the concern that Bruce has raised about the fact that there are other levels outside of HCFA that typically review regulation. ASPE, Assistant Secretary for Planning and Evaluation, typically within the Department of Health and Human Services, serves a coordinating function so that all of the operating divisions can review regulations. It goes then specifically to the Office of the Secretary, and then to the Office of Management and Budget.

Having said that, I don't think the right response is to make HCFA a separate agency. I think you will lose a lack of accountability. I think the proper relationship that Dr. Roper had mentioned earlier, of President and Secretary, HCFA Administrator is a good one, and that there needs to be appropriate pressures laid on the Secretary and the OMB Director to make sure that their administrative functions occur in a smooth way. These are not impossible to have happen, but if left on their own regulations can circle almost indefinitely within either HHS or between HHS and the Office of Management and Budget.

Mr. ROPER. If I could just quickly echo, I, too, would be opposed to separating HCFA out from the rest of HHS. I believe the primary thing that needs to be done is to put an expectation—in addition to resources, an expectation that decisions are going to be made and made expeditiously. It is always easier when you are facing a difficult choice, to put it on the back of your desk and come back to it later. And as Bruce earlier said, in so many of these areas we face difficult choices and tradeoffs, and I believe the most important thing—again, other than resources—is for Secretary Thompson and Tom Scully and everybody else to say, "We are going to manage this department, this agency."

There has not been, over time, routinely the notion that management is something that is worthy and important. Policy considerations are usually a whole lot more fun and whatever, but the day-to-day blocking-and-tackling of getting the job done is just as important.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Green to inquire.

Mr. GREEN. Thank you, Mr. Chairman. Dr. Roper, I want to reiterate some of the statements you made, and I agree, about HCFA. In your statement about many of the problems attributed to HCFA are actually not of its own making and created by Congress passing legislation that is very notable, but often unrealistic in objectives and its expectations. And, also, when you talk about the need for new resources, you said it is important to emphasize the need for resources for HCFA, and what people brag about, and your quote is, "When I hear people brag about how little Medicare spends on administration, I cringe. That should be a source of embarrass-

ment, not pride." And the Agency is under-staffed both in numbers and mix of skills, it is seriously hampered by inadequate systems and actually they have fewer staff in HCFA today than when you were Administrator 15 years ago, despite a tripling of the outlays or the requirements. I think those are important.

Let me ask a question of both Dr. Vladeck and Ms. De Parle. Both Drs. Roper and Wilensky have been on record, as mentioned in their testimony, they support transitioning Medicare from the traditional fee-for-service to a premium support program that is more similar to what we have as Federal employees. There is a number of us who have concerns about this—in other words, mixing—I guess as a senior citizen we would pay more than the amount.

Can you share a little bit your thoughts on a premium support system compared to what we have today?

Mr. VLADECK. Well, maybe I can repeat some of the conversations we had at the Bipartisan Commission or whatever. The first thing I would say is, if you use the model of the Federal Employees Health Benefits Program, if Medicare had had the cost increases over the last 3 years that the FEHBP has had, we wouldn't be talking about 25 years' remaining life on the Trust Fund, we would be talking about an imminent emergency in terms of the finances of the Trust Fund.

But I think the fundamental issue is the extent of who bears the risk for increases in the cost of providing health services and health benefits over a period of time, and I think, again, we do have 25 years' worth of experience with the participation of private plans on a capitated basis in the Medicare program. And what that experience seems to suggest is that you can save a substantial amount of money for the Federal Government by shifting costs to beneficiaries, or you can substantially increase the participation of private plans at greater expense to the program, but that you haven't been able to both reduce costs and increase the participation of private plans without running into some of the problems that the Medicaid program has had with some very low-cost providers in terms of the availability of services and availability of the benefits.

The notion that you can save money by the mere presence and competition of private plans in the Medicare program, while theoretically correct if you assume enough things about the nature of how you would design your program, is just directly contradictory to 25 years of empirical experience with the participation of private plans in the Medicare program.

And if the point is not to save money but is to provide opportunities to enhance benefits of one form or another, then I think you have to deal with the issue of equity and uniformity of a guaranteed benefit to all beneficiaries everywhere in the country, and you can only do that by having a base program, a core program, which has that level of benefits and has that common definition of benefits everywhere in the country.

Ms. DEPARLE. I agree with Dr. Vladeck. I have some concerns about the Federal Employees Health Benefits Program as a model. There are some appealing aspects to it. Allowing people to choose and having education for the consumers is an appealing thing and

something that we have actually, I think, done a pretty good job of in implementing the Medicare+Choice program. But the populations in those two programs, the FEHBP and Medicare, are very different, and the Medicare population is much more vulnerable both in terms of their health status and their financial status, and I think we should really think long and hard about moving in that direction.

I do support the proposal that the Clinton Administration put forward for a competitive defined benefit where there would be market-based pricing, competitive pricing, for managed care plans and where beneficiaries might have an incentive to go to a less-expensive plan, but where the fee-for-service program would be maintained because—I agree with Dr. Vladeck—the experience so far is that it is very difficult both to save Medicare money and increase access to these private plans in many areas of the country. There may be areas of the country where we will never have private plans in Medicare, and we need to maintain a strong and effective and well-managed traditional fee-for-service program for those areas.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. We now will start the second round, so any further members coming in will be inquiring as part of the second round, not as the first round. I thought I would make that clear.

Mr. GREEN. Appreciate that guidance, Mr. Chairman.

Mr. BILIRAKIS. That guidance, unfortunately, is necessary.

On the contractors, please furnish us with your suggestions on how that should be handled because apparently it is going to take legislation to give you that flexibility.

On the point that Dr. Vladeck emphasized, the flexibility versus uniformity, the opened or closed process, we would very much like to hear more in that regard.

I would like to ask a question, though, regarding the FDA approval which Ms. DeParle concentrated on. We were advised of this to some degree when we went to HCFA in Baltimore back in February. As Ms. Eshoo and Ms. DeGette mentioned, FDA spends all of its time approving new drugs and devices. Does HCFA play any part during that FDA approval process?

Ms. DEPARLE. No.

Mr. BILIRAKIS. They do not.

Ms. DEPARLE. No, sir. And it is a different question, but they are both important questions, but the question that FDA has in front of it is, is something safe and effective, and can it be generally approved for the public to use?

The question that HCFA has with respect to Medicare is, can and should Medicare cover this item or service? And as you well know, there are many items and services that, by statute, Medicare can't cover. Dr. Roper mentioned preventive benefits. Medicare's own statute says it has to cover things only for the diagnosis and treatment of a disease or a malformed body member. It says nothing about preventive treatment. So, when we have added preventive treatments, it has taken an act of Congress to do that.

Prescription drugs is another example. Those obviously aren't covered by statute by Medicare. Once the FDA has said something

is safe and effective, then the question for the Medicare agency is, should this be covered for Medicare as well? And that is where we made a change in the process a couple of years ago, to create an open and transparent process so that device companies, citizens, Medicare beneficiaries, everyone, could petition for coverage of a new item. But there might be some things what while the FDA would say they were safe and effective, might not be appropriate for Medicare coverage, or they might be appropriate only in certain circumstances, and that is where we need the staffing to help make those kind of decisions.

Mr. VLADECK. It might be helpful, Mr. Chairman, to actually provide an example because, in the abstract, these things get—but one subject of an oversight hearing when I was Administrator, was on the issue of lymphedema pumps. Lymphedema is a very common complication of surgery for breast cancer and for other major surgery for treatment of cancer, that involves accumulation of fluid and swelling that is very painful. It is a very serious and very real condition. It is most common, again, and the issue of Medicare payment arises most commonly relative to breast cancer.

There were a number of clinicians within HCFA and elsewhere within HHS who believe that physical therapy was the most appropriate treatment for lymphedema for almost all beneficiaries who experienced it, but there are two categories of pumps that are actually applied to the extremities involved in the swelling that have been approved by the FDA. One costs about $400 and the other costs about $4,000 apiece. And we found in the mid-1990's that 80 percent of the lymphedema pumps being ordered in the Medicare program were of the $4,000 variety, not the $400 variety.

Now, the FDA is not statutorily in a position to say when you should pay for the $400 pump and when you should pay for the $4,000 pump. They were able to say that both were safe and effective for the following kinds of indications. And what we needed to do in the absence of some of the new coverage processes which are desperately needed, is to say the $400 pump is appropriate in these circumstances, and the $4,000 pump is appropriate in these circumstances, and when the $400 is appropriate Medicare shouldn't be paying for the $4,000 pump. That is the kind of distinction that you need the processes and the resources to be able to make, that the FDA is not in the position, under its statute or its operating policies, to make.

Ms. WILENSKY. That is a very good example, to think about the difference between coverage and pricing, and sometimes they have gotten confused and it has delayed a coverage decision that needn't have been delayed.

When I was at HCFA, there was a decision that was requested about having coverage for high and low osmolar density contrast material, and they are very different in terms of the cost involved.

We had some advice from the American College of Radiology about eight or nine instances when the more expensive contrast material was medically important, but the coverage was allowed, and we weren't directing physicians or hospitals which of these contrast mediums to use, it was the payment that would be limited to the higher payment only at times when there was clear medical benefit.

One of the issues—and I have had discussions with some of the senior career people at HCFA and also with Nancy-Ann, at her invitation—is to try to help HCFA understand that the coverage decision may be easier. The pricing decision, which is very important, might allow for things to move forward while still being financially prudent. You obviously do want to do the spirit of what was just mentioned.

Mr. GREENWOOD. There isn't any way to speed up that process?

Ms. WILENSKY. There are definitely ways to speed up, yes. There are lots of ways to speed it up.

Mr. GREENWOOD. Is the answer additional dollars, additional personnel?

Ms. WILENSKY. It is that and, in fairness, while resources will be important, having an expectation and accountability within HCFA itself for being able to produce in an appropriate manner—produce results, produce decisions, produce pricing—decisions is going to be important and, in fact, without having the Congress have some expectation that the increased money is actually going to make a difference, it would be hard to expect the Congress to act. And I think all of us understand there is a little bit of a chicken-and-egg problem going on. HCFA behaves and performs badly and makes it hard to want to have Congress or the Administration give it lots more money. One of the reasons HCFA has had trouble performing well is that there has been this huge mismatch.

Mr. BILIRAKIS. think we have gotten that message—hopefully we have. Dr. Roper, very briefly.

Mr. ROPER. If I could add just one other thing. All too often, we view the coverage decision as a yes or no, and you need—we all need—to understand that it is much more a question of for which patient under which circumstance is a specific treatment or device or whatever appropriate, and that subtlety is one that it is very hard for a national organization with this kind of scrutiny and whatever to do fairly and routinely and whatever.

I would just cite one example from my watch. When we began to cover heart transplants under the Medicare program in 1986 or 1987 or thereabouts. Hugely expensive at the time, still thought by some to be experimental. And what we decided was to say that heart transplants would not be covered when done anywhere around the country, but we would cover them in specific centers where they were done with technical quality and so on. And those kinds of subtleties and complexities are much different than just a one-time, one-size-fits-all, "Yes, we will cover it today," we did not cover it yesterday for all the beneficiaries all over the country.

Mr. BILIRAKIS. Thank you. Mr. Brown.

Mr. BROWN. Thank you. Dr. Vladeck, each of the other panelists gave a range or a specific idea about what number of dollar, what percent of increase—Dr. Roper said 25, Dr. Wilensky said 10 to 15—I understand these are very rough estimates—Ms. DeParle said 100 percent over 5 years.

Could you give us a range, so we get an idea of——

Mr. VLADECK. Again, I would find a need to divide that into three pieces, if I could. The first is, I think the core administrative budget, which is now about $500 million a year, which is most of the staff and direct operations of the Agency, I would think over

a 3-to-5-year period, we are probably talking about a 50-percent increase, I would guess. But I am still missing—on the contractors, the contractor budget is now about $1.4 billion a year. I think several hundred million dollars would rebuild, so that is 25 percent perhaps, would rebuild a lot of that customer service function.

I am still missing from that 1500 staff in Social Security offices—I don't know where that comes from—and a one-time investment that I think probably runs to several hundred million dollars over a period of years in a major, sort of quantum modernization of information technology. But then, again, I think you can get back to a steady-state that is lower than that.

So, I would add those up and I guess it would come to probably about a 50-percent increase, if you did the arithmetic on all those parts, over several years.

Mr. BROWN. Thank you. Most of your trips, each—at least the two of you that came to the Hill since I have been here, and Dr. Wilensky, too, in her trips not as the HCFA Administrator—mostly they were about Medicare, and I want to talk about Medicaid a little bit, not that you didn't come to the Hill to talk about that, too, but much more often Medicare.

Medicaid, as you know, covers roughly the same number of people, roughly 40 million, pays for health and long-term coverage for 1-in-7 Americans, the country's largest health insurer for children, six times the Children's Health Insurance Program, single largest insurer for maternity care, 1-out-of-3 deliveries is Medicaid, single largest purchaser of nursing home care, as you know, and the single most important source of financing for hospitals like Metro in Cleveland, safety-net hospitals, inner-city hospitals, public hospitals.

Some have suggested possibly separating—including Dr. Wilensky—separating Medicaid out from HCFA and assigning its responsibilities to another agency.

I have concerns about such proposals. First, that this may have a negative implication for beneficiaries. We have worked hard to sever the link between Medicaid and Welfare and eliminate the Welfare stigma, placing that program in a part of the Department of Health and Human Services that deals with low-income programs, like they could potential stigmatize the health care programs, stigmatize Medicaid. Placing the program's administration with HRSA also sends the wrong message, it is not a block grant but obviously an insurance program, and HCFA runs insurance programs, Medicare obviously as well as Medicaid. Additionally, many of the staff and activities of HCFA work on both programs and perform functions that serve both programs.

A question for Dr. Vladeck and Ms. DeParle, since you are the only Administrators here who were here during and after Welfare Reform, which really did sever the link between Medicare and Welfare. Give us each your thoughts on moving Medicaid out from HCFA's responsibility, if you would.

Mr. VLADECK. As I said in my statement, I think the trick on Medicare—and it is a very, very difficult program for anyone in the Federal Government to administer—is to recognize the extent to which it is a partnership with the States in the sense of the States having initiatives, but that there are very powerful Federal finan-

cial risks and issues associated with it. And, in fact, all of us were involved in quite intense debate in 1995 and 1996 and 1997, about the extent to which the Federal Government had a continuing responsibility to protect beneficiaries directly rather than delegating that entirely to the States.

And I think if you think about the history of the regulation of nursing homes, which is the largest single thing on which Medicaid spends its money in most of the States, if you think about the controversy that you are going to have the pleasure of dealing with and Mr. Scully is going to have the pleasure of dealing with on the proposed rules for the regulation of Medicaid managed care plans coming out of the Balanced Budget Act, I think there are very sort of profound issues of beneficiary protection that most of my familiarity with the other organizations in town that might take administrative responsibility for this make me very nervous about. At the same time, there are very significant issues of financial management in the Medicaid program, and if you didn't have the expertise in HCFA you would have to reinvent somewhere else or else be creating very substantial risk to the Federal Treasury, I think.

Ms. DEPARLE. Just quickly, I always wished I had more time to spend on Medicaid. I think you are right, it does cover almost as many people, spends almost as many dollars now, and the trends are going in that direction with Medicaid. I always felt that I was struggling to keep up with the demands in Medicare and not able to spend as much time on Medicaid as I wished. And from talking to my fellow former Administrators, I think they all felt that way.

Gail's approach to it is to try to separate it out, I think, in the hope of giving it more attention. My concern about that is I think you need a single point of accountability for insurance programs in the Federal Government, and I think you would lose some of the coordination that we have tried to ensure between Medicare and Medicaid, if you were to do that. So, that would not be the first place I would go.

Ms. WILENSKY. It really has been the stepchild, though, of HCFA. I appreciate your concern, having lived there, and I guess I would invite you maybe to spend some time—it is a frustration because it is such an important program, and it gets so little of the attention. I mean, HCFA is really running Medicare, it is a Federal program, but how you deal with the State-run program with Federal guidelines and oversight is so fundamentally different, although that is why I made the distinction between the mom and kids part and the part of Medicaid that overlaps with Medicare, which is fewer people but large dollars, although that is probably the worst functioning part of all the areas in terms of functioning, which is the dual eligibles, in my opinion.

So, I appreciate the concerns that have been raised, I just wouldn't want you to think that where it is now means it gets anything like good attention. I mean, it really is the stepchild of the Agency.

Mr. ROPER. This is a classic case of the old expression, "Some of my friends are for it, some of my friends are against it, and I agree with my friends." I happen to disagree with the notion of moving Medicaid out of HCFA, but to make Gail's point, I think a fair esti-

mation of my time as HCFA Administrator, I spent about 15 percent of my time on Medicaid and 85 percent on Medicare.

Mr. GREENWOOD. The gentleman's time has expired. The Chair recognizes himself for 5 minutes.

Dr. Wilensky, you talked about what you referred to as the pay-and-chase methodology. It seems to me some claims are paid immediately without any question, some are delayed and then not paid, some are delayed and then paid, some are denied right off the bat, I assume.

Do we know anything about the percentages of claims that are rejected or delayed because a "t" isn't crossed and then the provider amends, corrects the claim, and then it is paid? Do we know that, in fact, there is a substantial savings resulting from the ones that are screened out before they are paid?

Ms. WILENSKY. I don't personally know that. This is information that the Agency may be able to provide you. I don't know whether it is readily available. But in some ways, it is worse than that because—the reason it is worse than that is that in order to try to not have to chase—because they don't have any money, among other things—that you have a series of automated screens and documentation requirements, and they differ from contractor-to-contractor.

I think there are times when having different coverage decision-making at a local level gives you a benefit because medicine is practiced different ways around the country. This kind of differentiation, which has to do with amount, scope and duration, brings little gain and an awful lot of frustration, but I don't know those numbers. I think that would be a reasonable thing to ask the Agency to provide you with.

Mr. GREENWOOD. Thank you. Direct a question to Dr. Roper, if I could. Several points in your testimony, you state that HCFA staff are stuck in a fee-for-service mentality. Discussing the managed care option for seniors, you state, "A hostile environment and ambivalence toward an integrated or managed care approach doomed its implementation. In fact, the way it was created was directly linked to its downfall as it resulted in so many onerous regulations on health plans." Could you elaborate on that?

Mr. ROPER. Sure. I think that the point about the staff is one that is a simple observation, that most of the people came to the Agency at a time when it had responsibility that was only fee-for-service. Their life experience and training and so on is rooted in that, and that is important for the fee-for-service part of Medicare. But there is this other part that requires different understanding, different expertise, different mindset, et cetera, and that is the argument that I am making.

Just to add a point, it is going to be awfully hard to do what I am suggesting because, to hire people from the private sector at a time when the Agency is under fire, but also at the pay levels in the Federal Government compared to what they can make in the private sector, that is a real challenge. So, it is glib to say what I am saying, but it is awfully hard to do it.

To the other point, Medicare+Choice, when it passed the Congress, and the predecessor programs that went by slightly different names, were the product of compromise, and the legislative process

brought to the eventual legislation lots of built-in inconsistencies and things that were hard for anybody, even very well-meaning colleagues that are here, to implement, and those very inconsistencies were codified in the regulations and the oversight and so on. And I think we have succeeded in producing—collectively, we have succeeded in producing a program that is almost impossible to administer, and surely not attractive to the folks in the private sector.

Mr. GREENWOOD. I agree with Mr. Brown on the urgency of fixing Medicare+Choice, I think it should be a very high priority.

Let me ask a very, very specific question about AWP. In looking at this issue, we have these drugs that are covered by Medicare, that are reimbursed at statutorily determined phrase, "average wholesale price," and yet it appears quite obvious that there is nothing average or wholesale about that price and it is based on absolutely nothing, it is a fiction. It appears to be designed fundamentally to create the largest spread possible between what the physician provider actually pays and what Medicare is reimbursed in order to get market share, and it is costing us billions of dollars. It doesn't reach the pharmaceutical companies because they are not making any of the money, it is enriching the providers. Anybody know how to fix that? Obviously, we have to look at the whole issue of practice expense, but I would appreciate anyone's thoughts on what to do about this.

Ms. WILENSKY. The real question is why you are not paying actual acquisition, and the answer is only because of the concern that too many physicians would drop out because they are claiming they need the cost subsidy from average wholesale price in order to continue participating.

There probably are some real problems in terms of the practice expense portion, and perhaps even in terms of the actual amounts we are paying physicians for administering certain chemotherapies or other covered drugs.

It is hard to come up with a good rationale for why we should do it by reimbursing at what we know, or what we have good reason to believe, is not actually the acquisition price.

Mr. GREENWOOD. It is not even clinically right because it is driving the use of particular products that may or may not be indicated. It is driving the frequency that they are administered.

Ms. WILENSKY. It is a very clumsy way to fix what is an issue that you need to look at at the same time. I don't want to have it be the recommendation is actual acquisition price and ignore the other issue. There is a serious issue, but what we are doing now does not make much sense.

Mr. GREENWOOD. My time has expired. The gentleman from Florida.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. GREENWOOD. Did anyone else want to respond?

Ms. DEPARLE. No, I think we all agree.

Mr. GREENWOOD. All agree. Okay, fine.

Mr. DEUTSCH. I wanted to shift a little bit and talk about Medicare and the administration that you do, that all of you have done. It is not an insurance plan. It functions in many ways like an insurance plan, but it is still a Government plan in terms of having public policy goals. And that changes. And I want to focus at least

in an area of screening and prevention. And when you are making those decisions, you are not making those—an insurance company would make those decisions and just doing a cost-benefit analysis of it.

Each of you, independently, No. 1, are there goals, public policy goals that we should be using HCFA Medicare for that we are not using it for today, No. 1? And, No. 2, specifically in the prevention side of the health care equation, what else can we do? And, again, as all of you know—I mean, the utilization is shockingly low, so what else can we do? And as part of that, is it driven by reimbursement levels? So, if we can kind of talk about—is there things that we can do with Medicare on the public policy side of it, that we are not doing, and then, more narrowly, within the area of screening/prevention, what else can we do that we are not doing today?

Ms. DEPARLE. I think there is a lot we can do to promote quality in the health care that Medicare beneficiaries receive, and I will give you an example of that. In September of this past year, the Agency published an article—some of the clinicians in the Agency published an article in the Journal of the American Medical Association, where they had looked on a state-by-state basis and picked out some clinical indicators of things that are beyond controversy among clinicians, things that people who experience certain conditions need to receive—beta-blockers after a heart attack, that kind of thing—and then looked at all the data that Medicare has to see whether they were receiving it or not, and there was quite a wide disparity among the States as to whether beneficiaries in certain States were getting it or not, and there is no reason why that should be the case. Medicare covers these things.

So, what the Agency is trying to do now is to work with the peer review organizations that Dr. Wilensky talked about, to drive those numbers up and to make sure that beneficiaries are getting the care that they need.

It could also be used in the medical error context, which is something that Dr. Roper is working on, I know, through his work with the National Quality Committee. What I have been talking about are errors of omission, but there are also errors of commission, and Medicare might be able to play a role there as well in helping to reduce the number of medical errors. So, I think there is a lot we could be doing in terms of quality to make sure that having Medicare means more than just having the health security, it means also improving your health status.

Mr. ROPER. If I could just add, I strongly agree with the need for a much more intentional focus on improving quality in the program. I think we have begun to make some progress of late. It needs to be extended.

On the prevention notion, the key obstacle, I think, to further progress is we are locked in a process whereby changes to the program, prevention in this case, are scored for their short-term budgetary costs, and any longer-term cost-savings that might accrue to the program are way in the outyears, and with the current rules administered by CBO, whatever, we just never can show the appropriate value to the program, the value to American seniors. And, furthermore, I think we need to step back and say, much of what is done in prevention is really not about saving money, it is about

improving people's lives and the quality of those lives, and we ought to just admit that and recognize that we are going to spend some more money in accomplishing that.

Ms. WILENSKY. Let me direct a comment or two—I think the other part you address, which is the very low use of the currently covered benefits because while I agree that we certainly ought to be willing to have the discussion even if it doesn't appear to be cost-effective in a reasonable timeframe, is it appropriate to cover a preventive benefit because we believe it will have an effect on quality of life? But we need to give equal thought to actually making use. I assume you were referencing to at least numbers that I have looked at, which are the pitifully low use of mammography, which is—I think the last time I looked it was about 32 or 33 percent—very low rate, and that is, unfortunately, much harder than passing legislation to provide a new benefit. And it may mean working through either the AMA or some of the specific colleges, of trying to do something that when advanced directives was passed in the early 1990's, there was a big effort to have an outreach to work with different groups that interact with seniors, to try to encourage the use of some of these preventive benefits, to make use of public service announcements in a way that has coordination, as we do with some of the healthy baby PSAs that are used. But I think we need to recognize that we have ample documentation that coverage and the payment per se is a first step, it doesn't seem to solve the problem particularly in some of the efforts that have taken a lot of work by the Congress to get covered.

Mr. VLADECK. I was going to say that Dr. Wilensky mentioned earlier her efforts to reform the PRO program, which I think is one of the more successful changes in HCFA in the last decade or so. The only thing she didn't succeed was getting them to overcome their extraordinary institutional aversion to publicly reporting what it is they do, or taking credit for what they do. But as this committee continues its oversight and monitoring function, particularly around these issues of quality but then into the issues of prevention and provider education, I think there has been, over the last decade, an awful lot more accomplished than anyone has acknowledged or taken credit for, or talked about. And I would encourage you to take a look at what, beginning in the first Bush Administration through the Clinton Administration into this current Administration, that part of the program has done, which no one has given very much attention to but has been enormously positive and sets the model, as Gail suggested, for some other ways you might change the Agency in the future.

Mr. DEUTSCH. Mr. Chairman, I know we are on the last round, could I just very quickly ask one final question?

Mr. GREENWOOD. You may.

Mr. DEUTSCH. Thank you very much. You have all talked about this quality thing. While we are talking about it—obviously, I can talk to you afterwards, but while we are in this setting—you mentioned the betablocking specifically. It just seems crazy, so how do we change it? I mean, you know——

Ms. WILENSKY. This is not just a Medicare problem. The first thing to recognize—and I will turn it over to the real doctor on the panel—is that what we are aware of now, increasingly aware of, is

the systems and quality problems in how health care is delivered in this country, and we spend a lot of time sometimes worrying about whether things are slightly better in fee-for-service or managed care, and not focusing on that. In both of these places, six or seven out of ten times, somebody might not get the care that is regarded as appropriate by a clinical expert, so that it is a countrywide issue of how to deal with getting the right care.

Mr. DEUTSCH. I don't want to take anymore time. I guess I would just say, though, that one of the things that maybe we have been thinking of, if we aren't reimbursing for the wrong care, maybe providers would all of a sudden thinking pretty quickly what is the appropriate care. I mean, in other words, HCFA has been so incredibly creative in terms of getting people to make choices based on incentives, and the success story of all four of you has been an amazing success story. I mean, Dr. Vladeck pointing out if HCFA was run the way the Federal Health Insurance Plan, we would be at zero-life expectancy in the plan. And all four of you, I think, have specific records that you each can be very, very proud of in terms of. And I guess maybe this aspect of health care in general—I mean, the creative energies that you have had, you have used basically to do cost-containment. I mean, that is where most of the creative energies have been done. And I think maybe we really need to shift some emphasis and use creative energies for quality of care type issues and, beyond quality of care, prevention as well.

Mr. ROPER. I can't resist saying, in 30 seconds, you are right and we need to do it. It requires much better information systems, not just within HCFA but within our health care system, broadly speaking, to accomplish that.

And the other thing it requires is that purchases of care, especially in this case, public purchasers need to use their clout to demand quality, and I think we need to, with your prodding, get HCFA to be much more focused on that, but recognize that what will happen is a push-back from the doctors and others who are threatened by that.

Mr. VLADECK. This is a whole other debate, but purchasers can leverage quality except at the margins. All the data we have suggest doctors practice medicine the way they think they ought to practice medicine, and they want to do a good job, and there are techniques in terms of education and professional communication and professional leadership some of them developed in the PRO program, but you can't improve the quality of medicine the way you want to through manipulation of financial incentives. You have to appeal to the higher motives which drive the decisionmaking of most physicians.

I think we have got a lot of experience in public and private programs to that effect, and I think that is worthy of another very big discussion because I think there are important responsibilities. But at the end of the day, it is not payment that is going to drive it, it is a whole set of different incentives, which is why some people become doctors as opposed to businessmen or other.

Mr. GREENWOOD. Mr. Pitts has arrived. Would you care to—recognize Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. I am sorry I was in and out. Dr. Vladeck, thank you very much for your report, it is very

helpful. You mention in your report how fraud and abuse activities have created the impression of a police state. Providers in my district have mentioned their concern that if they make an honest mistake, they will be penalized or that they are guilty until proven innocent. Certainly, no one in this room would argue that we should not do everything in our power to root out true fraud from the system, but do you think that these efforts have gone too far, or that this is another area requiring reform?

Mr. VLADECK. Well, again, I think we have spoken about this already, and I think Ms. DeParle spoke to it effectively well. The fact is that I think the large majority of physicians in the United States believe that they are at risk of going to jail if they fill out a Medicare claim incorrectly, and that is simply not true. And so there is some basic educational investments and basic informational investments that need to be undertaken. They are to some extent resources, but to some extent a matter of policy and approach.

I do believe that in a society like this one, in every aspect of life, we have to strike a balance between having in place the basic rules and the basic systems and the basic law enforcement capabilities and the basic detection capabilities to protect the overwhelming proportion of citizens who are honest against crime, without becoming a police state. And that is just a balance that you have to strike all the time. And I think we have to be more open in our discussions about the need to strike a balance like this relative to program integrity in health care as well as everything else. You don't want a system that is 100-percent foolproof because then nobody would ever be able to have any time to see a patient. You don't want a system that is as wide open as things were in the early 1990's in parts of the Medicare program, where Mr. Deutsch read about some of the experiences we had.

And I don't know that there is a clear answer to this, this is just a constant balancing that all of us, I think, have to take responsibility, and recognize there is a tendency to oversimplify this, to put it all in rhetoric to say "these guys are all good guys, these guys are all bad guys." I think particularly when you talk about issues of law enforcement and so forth, the need to have sort of a reasoned balanced discussion of it is often contrary to the dynamics of the process, but that is where we need to come out. We are talking about taxpayer dollars. We are talking about a track record with very, very significant problems. On the other hand, we are talking about no one disagreeing that the overwhelming proportion of all providers in the system are basically well motivated and honest, and you don't want to make their lives anymore difficult than they already are, and I think the issues of communication, education and openness of discussion are a very important part of that process in dealing with that.

Mr. PITTS. Do you—and anyone on the panel can respond—do you favor a more open or more closed process at HCFA?

Mr. VLADECK. Well, I would say again, I think we have to be much more honest and more direct and open about these things.

Ms. WILENSKY. I think one of the frustrations that I hear about is that people can't—providers can't seem to get clear answers of how do they bill, and there has been a lot of debate about, well, if you told them various kinds of approaches or screens, everybody

would go up to the screen—it seems to me that you ought to know how to bill and what the rules are, and if you were to call in to your contractor's office four times in a row, that you would get the same answer. What people claim is that when that happens, they are subject to getting different answers for the same kind of procedure, and that while they may hate the decision of a private insurer on a particular issue, they are quite confident that if they call in four different times, they will get exactly the same hated answer each of those four times.

So, I think there are ways that we ought to be able to have the providers know, here are the rules, follow them. If you don't, here are the consequences, and to have a clear understanding about what those rules are.

Ms. DEPARLE. I just wanted to make one point about what Dr. Wilensky said. There is software that the Agency uses to edit claims, and there is one package of that software that was implemented probably during Dr. Vladeck's tenure sometime in the early to mid-1990's. At this committee's behest, Chairman Greenwood's committee's request, we implemented another set of what is called off-the-shelf software that contained additional edits, and because we negotiated with a private sector company to get those edits, we could not disclose them to the physicians. But just to sort of complete the circle here, that was at the behest of this committee, and I agreed to do it because I thought we had such a severe problem that if there were private sector alternatives, that we needed to use them. So, we purchased this one, implemented it, but a condition of it—and we worked with the committee staff on this—was that we could not reveal the edits to providers whereas we had done that before, and they didn't like it very much at all. They felt that we should be telling them what the edits were. So, that kind of brings us full-circle in the difficulties and the tensions here.

Mr. GREENWOOD. Let the record show that I was not the chairman of this subcommittee at the time.

Ms. DEPARLE. You were not.

Mr. GREENWOOD. Again, thank you, all four of the witnesses. I am not sure if the Mount Rushmore analogy was appropriate, but you really are a "brain trust," and we are going to have to rely on you because you know the system best of anyone else. So, we look forward to working with you in the future. Thank you again. The hearing is adjourned.

[Whereupon, at 12:55 p.m., the joint hearing was adjourned.]