SECOND IN SERIES ON MEDICARE REFORM: BRINGING REGULATORY RELIEF TO BENEFICIARIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

MARCH 15, 2001

Serial No. 107–12

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PRINTING OFFICE

74–213 WASHINGTON : 2001

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

COMMITTEE ON WAYS AND MEANS

BILL THOMAS, California, *Chairman*

PHILIP M. CRANE, Illinois
E. CLAY SHAW, JR., Florida
NANCY L. JOHNSON, Connecticut
AMO HOUGHTON, New York
WALLY HERGER, California
JIM MCCRERY, Louisiana
DAVE CAMP, Michigan
JIM RAMSTAD, Minnesota
JIM NUSSLE, Iowa
SAM JOHNSON, Texas
JENNIFER DUNN, Washington
MAC COLLINS, Georgia
ROB PORTMAN, Ohio
PHIL ENGLISH, Pennsylvania
WES WATKINS, Oklahoma
J.D. HAYWORTH, Arizona
JERRY WELLER, Illinois
KENNY C. HULSHOF, Missouri
SCOTT MCINNIS, Colorado
RON LEWIS, Kentucky
MARK FOLEY, Florida
KEVIN BRADY, Texas
PAUL RYAN, Wisconsin

CHARLES B. RANGEL, New York
FORTNEY PETE STARK, California
ROBERT T. MATSUI, California
WILLIAM J. COYNE, Pennsylvania
SANDER M. LEVIN, Michigan
BENJAMIN L. CARDIN, Maryland
JIM MCDERMOTT, Washington
GERALD D. KLECZKA, Wisconsin
JOHN LEWIS, Georgia
RICHARD E. NEAL, Massachusetts
MICHAEL R. MCNULTY, New York
WILLIAM J. JEFFERSON, Louisiana
JOHN S. TANNER, Tennessee
XAVIER BECERRA, California
KAREN L. THURMAN, Florida
LLOYD DOGGETT, Texas
EARL POMEROY, North Dakota

ALLISON GILES, *Chief of Staff*
JANICE MAYS, *Minority Chief Counsel*

SUBCOMMITTEE ON HEALTH

NANCY L. JOHNSON, Connecticut, *Chairwoman*

JIM MCCRERY, Louisiana
PHILIP M. CRANE, Illinois
SAM JOHNSON, Texas
DAVE CAMP, Michigan
JIM RAMSTAD, Minnesota
PHIL ENGLISH, Pennsylvania
JENNIFER DUNN, Washington

FORTNEY PETE STARK, California
GERALD D. KLECZKA, Wisconsin
JOHN LEWIS, Georgia
JIM MCDERMOTT, Washington
KAREN L. THURMAN, Florida

Pursuant to clause 2(e)(4) of Rule XI of the Rules of the House, public hearing records of the Committee on Ways and Means are also published in electronic form. **The printed hearing record remains the official version.** Because electronic submissions are used to prepare both printed and electronic versions of the hearing record, the process of converting between various electronic formats may introduce unintentional errors or omissions. Such occurrences are inherent in the current publication process and should diminish as the process is further refined.

CONTENTS

SECOND IN SERIES ON MEDICARE REFORM: BRINGING REGULATORY RELIEF TO BENEFICIARIES AND PROVIDERS

THURSDAY, MARCH 15, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:10 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairwoman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
March 8, 2001
HL–2

CONTACT: (202) 225–3943

Johnson Announces Second Hearing in the Series on Medicare Reform

Congresswoman Nancy L. Johnson (R–CT), Chairwoman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold the second day in the hearing series on Medicare reform. On this occasion, the Subcommittee will examine ways to bring regulatory relief to beneficiaries and providers and restructuring the Health Care Financing Administration (HCFA) in the context of efforts to improve the Medicare program. **The hearing will take place on Thursday, March 15, 2001, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include a panel of health care providers representing doctors, hospitals, nursing homes, and home health agencies. The second panel will include Dr. Gail Wilensky of Project HOPE and other Medicare experts to discuss regulatory relief and to provide suggestions on how HCFA can be more responsive to beneficiaries and providers, possibly through agency restructuring. Any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

This hearing will be the second in a series of Subcommittee hearings intended to lay the groundwork for the development of legislation to improve and strengthen the Medicare program, including the addition of a much needed prescription drug benefit to the program. The first hearing, held on February 28th, gave members a general overview of the reform debate. This and subsequent hearings will focus on particular areas in need of reform.

In announcing the hearing, Chairwoman Johnson stated: "Regulatory relief has to be at the center of any effort to improve the Medicare program. Too many providers are spending too much time struggling with paperwork rather than treating patients. It is time to introduce a little common sense into the HCFA bureaucracy."

FOCUS OF THE HEARING:

The March 15th hearing is not intended to convey that all regulation is inappropriate—in fact, many regulations addressing patient protections, financial accountability standards, and operational guidance are a vital part of the Medicare program. However, some of HCFA's 130,000 pages of regulations place an unnecessary, and oftentimes duplicative and cumbersome burden on providers that can negatively affect the beneficiaries who rely on them for needed services. Witnesses will provide specific examples of burdensome regulations—and specific suggestions for regulatory changes that can be made to promote, rather than hinder, efforts to improve the Medicare program. The Subcommittee will be presented with testimony on how the government can do its job better, to ensure that beneficiaries are protected, and that taxpayer dollars are used wisely and responsibly without placing undue burdens on providers.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should *submit six (6) single-spaced copies of their statement,*

along with an IBM compatible 3.5-inch diskette in WordPerfect or MS Word format, with their name, address, and hearing date noted on a label, by the close of business, Thursday, March 29, 2001, to Allison Giles, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, by close of business the day before the hearing.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be submitted on an IBM compatible 3.5-inch diskette in WordPerfect or MS Word format, typed in single space and may not exceed a total of 10 pages including attachments. **Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.**

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers where the witness or the designated representative may be reached. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press, and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are available on the World Wide Web at "http://waysandmeans.house.gov".

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairwoman JOHNSON. Thank you. Today's Subcommittee holds the second in a series of hearings designed to lay the groundwork for the development of legislation to improve and strengthen the Medicare Program, while adding a much needed prescription drug benefit to that program.

The first hearing, held last week, gave Members a general overview of the reform debate. This and subsequent hearings will focus on particular aspects of the Medicare Program in need of reform.

The purpose of this hearing is to examine the impact of the regulatory burden on beneficiaries and the providers that serve them and to examine specific proposals to provide regulatory relief. Our intent is to distinguish between unnecessary regulations and those

that are critical to program integrity and effectively deterring fraud and abuse.

Our witnesses will provide us with specific examples of burdensome regulations and specific suggestions for regulatory changes that can be made to promote efforts to improve the Medicare Program.

The Subcommittee will be presented with testimony on how the Government can do its job better to ensure that beneficiaries are protected and that taxpayer dollars are used wisely and responsibly, without placing undue burdens on providers.

I thought it was important to begin with this topic because, like many of my colleagues, I hear every day from doctors and home health agencies, from nursing home administrators and ambulance companies, that the status quo is not only unacceptable, it is destructive. Not only is the tremendous explosion of payments diverting valuable nursing hours from patient care, but it is on the verge of severely reducing seniors' access to essential health care services. Indeed, if we cannot return common sense to the Health Care Financing Administration (HCFA) bureaucracy, we will lose the services of small nursing homes whose two Medicare patients are imposing loads of paperwork for all patients, the services of small home health care providers who will simply be unable to serve the dual-eligible because delayed reimbursements cause such severe cash flow problems, and the shower of paperwork imposes such significant new and unreimbursed costs.

The testimony today dramatizes the challenge this Committee faces to preserve Medicare, to strengthen Medicare, to preserve it for our seniors. As this Committee continues to prepare through our hearings and our bipartisan seminars for the development of Medicare improvement legislation, we need to keep what we will hear today from witnesses in the forefront of our minds. We must not, we simply cannot compound the regulatory problems we face. We must instead make it a priority to improve administration responsiveness to beneficiaries and providers.

We will work closely with Secretary Thompson, whom we heard from yesterday, to explore how HCFA can restructure as we work to modernize Medicare. As we think about regulatory relief, however, it is vitally important that we not allow ourselves to believe that all regulation is inappropriate. In fact, patient protections, financial accountability standards, and operational guidance are a vital part of the Medicare Program.

Just last week, the Office of Inspector General reported that inappropriate Medicare claims had fallen to 6.8 percent from 14 percent in 1996. That is good news for beneficiaries who are paying the bills and for taxpayers. However, simplifying HCFA's 130,000 pages of regulations will bring these numbers down steeply, as the testimony today clearly indicates, and at the same time protect seniors' access to quality care.

While we must balance accountability and relief, as we will hear from witnesses today, we must move forward in developing legislation, and I am confident that as we work together, we will get it right. No matter what shape a modernized Medicare Program ultimately takes, we all know that one of the most important measures of success will be whether we can protect program integrity while

ensuring that health care providers can focus on patients rather than paper.

I would like to recognize now Mr. Stark.

[The opening statement of Chairwoman Johnson follows:]

Opening Statement of the Hon. Nancy L. Johnson, a Representative in Congress from the State of Connecticut, and Chairwoman, Subcommittee on Health

Today this Subcommittee holds the second in a series of hearings designed to lay the groundwork for the development of legislation to improve and strengthen the Medicare program while adding a much needed prescription drug benefit to the program. The first hearing, held last week, gave members a general overview of the reform debate. This and subsequent hearings will focus on particular aspects of the Medicare program in need of reform.

Today, there are more than 130,000 pages of Medicare regulations. That's four times the number of IRS! This regulatory burden is a consequence of Medicare's administered pricing system, which requires government micro-management of health care. Certainly, this is not all the fault of the Health Care Financing Administration (HCFA). Indeed, Congress has enacted significant Medicare legislation in three of the last four years.

The purpose of this hearing is to examine the impact of the regulatory burden on beneficiaries and the providers that serve them, and to examine specific proposals to provide regulatory relief. Our intent is to distinguish between unnecessary regulations and those that are critical to program integrity and effectively deter fraud and abuse.

Our witnesses will provide us with specific examples of burdensome regulations—and specific suggestions for regulatory changes that can be made to promote efforts to improve the Medicare program. The Subcommittee will be presented with testimony on how the government can do its job better, to ensure that beneficiaries are protected and that taxpayer dollars are used wisely and responsibly without placing undue burdens on providers.

I thought it was important to begin with this topic because, like many of my colleagues, I hear nearly every day from doctors and home health agencies, from nursing home administrators and durable medical equipment providers, that the status quo is unacceptable. Too many health care providers are spending too much time struggling with paperwork rather than treating patients. It is time to introduce a little commonsense into the HCFA bureaucracy.

As this Committee continues to prepare, through our hearings and bipartisan seminars, for the development of Medicare improvement legislation, we need to keep what we will hear from our witnesses today in the forefront of our minds. We must not simply feed the regulatory monster—we must instead make it a priority to improve administrative responsiveness to beneficiaries and providers. We will work closely with Secretary Thompson, who we heard from yesterday, to explore how HCFA can be restructured as we work to modernize Medicare.

As we think about regulatory relief, however, it is vitally important that we not allow ourselves to believe that all regulation is inappropriate—in fact, patient protections, financial accountability standards, and operational guidance are a vital part of the Medicare program. Just last week, the Office of Inspector General reported that inappropriate Medicare claims had fallen to 6.8% from 14% in 1996. That's good news for taxpayers and beneficiaries who are paying the bills. However, some of HCFA's 130,000 pages of regulations clearly cross a line and place an unnecessary burden on providers—a burden that can negatively affect the beneficiaries who rely on them for needed services.

We will have to be sensitive to this balance between accountability and relief as we hear from our witnesses today and as we move forward in developing legislation. But, I am confident that as we work together we will get it right. No matter what shape a modernized Medicare program ultimately takes, we all know that one of the most important measures of its success will be whether we can protect program integrity while ensuring that health care providers can focus on patients rather than paper.

Mr. STARK. Thank you, Madam Chairman.

Just very quickly, as we begin studying possible reforms to HCFA and its regulatory process, I think it is important that we remember that we are responsible for providing the resources to HCFA and the flexibility they need to fulfill their responsibilities. So I am pleased that you are having these hearings and that Secretary Thompson agrees with this notion and said so, I think, in this room just yesterday that he would work with us to see that we get the resources to HCFA to carry out the responsibilities with which we have charged them.

I think it is also important to note, most importantly, that Medicare regulations and policy guidance, as issued by HCFA, merely implement the laws that we—and, actually, we on this Committee—have enacted and that the relative complexity and burden of Medicare regulations rests with us, not HCFA. I also want to congratulate the Chair because this Committee hasn't met for over 6 years to review the regulations and the procedures at HCFA. And, Madam Chair, you are to be commended because we should have been doing this every year, as it used to be done years ago.

HCFA cannot operate with laws that have not been updated and reviewed, and so you are to be credited with understanding this process. HCFA can only promulgate regulations that we tell them to promulgate. They have no independent authority, which means we have to look at ourselves when we look at the problem.

I would also like to point out that, in regard to this burden of paperwork that these poor, overburdened providers face, the physicians in this country continue to be the highest-paid profession in the United States with median incomes of nearly $175,000 a year—exactly those people whom the new tax bill will help the most.

We say nothing about what we are doing to lift the burden on children who don't qualify for CHIP or the 42 million uninsured Americans who are unable to see these well-to-do physicians who are going to complain to us this morning about how tough it is to make $175,000 to $600,000 or $700,000 a year. The same is true of the hospitals. They have had the highest margins, some as high as 45 percent, on their Medicare payments, and they are going to be in here whining about it is so difficult to run a hospital. Boy, if you could run the dotcom businesses with a 45-percent margin today, the stock market would be doing a whole lot better.

We have, because of these regulations, I would like to point out, significantly lowered the improper payment rate. That is not necessarily all illegal activity. That may be mostly mistakes. But the improper payment level has dropped to 6.8 percent from 14 percent 5 years ago. That is a $12-billion saving since 1996. Madam Chair, that these tough regulations have saved the taxpayer. That is a lot of money.

Finally, I would suggest that I have heard from some physicians that they are being harassed by HCFA. I suppose that could be a good rap song, but there were fewer than 100 physicians arrested for Medicare fraud last year; just 12 were convicted. That is out of about 600,000 physicians in our country. My math shows me that that is 0.02 of a percent. Now, I happen to be familiar with the one Member of Congress that I know is under active criminal investigation. That is 0.23 of a percent for our group. So I am saying, Docs, that you are doing a lot better than Congress in terms of those of

you who are subject to arrest for fraudulent behavior, and I would count your blessings. When there are as many doctors in jail as a percentage as there are Members of Congress, or former Members, then you might have a reason to complain.

So I think that we do have to look to our own Committee and our own actions to see how we can continually improve and upgrade Medicare, which is the finest, most efficient bill-paying system in the country today. And I thank you very much for beginning these hearings, and I hope it will lead to some serious legislation that will help make our system of Medicare and Medicare reimbursement to the providers continue to be the most efficient, lowest overhead system in the United States.

Thank you, Madam Chair.

[The opening statements of Mr. Stark and Mr. Ramstad follow:]

Opening Statement of the Hon. Fortney Pete Stark, a Representative in Congress from the State of California

As we begin deliberations on possible reforms to the Health Care Financing Administration (HCFA) and its regulatory process, it's important to provide HCFA with the resources and flexibility needed to fulfill its responsibilities. There seems to be broad agreement among experts and stakeholders that HCFA's resources need to be dramatically increased. I hope we will hear from Gail Wilensky with respect to that concern later this morning.

I am also pleased that Secretary Thompson agrees with this notion and has said so in numerous public settings. We should not wait to increase HCFA's administrative budget and staffing opportunities until there is consensus on whether or how to restructure HCFA or reform Medicare. With the budget season upon us, there should be a coordinated effort for a significant increase this year.

During the last five years, Congress has significantly increased HCFA's responsibilities, without adding the commensurate, necessary resources to accomplish the work.

In 1996, the Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), the Mothers and Newborns Protection Act and mental health parity legislation; in 1997, the Congress enacted the BBA of 1997; in 1999, the Congress enacted BBRA; and in 2000, the Congress enacted BIPA. These laws added hundreds of new provisions for HCFA to implement. Yet Congress increased HCFA's administrative budget by only 2.6 percent since 1997; if you subtract out the earmarks for research projects, the increase was only 1.6 percent.

That leads directly into the point that it is also important to remember that the Medicare regulations and policy guidance issued by HCFA implement the laws that the Congress enacts, and the relative complexity and A burden of Medicare regulations reflect those laws.

In promulgating regulations, HCFA has only the regulatory authority that it is given by the Congress; it has no other independent regulatory authority. As we examine these issues today, we should also examine the complexity and burden of the Medicare statute.

There are steps we can take to improve HCFA's ability to fulfill its responsibilities under the law, while easing legitimate concerns about regulatory burden. But it is critically important that we do not do so in a vacuum. Regulations and other guidance materials are needed to protect beneficiaries from abuse and to assure the financial integrity of the Medicare and Medicaid programs.

The Department of Health and Human Services (HHS) has very recently reported that improper Medicare payments to doctors, hospitals and other health care providers declined in fiscal year (FY) 2000 to an estimated level of 6.8 percent. This level compares favorably with an error rate of approximately 8 percent in FY 1999, and is roughly half of the original FY 1996 rate of approximately 14 percent.

This continued decline in the Medicare payment error rate demonstrates the success of HCFA's efforts to reduce billing errors in Medicare over the past five years. According to the Inspector General, the significant, sustained improvement reflects HCFA's improved oversight, its efforts to clarify Medicare payment policies, and its insistence that doctors and health care providers fully document the services that they provide. Other factors have been new initiatives and resources to prevent, detect and eliminate errors and fraud in Medicare.

Many criticized HCFA when the payment error rate was 14 percent and demanded that HCFA reduce it. Now many criticize HCFA for the actions it has taken to reduce payment errors and for insisting that providers file claims accurately. It is my understanding that fewer than 100 physicians were arrested for Medicare fraud last year B and only 12 were convicted. That is out of more than 600,000 physicians across the country. I say that we should praise HCFA for its efforts to reduce Medicare payment errors, and we should ensure that HCFA does not diminish its efforts to reduce those errors still further.

Finally, while I know today's hearing is not specifically focused on HR 868, the Medicare Education and Regulatory Fairness Act, many of the providers testifying before us have endorsed that legislation. While I agree that there are some legitimate issues relating to provider regulation that need to be addressed, the over-reach of MERFA as introduced undermines the credibility of its champions. And could easily return us to the days of 14% overpayment rates.

Attached is a much more detailed list of broad ideas and principles for consideration in the debate on HCFA reform. I look forward to hearing from our panelists this morning.

1. First, do no harm

Along with Social Security, Medicare is the most effective and popular government program in existence today. It provides health and financial security for nearly 40 million persons with disabilities and senior citizens that was not available prior to its enactment.

Every major poll reaffirms the popularity of Medicare among seniors and their families. HCFA announced December 22nd that for the second year in a row, Medicare beneficiaries had rated the agency A excellent in the way it provides information, the usefulness of that information, and the courtesy and professionalism of its staff.

In 2000, HCFA went up three points from last year's score of 74 out of 100 on the American Customer Satisfaction Index (above the average Federal score of 68.6).

In addition, surveys show that Medicare is more popular among providers, including physicians, than private insurance or Medicaid.

While improvements are needed in HCFA's management of Medicare, Congress should proceed with caution and with the acknowledgment that we are examining ways to improve a program that already does well according to many objective measures and has strong public support.

2. Increase HCFA resources B and give priority to information technology (IT) modernization

We cannot discuss the problems associated with Medicare regulations and guidance without discussing the lack of resources given to HCFA to carry out its regulatory responsibilities, and to educate affected parties about the rules of the game.

In the January/February, 1999 issue of *Health Affairs*, 14 of our nation's leading Medicare policy analysts—ranging from conservative to liberal—published an open letter titled, "A Crisis Facing HCFA & Millions of Americans," regarding the lack of resources allocated to administer Medicare. The Medicare Payment Advisory Commission (MedPAC) agreed with that letter, and published it in their March 1999 Report to Congress.

In MedPAC's March 2001 Report to Congress, MedPAC makes the following points that are particularly relevent to this discussion:

> *A HCFA cannot do everything at once*. The BBA required many changes in Medicare's payment policies within a very short period. . . . *HCFA lacked the staff resources and time to fully prepare new payment systems and make necessary changes in its administrative systems*.
>
> *As a result of Congressional time deadlines, some tasks*, such as delivery of critical coding, patient assessment, and billing software to HCFA's billing agents and providers for pre-testing, and the development and dissemination of edit standards—were often delayed until new payment systems were about to go into effect. . . . *leaving providers little time to prepare*.
>
> A second lesson is that you get what you pay for. *Many of the data limitations that cause problems in establishing accurate payments for some settings are due, at least in part, to chronic under funding of HCFA's administrative budget*. Activities that help to improve the accuracy and reliability of providers' reported data—such as auditing cost reports or developing and disseminating coding instructions—have received inadequate support for many years. *HCFA's administrative expenses generally have accounted for less than 2 percent of total outlays in recent years, well below the comparable proportion of private insurers' expenses for similar activities. The lack of adequate monitoring tools and data is*

a major problem. This problem will be difficult and costly to remedy. Consequently, additional resources will be needed.

While critics of HCFA may complain about HCFA's performance, MedPAC and other independent experts have pointed out that they have been tasked with the impossible under the circumstances.

Information technology (IT) systems

We need to undertake a "Manhattan Project" in Medicare information technology (IT) to improve quality, fight fraud, and slash paperwork costs.

As we all know, HCFA's IT systems are obsolete. HCFA has tried for more than a decade to develop new IT systems, and we still haven't achieved that goal.

Without modern information systems, HCFA cannot effectively and efficiently administer the Medicare program—regardless of administrative structure or process. We cannot pay bills efficiently, we cannot limit paperwork hassles, we cannot monitor and assure coordination of services and quality, and we cannot identify fraud and abuse.

Equipment alone won't solve the problem. Information technology experts are needed, too. Problems attracting and retaining good personnel to work on IT issues are not limited to HCFA. Agencies and departments throughout the entire Federal government are having difficulty hiring and keeping IT staff. Good computer personnel can make many times more in the private sector than we can pay in the Federal government. While we may never be able to pay enough to attract and retain good computer professionals, we clearly need to do better than we are doing now.

Medicare is not alone in facing these challenges. The entire health sector needs to make major advances in this area. In general, American business spends about 7.1% of its gross company revenue per year on IT improvement.[1] The health care sector spends about 3.2%, yet IT improvements are the key to error reduction, quality improvement, and paperwork savings.

HCFA provides FREE software to physicians via the Internet to enable electronic claims filing. In addition, Medicare carriers help teach physicians how to file their claims electronically. It costs Medicare an extra dollar to process each paper claim that is filed. It's not too much to make electronic filing the default for all providers, while allowing those who may to file paper claims to do so for a fee consisting of the extra dollar that it costs to process that claim.

I have asked GAO to review current HCFA activities to develop new IT systems for Medicare, and to make recommendations on how to proceed in terms of hardware, software, and staffing. I expect the report later this Spring.

Direct Appropriations

We should consider funding HCFA's administrative budget through a direct appropriation. Currently, HCFA staffing and administration must be approved through the appropriations process, where HCFA resources must compete for scarce resources with NIH, education, and other Congressional and Administration priorities.

However, for many years, Peer Review Organizations (PROs) have been funded through a "direct appropriations" process, in which the Secretary of HHS (with OMB approval) simply transfers funds from the Medicare Trust Funds to fund the activities of the PROs.

We should consider this approach for all Medicare management functions and needs, and not just the PROs. All funds for Medicare management already are appropriated from the Trust Funds, so the only change would be to shift the oversight of funding from the Appropriations Committees to the authorizing committees.

3. Regulations Process

When Medicare began in 1965, Congress wrote:

"No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)." (Section 1871(a)(2))

The statute requires HCFA to make policy changes through the *regulatory* process, which provides for public involvement. However, HCFA for years has made policy changes and issued guidance through "manual instructions". Manual instructions are not subject to a public comment process, which has frustrated some pro-

[1] From Dr. Howard A. Rubin's A Industry Watch, 1998.

viders. In addition, because manual instructions can be issued more easily than regulations, providers feel that HCFA is overwhelming them with new policies.

Too many directives have been issued that have had to be corrected and re-issued, and I am sympathetic to rational efforts to improve coordination of the various components of policy guidance.

4. National v. Regional Policies

Throughout the history of Medicare, we have relied on contractors to establish many Medicare policies B including Medicare coverage policies.

In addition, the 10 HCFA regional offices establish separate policies on many issues, and often offer differing interpretation of national policies.

Although that approach worked well for many years, we should consider a move toward more national policies in Medicare, and minimize B as appropriate— regional variations in policies.

Clearly, we need fewer contractors processing claims, and we need to separate contractor activities along functional lines (e.g., bill paying, anti-fraud, quality, appeals, and beneficiary services) rather than geographic lines. In addition, we should continue to move toward specialized contractors for specific services, such as the four DME carriers and the five home health intermediaries.

The Congress needs to reform Medicare contracting rules, as supported by many experts and repeatedly proposed by previous Administrations, including the previous Bush Administration. This Committee should pass that legislation.

5. Information and Education

We need to do more to help beneficiaries and providers understand the rules and options under Medicare.

We must find a way to simplify and consolidate the information being provided to physicians and other providers, and to provide adequate funding for these activities.

Funding and operating the recently reinstated toll-free telephone service for providers and physicians is but one step that we can take to help increase HCFA's communication efforts.

6. Reduce Complexity of Medicare Laws

In large measure, regulatory burden is a direct result of legislative complexity. Frequently when Members of Congress criticize HCFA, they are really criticizing laws that Congress has passed and, in some case, that they have voted for.

As MedPAC has pointed out, the Congress should give HCFA more lead time to implement changes, and should listen to technical experts about the feasibility of legislated changes. For example, in the BBRA 1999, the Congress added legislation creating the hospital outpatient department pass through provision for medical technology, which greatly added to the complexity of the Medicare payment system. In BIPA 2000, the Congress added a new-technology DRG, making the inpatient hospital PPS more complex.

Too often, Congress legislates failure; yet, when the agency is unable to fulfill an impossible demand on deadline, Members accuse the agency of incompetence.

7. Payment Errors/CFO Audit

Just last week Department of Health and Human Services (HHS) reported that improper Medicare payments to doctors, hospitals and other health care providers declined in fiscal year (FY) 2000 to an estimated level of 6.8 percent. This level compares favorably with an error rate of approximately 8 percent in FY 1999, and is roughly half of the original FY 1996 rate of approximately 14 percent.

The FY 2000 payment error rate represents improper payments of $11.9 billion out of total payments of $173.6 billion in the traditional fee-for-service Medicare program.

This continued decline in the Medicare payment error rate demonstrates the success of HCFA's efforts to reduce billing errors in Medicare over the past five years. According to the Inspector General, the significant, sustained improvement reflects HCFA's improved oversight, its efforts to clarify Medicare payment policies, and its insistence that doctors and health care providers fully document the services that they provide. Other factors have been new initiatives and resources to prevent, detect and eliminate errors and fraud in Medicare.

Many criticized HCFA when the payment error rate was 14 percent and demanded that HCFA reduce it. Now many criticize HCFA for the actions it has taken to reduce payment errors and for insisting that providers file claims accurately. I say that we should praise HCFA for its efforts to reduce Medicare payment errors, and we should ensure that HCFA does not diminish its efforts to reduce those errors still further.

To achieve further reductions in Medicare payment errors, we must reduce the complexity of Medicare payment rules and improve provider education, but we must also continue to insist on the filing of accurate claims. HCFA should have additional resources to help providers file their claims properly and to monitor claims for accuracy.

8. Simplifications for Beneficiaries

We need to look for simplifications not only for providers, but also for beneficiaries. As a result of the BBA, HCFA recently established the toll-free number, 1–800–MEDICARE, that has been a great success by all accounts. HCFA should consider expanding it to become a single entry point to Medicare for beneficiaries. For example, the latest national Medicare handbook includes 14 pages of telephone numbers for beneficiaries to call with specific questions. It seems reasonable to allow beneficiaries to call one number for triage to the appropriate person or department.

In addition, HCFA should establish or support caseworkers to help beneficiaries with their Medicare problems. In the past, HCFA has relied on the contractors, but many of the problems are with the contractors themselves. HCFA now relies on State Health Insurance Counseling and Assistance Programs (HICAP) organizations to help beneficiaries. While I am a strong supporter of these organizations, they are underfunded, staffed by volunteers and cannot accommodate the demand for assistance. It is absurd for a huge public program the size of Medicare to rely on volunteers to be the main source of assistance for its beneficiaries.

We need only to look to Social Security to learn other ways to help beneficiaries—for example, Social Security has regional teleservice centers to staff their national toll-free line and help beneficiaries with their questions. SSA also has Program Service Centers to perform casework for Social Security beneficiaries with specific problems. We need a similar effort for Medicare beneficiaries.

Currently, Medicare casework is handled by Congressional offices, since no casework office exists in Medicare. We should consider whether to station Medicare staff in Social Security field offices to help answer Medicare questions.

Opening Statement of the Hon. Jim Ramstad, a Representative in Congress from the State of Minnesota

Madam Chairwoman, thank you for calling this important hearing on regulatory reform within the Medicare system.

In my meetings with health care providers in Minnesota, I hear every time about the crushing paperwork burden imposed on providers by HCFA. Why should duplicative documents and redundant forms be necessary to treat patients and obtain reimbursements?

Too many providers are spending too much time struggling with paperwork rather than treating patients. In my view, it is time to introduce a little common sense into the HCFA bureaucracy. Clearly, 130,000 pages of rules and regulations are excessive and must be streamlined.

Too often, providers are considered guilty until proven innocent and it seems that HCFA is more interested in enforcing arcane regulations than in patient care.

Our health care dollars should be spent on care not so heavily on administration. A hospital or doctor's office should spend their scarce resources on patients not on excessive paperwork.

I also believe that this unreasonable regulatory burden is delaying and even denying new technologies to seniors. This is simply unacceptable.

I certainly believe it is a necessary to have a reasonable level of documentation to prevent fraud and improve patient care. However, I believe it is time for HCFA to start focusing on working with the health care industry in a collaborative way, rather than working against honest providers in an adversarial way.

Of course, this requires a careful balancing act and I hope today's hearing will begin to shed light on this subject.

Thanks again, Madam Chairwoman for calling this important hearing. I look forward to today's testimony.

Chairwoman JOHNSON. Thank you.

I would like to call the first panel forward: Dr. Richard Corlin of the American Medical Association; Gary Mecklenburg, Northwestern Memorial Healthcare from Chicago for the American Hospital Association; Mary Ousley, the senior vice president of health services for the Marriot Senior Living Services for the American Health Care Association; and Susan Wilson, from my own hometown in New Britain, a person I have worked with many years on home care issues and I am particularly pleased to welcome here today for the National Association of Home Care.

Let me just say as you start that I do wholeheartedly agree with Mr. Stark that this is an important time for us to try to do our work fairly. We do seem to have the backing of the administration in looking at both resources and legal authority for HCFA, and I think we do need to do some serious work in that area.

Dr. Corlin, let me just remind you that because we have two long panels, you do have 5 minutes each, and then the lights will go on, as you can see there, and then we will have time for questioning.

Dr. Corlin.

STATEMENT OF RICHARD F. CORLIN, M.D., PRESIDENT-ELECT, AMERICAN MEDICAL ASSOCIATION

Dr. CORLIN. Thank you. Good morning, Madam Chairman and Members of the Subcommittee. My name is Richard F. Corlin, M.D. I am president-elect of the American Medical Association, and I am a practicing gastroenterologist from Santa Monica, California. On behalf of the AMA, I would like to thank you, Madam Chairman, for your commitment to making Medicare more effective and less bureaucratic. Physicians want to spend time on what matters—patient care—and not on paperwork.

We welcome the opportunity to work with the Subcommittee on regulatory relief, the need to modernize the Medicare Program, and to create a prescription drug benefit. The AMA recognizes that one of HCFA's most important functions is to maintain program integrity. We also recognize that post-payments audits, if they follow sincere education efforts, can ensure that improper payments do not occur.

I want to emphasize that the AMA in no way condones the behavior of fraudulent providers. We support the government's effort to root out true causes of fraud from the system.

At the same time, it is becoming increasingly difficult for physicians to comply with Medicare rules. We have reached a point where there are over 110,000 pages of Medicare rules, policies, and regulations. In a recent AMA survey, more than one-third of the responding physicians reported spending an hour completing Medicare forms and administrative requirements for every 4 hours of patient care.

We have also reached the point where physicians are creating documentation in their patients' charts not for the patient's benefit, but simply to meet the Government's demands. Extraneous documentation in patients' charts can lead to unnecessarily delayed care for the critically ill.

Tuesday night I was on call. I spent all except 2 hours of it in the hospital in Santa Monica, and the one patient who was in the intensive care unit, hemorrhaging from an ulcer, it took me 20

minutes longer to go through an unnecessarily long chart to figure out what was going on with that patient before I could get to the patient to take care of him.

Medicare requirements are not only complex, but they are constantly changing so that even carrier employees are not aware of all the current Medicare standards. In the AMA survey, 80 percent of physicians stated that carriers do not give them clear guidance on Medicare requirements with which they are expected to comply. Physicians who call their carriers face personnel who give incorrect answers, refuse to divulge what their names are, and refuse to send physicians written confirmation of the conversations so that they can be used as guidelines in that physician's practice.

In my written statement, I have described in detail the situation physicians face when a carrier alleges they have received an overpayment by mistake, and I want to stress that these situations involve carrier allegations regarding unintentional billing errors, not fraud. When fraud is alleged, HCFA requires the carrier to refer these cases directly to the OIG, and we strongly support the continuation of this policy.

To address these egregious situations, the AMA urges this Subcommittee to support the bipartisan Medicare Education and Regulatory Fairness Act (MERFA), which was recently introduced by Representatives Pat Toomey and Shelley Berkley and which currently has nearly 60 cosponsors. Under MERFA, HCFA contractors would educate physicians and providers on Medicare requirements so that fewer billing errors occur.

On a separate note, we commend Representative Stark for his recognition of the need for this education in his recent comments before the National Academy of Social Insurance.

MERFA would also provide physicians and providers with greatly needed due process rights in these post-payment audit situations and require HCFA to pilot test documentation guidelines to minimize the burden and focus on clinically relevant documentation before they are put into effect nationwide.

Recently, a cardiologist reported that when he made hospital rounds, he found two nurses taking care of patients and six nurses checking documentation, and this simply does not serve patients well.

We also heard from a critical care physician whose practice group staffs a local hospital on a 24-hour-a-day basis, and who was actually the advisor to the local carrier on coding issues. He is now going through a post-payment audit because the carrier has denied all of that physician's nighttime critical care billing charges. The idea that a patient may be critically ill during the day but not critically ill at night is an absurdity.

MERFA provides incremental, modest reforms that should provide immediate relief to physicians and providers who are extremely frustrated with the Medicare program. These changes would help ensure that patients continue to have access to a wide range of physicians and providers in the Medicare Program, and we look forward to working with Congress and Secretary Thompson to reform Medicare so that it effectively continues to meet the needs of patients now and in the future.

Thank you.

[The prepared statement of Dr. Corlin follows:]

Statement of Richard F. Corlin, M.D., President-Elect, American Medical Association

RE: Patient Care, Not Paperwork—the Need for Medicare Regulatory Relief

Good morning Chairwoman Johnson and members of the Subcommittee, my name is Richard F. Corlin, M.D., and I am President-Elect of the American Medical Association (AMA). I am a practicing gastroenterologist from Santa Monica, California. On behalf of the AMA, I would like to thank you for holding this hearing regarding regulatory reform for physicians and providers. This issue is a top priority for America's physicians, who want to spend time on what matters—patient care—rather than paperwork.

We very much appreciate the new Administration's recognition, during Secretary Thompson's confirmation hearings and in the President's Budget Blueprint, that the growing complexity of the Medicare program's rules and policies is driving physicians from the program. We were gratified that one of the President's first steps was to place a 60-day stay on the numerous Department of Health and Human Services (HHS) regulations impacting physicians that were issued in the final weeks of the last Administration, pending a new review.

The AMA recognizes that one of the most important functions of the Health Care Financing Administration is to maintain program integrity, and that post-payment audits, if they follow sincere education efforts, can be a valid way of ensuring that improper payments do not occur. In addition, the AMA wants to emphasize that it in no way supports or condones the behavior of fraudulent providers. We support Medicare's efforts to root true fraud out of the system.

At the same time, we have several concerns regarding some the most recently-issued regulations, as well as more longstanding regulatory burdens, which we have shared with the new Administration, and which we would like to share with the Subcommittee.

For example, we have reached the point where there are now over 110,000 pages of Medicare rules, policies, and regulations. In a recent AMA survey, more than one-third of the 653 responding physicians report spending one hour completing Medicare forms and meeting administrative requirements for every 1–4 hours of patient care.

We have also reached the point where physicians are creating documentation in their patients' charts often not for the benefit of the patient's care, but purely to meet the government's demands. These regulatory requirements have resulted in voluminous charts filled with layers and layers of extraneous information. All this additional documentation in patients' charts can actually result in unnecessarily delayed care for the critically ill while physicians are attempting to access the truly relevant information.

Regulatory Overload Has Resulted in Allegations of Overpayments

Due to the overly complex nature of Medicare documentation requirements, physicians are often not entirely certain if they are submitting the correct information to their carriers. Medicare requirements are constantly changing, so that even carrier employees are not aware of all the current Medicare requirements. Physicians who try to contact their carriers are faced with carrier personnel who give incorrect answers, refuse to divulge their true names, and refuse to send physicians written confirmation of their conversations upon which they can rely. In the AMA survey, "80% of physicians believe that carriers do not give them clear guidance as to the Medicare rules and requirements (with which) they are expected to comply . . ." Physicians with rural practices are 7% more likely than non-rural practices to experience this lack of communication from the carrier.

As a result, carriers and physicians understandably can disagree over the correct coding, documentation, and billing requirements. At this point of disagreement, physicians have found that under the current system, they receive no education from the carrier and that they have very few rights to contest these overpayment accusations.

Madam Chairman, I would like to give the Subcommittee an example of what physicians are faced with when a carrier alleges that a physician has received an overpayment by mistake. As background, I must stress that such situations involve carrier allegations regarding unintentional billing errors—not fraud. When fraud is alleged, the Health Care Financing Administration (HCFA) requires the carriers to refer these cases directly to the Office of the Inspector General.

(1) The carrier identifies a suspected billing error involving significant payment amounts. Without making an effort to educate Dr. Smith or other physicians about the problem, the carrier sends Dr. Smith a request for records and documentation surrounding 20–40 claims the carrier has selected. Dr. Smith sends the requested documents to the carrier for review within the very short deadline provided by the carrier.

(2) The carrier generally sends another letter (a consent settlement letter) to Dr. Smith approximately one year later. Frequently, this letter will allege an "actual overpayment amount" which the carrier uses to "extrapolate"[1] to arrive at a larger "projected overpayment amount." As an example, a carrier could allege an "actual overpayment" of $10,000 and then could extrapolate this amount to a $150,000 (or even more) "projected overpayment."

(3) Once the carrier presents Dr. Smith with the consent settlement letter, Dr. Smith has up to 60 days to choose one of three options:

Option One:

admit liability, waive appeal rights and pay the $150,000;

Option Two:

admit liability, waive appeal rights and submit additional information to ask the carrier to reduce the $150,000 to a lower projected overpayment; or

Option Three:

not admit liability and open up his/her practice to a statistically valid random sample (SVRS) in order to maintain his/her appeal rights.

To address these egregious situations, the AMA urges this Subcommittee to support the bipartisan Medicare Education and Regulatory Fairness Act of 2001 (MERFA) (H.R. 868), which was recently introduced by Representatives Patrick Toomey (R–PA) and Shelley Berkley (D–NV), and which currently has over 50 cosponsors. This bill would require HCFA contractors to educate physicians and providers as to coding, documentation and billing requirements, so that fewer billing errors ultimately occur. Passage of this legislation, independent of any HCFA reform efforts, would send a clear message to HCFA and its contractors that Congress wants them to focus on educating physicians and providers about how to bill correctly rather than to conduct heavy-handed audits of already-submitted claims. Such an approach would be a paradigm shift for Medicare contractors, whose focus has been punitive rather than preventive.

MERFA would also provide physicians and providers[2] with greatly-needed due process rights in these post-payment audit situations. MERFA would also address problems with HCFA's documentation requirements. Under MERFA, HCFA would be required to undertake four pilot projects to test documentation guidelines prior to any new guidelines being put into effect. A Section-by-Section Summary of the legislation is attached to my written statement.

At a press conference held last week by the sponsors of MERFA, we heard the following disturbing accounts of how medical care has been adversely affected by this type of regulatory overload:

- A cardiologist recounted how when he made rounds on one of the hospital floors, **two** nurses were taking care of patients, and the other **six** nurses were checking documentation to make sure that it complied with regulations.
- The same cardiologist had been though prepayment review (when payment is withheld pending review) for 793 claims. These claims were worth $50,000. The costs to the practice of processing and producing documentation and reprocessing was $44,000. The eight denied claims (for which services were provided, but for which the physician and his staff concluded that documentation did not exist) were ultimately worth $356.
- A critical care physician whose practice staffs a local hospital 24 hours a day, and who actually advises the carrier on coding issues, is now going through a post-payment audit. In years past, the carrier has cited this physician as providing laudable care; however, the carrier has denied the physician's nighttime critical care claims. Since his practice staffs the hospital 24 hours a day/7days

[1] "Extrapolation" refers to the carrier/fiscal intermediary practice of using alleged overpayments amounts to assume that all similarly coded claims during the same time period were incorrectly submitted. It is analogous to the IRS assuming that a taxpayer has made the same mistake on all of her past tax returns.

[2] "Providers" is defined as hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program. (Section 1861(u) of the Social Security Act). Ambulance Service Providers are also covered by the MERFA provisions.

a week, it is absurd to suggest that patients do not require care in the middle of the night. In fact, this 24/7 staffing resulted in the practice being singled out as substantially reducing the mortality rates in this hospital.

- In his audit, 29 records were originally requested. His alleged overpayment was extrapolated from approximately $7,000 to $340,000. To maintain his appeal rights, the physician agreed to an SVRS, which reduced the overpayment projection to $220,000, which the carrier gave his practice 30 days to pay. This demand for payment would have put this critical care practice out of business, and would have denied hospital patients access to this type of intensive care, well before this physician had exercised his appeal rights. The OIG recently released a report stating that HCFA had been incorrectly denying payments to critical care physicians. Even so, this physician was still faced with this audit and an alleged overpayment demand that would have shut down his practice.

We hope to work with members of this Subcommittee during the coming months to advance MERFA through the House. These are incremental, modest reforms that should provide immediate relief to physicians and providers who are extremely frustrated with the Medicare program. These changes would help ensure that patients continue to have access to a wide range of physicians and providers in the Medicare program in the future.

The following are other substantial AMA regulatory concerns upon which we urge the Subcommittee to take action:

Office of Civil Rights Policy Guidance on Persons with Limited English Proficiency

The AMA strongly disagrees with the "policy guidance" issued last August by the previous Administration that would require physician practices treating Medicaid patients and other public program beneficiaries to incur, at their own expense, the cost of hiring trained clinical interpreters to assist the physician's patients who have limited English proficiency.

The cost of retaining an interpreter vastly exceeds the Medicaid payment for an office visit. As an example, one physician reported recently that he had to pay $237 to hire an interpreter for a non-English speaking patient, while his Medicaid reimbursement for the visit amounted to $38. Such a policy, which also prohibits using the services of family members (who are often most familiar with the patient's history), is an unfunded mandate which is likely to discourage physicians from treating Medicaid patients. It will have the opposite results of its intention by exacerbating problems with patient access to needed physician services. There are other more appropriate ways to deal with this issue which include, but are not limited to: demonstration projects with community and faith-based organizations, allowing family members to serve in this capacity, and providing full federal reimbursement for these translator services.

This is an instance where HHS has issued a new directive without any physician or provider input. This new requirement will have substantial negative consequences on the population it was intended to aid. The AMA recognizes that valid and important issues exist regarding patients with limited English proficiency, but we have called upon the new Administration to withdraw this ill-conceived initiative and to work with the physician and provider communities to fashion a desired workable solution.

Pending Regulations Expanding the Scope of the Emergency Medical Treatment and Labor Act (EMTALA)

HCFA has been attempting to expand the scope of EMTALA to reach well beyond hospital emergency departments to encompass non-emergency inpatient facilities and hospital outpatient department care. This expansion will result in extremely serious implications for hospital-owned physician practices and outpatient facilities, which may have to maintain emergency personnel on site as a result of these guidelines and impending regulations. There are many additional issues surrounding follow-up care and transfer requirements that may also be addressed by these new guidelines.

Congress expressed serious concerns last year regarding the direction and impact of EMTALA on the physician and provider community. In fact, in the Beneficiary Improvement and Protection Act, Congress required the General Accounting Office (GAO) to conduct an important assessment of EMTALA by May of 2001. The Office of the Inspector General (OIG) also recently published a report on EMTALA which urged the HHS to create a multidisciplinary group of public and private sector representatives to address issues associated with EMTALA. This type of communication between the agency and physicians and providers is essential prior to the Agency moving forward with the promulgation of new regulations. We urge the Sub-

committee to evaluate carefully HCFA's efforts in this regard and the attendant, disproportionate burdens being placed on the country's physicians and providers.

HHS Rules on Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA)

The AMA strongly supports the principles of standardization embedded in the HIPAA Administrative Simplification provisions. However, we have urged the Administration to create a uniform compliance date of two years after the last Administrative Simplification rule is published (with exception for the individual identifier rule, which may be significantly delayed).

These HIPAA provisions are intended to address the multitude of conflicting rules and requirements imposed by public and private payers which result in physicians spending more time on the administrative requirements of their practices and allowing them less time for patient care. Initially, the volumes of regulations that comprise these HIPAA provisions will entail significant financial and staff expenditures. To minimize this burden and to realize the goals of administrative simplification, an orderly implementation process will be needed. Physicians need to know which aspects of their administrative practices need to be modified, as well as how and in what manner this should occur. Adjusting to moving targets with rolling deadlines is neither cost effective nor efficient for small physician practices.

HCFA Final Rule on Hospital Conditions of Participation for Anesthesia Services

HCFA issued a Final Rule late last year that would eliminate physician supervision of nurse anesthetists from the Medicare/Medicaid Conditions of Participation for hospitals and ambulatory surgical centers. The AMA strongly supports the position of the American Society of Anesthesiologists and the Anesthesia Patient Safety Foundation that revision of the current physician supervision requirement should be considered only after the development and review of current scientific outcomes data. We are deeply troubled by the position of the Department that the elimination of physician supervision can be presumed to be safe—without scientific proof—especially in light of the overall improvement of anesthesia safety over the past several years during which physician supervision has been required. We believe that Medicare and Medicaid beneficiaries deserve better than a mere presumption of safety that has no basis in the scientific literature.

We appreciate the opportunity to testify before the Subcommittee, and we are heartened that the Subcommittee has held this hearing to examine the regulatory burdens on physicians and providers. We look forward to working with you to craft solutions to these issues, and we believe that MERFA would provide an effective solution to physicians' most immediate concerns.

[The attachments are being retained in the Committee files.]

Chairwoman JOHNSON. Thank you very much, Dr. Corlin.
Mr. Mecklenburg.

STATEMENT OF GARY MECKLENBURG, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NORTHWESTERN MEMORIAL HEALTHCARE, CHICAGO, ILLINOIS, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION

Mr. MECKLENBURG. Madam Chairman, Members of the Subcommittee, my name is Gary Mecklenburg. I am CEO of Northwestern Memorial Hospital, a large teaching hospital in downtown Chicago. But I am here today as chairman of the board of the American Hospital Association, representing the AHA's nearly, 5,000 hospital and health system members. Thank you for the opportunity to testify.

To be clear, the American Hospital Association does not believe that all regulations are bad. But we do think government regulations should do at least one of three things: improve the delivery of health care services to patients, enhance patient safety, or facilitate the timely and appropriate distribution of Federal funds to the

health care system. Our experience, however, shows that regulations often do not achieve the desired effect. We are subject to 132,000 pages of rules that govern the Medicare and Medicaid program. That is 3 times the size of the IRS Code and its Federal tax regulations.

In addition to Medicare and Medicaid, we face rules from an alphabet soup of Federal agencies, from OSHA and the EPA, to the FDA, the FAA, and the IRS, just to name a few. We have a chart before you that helps show the more than 30 agencies hospitals must answer to.

Complying with standards of this many agencies and so many regulatory tasks is no small task, especially in our small and rural hospitals. For example, I am told that Memorial Hospital in Gonzales, Texas, a 33-bed hospital, has 20 billing staff. At my hospital, I can tell you we spend more than 3,200 staff hours per month sorting through Medicare billing requirements alone. In total, we employ more than 100 full-time staff solely to ensure compliance with a variety of regulatory requirements, 26 of whom have been added just this year. This includes new staff hired to work exclusively on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and new Medicare outpatient billing requirements.

But the impact of excessive regulation goes far beyond finances. As you know, the health care system is facing a critical, long-term shortage of nurses and other patient care personnel. We also know that one of the significant factors driving staff away from hospitals and making health care a less attractive field for students is the diminished time for bedside care and increasing responsibility for paperwork and compliance. If we are going to meet the future needs of an aging population, we have to get a scarce number of caregivers back to what they were trained for and want to do, that is, patient care.

Excess regulations also affect our patients and families who become frustrated and confused when we can't explain billing procedures or why they must answer the same question over and over again.

To tackle these issues, the AHA Board of Trustees formed a 30-member advisory committee. Allow me to share a few of our suggestions with you now.

First, implementation of regulations should be better coordinated. Hospitals have had to implement too many regulations at the same time that have required wide-ranging impact on our operations. Therefore, we recommend enhancement of the duties of the Office of Information and Regulatory Management at OMB to allow for the more orderly release of regulations to ease these transitions.

Second, hospitals must be able to challenge attempts by HHS to overstep their authority. Today, if hospitals wish to seek judicial review of a regulation, they must knowingly violate Medicare law and risk exclusion from the program. That is too high a price to pay. We are not looking to bring every disagreement to court, but when rulemaking procedures are not followed, hospitals deserve due process. Congress should enact legislation to provide hospitals and other providers with a specific opportunity to appeal decisions made by HHS on questionable Medicare policies.

Third, MedPAC should be required to include hospitals' compliance costs when recommending payment rates. Complex regulations are an increasing hospital cost. An AHA-commissioned study found that the cost of implementing HIPAA could cost as much as $22.5 billion over 5 years for just three of the rule's proposed provisions.

Fourth, paperwork requirements should be streamlined. For example, patients must fill out the 25-question Medicare Secondary Payor questionnaire every time they come to the hospital. We recommend altering this standard to require completion of the MSP every 90 days for recurring services.

Finally, Congress should enact the Regulatory Fair Warning Act, introduced by the 106th Congress. This bill would help stop the enforcement of ambiguous and conflicting regulatory pronouncements.

Though most of the examples I have given today come from my hospital's experience, I believe I speak for hospitals across the country. We need to carefully examine the impact regulation is having on our organizations. We pledge to work to make the health care system better for patients, but need the assistance of the regulatory agencies and Congress to achieve this goal.

Thank you again for the opportunity to testify, and I look forward to answering your questions.

[The prepared statement of Mr. Mecklenburg follows:]

Statement of Gary Mecklenburg, President and Chief Executive Officer, Northwestern Memorial Healthcare, Chicago, Illinois, on behalf of American Hospital Association

Madam Chairman, I am Gary Mecklenburg, president and CEO of Northwestern Memorial Healthcare in Chicago. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network, and other health care provider members. We are pleased to have the opportunity to testify on the complexity and burden of Medicare's regulations on providers.

Though Northwestern Memorial Hospital's history dates back to the mid-1860s, the Northwestern of today was created in 1972 when two leading Chicago hospitals, Wesley Memorial and Passavant Hospital, consolidated their services. Today, Northwestern Memorial is the primary teaching hospital for the Northwestern University Medical School and enjoys a national reputation as a strong, well-managed organization. The hospital is staffed by more than 5,000 caregivers, in addition to 1,200 physicians in 30 medical and surgical specialties, all dedicated to the organization's mission of putting "Patients First." In 2000, Northwestern Memorial provided care for more than 304,000 outpatients and admitted more than 35,000 patients. The hospital has a diverse patient population in its urban locale, serving patients with many ethnic and socioeconomic backgrounds.

MAZE OF REGULATIONS

As a large urban hospital, Northwestern Memorial is well acquainted with the maze of regulations Medicare and Medicaid requires us to comply with on a daily basis. Government regulations should improve the delivery of health care services to patients, enhance safety, and facilitate the timely disbursement of federal funds in the health care system. However, regulations can also have the opposite effect. Regulations that miss the mark can force a wedge between patients and their caregivers. They divert limited resources to administrative paperwork and create a morass of complicated and duplicative requirements that confuse those they are supposed to guide.

Allow me to share with you the regulatory maze that hospitals, health systems and other providers must navigate every day. In addition to Medicare and Medicaid, hospitals and health systems face laws, regulations and guidance from the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Federal Aviation Administration, Federal Communications Commission, the Internal Revenue Service (IRS), and other regulatory agencies. The attached chart depicts the web of regu-

lators to whom hospitals must answer. There are at least 30 entities issuing some type of rules, regulations or instructions to hospitals.

The Mayo Foundation estimates that we are subject to 132,720 pages of rules that govern the Medicare and Medicaid programs—that's three times the size of the IRS Code and its federal tax regulations. Besides federal regulations, hospitals must comply with state and local regulations, which can be complex and costly. For example, hospitals in California are required to meet sweeping seismic safety regulations that require hospitals at risk for collapse during an earthquake to be retrofitted, rebuilt or closed by 2008. These requirements are estimated to cost $24 billion.

Complying with this many pages of regulation is clearly no small task. In fact, some rural hospitals have almost as many billing clerks as they do beds. In Gonzales, Texas, Memorial Hospital has 33 beds and a billing staff of 20 employees. At Northwestern Memorial, our patient financial services department spends more than 3,200 staff hours per month, or 38,400 staff hours per year sorting through Medicare billing requirements alone. This year, Northwestern Memorial Hospital is adding 26 new FTEs solely to ensure compliance with regulations. This includes new staff hired to work exclusively on the Health Insurance Portability and Accountability Act (HIPAA) and our staff devoted to Quality Strategies and Management. Our estimated costs for these activities thus far, excluding space and support expenses, is nearly $5 million annually.

Hospitals are drowning in this sea of government rules and regulations. Lost is a sense of fairness, due process and common sense. And the real victims are patients, because regulatory burdens are impeding the efficient delivery of health care. Hospitals are forced to direct more and more resources to paperwork—resources that could be better used on direct patient care. It is time to make the regulatory process make sense.

We are not the only ones who feel this way. Health and Human Services (HHS) Secretary Thompson echoes our concerns. In his confirmation hearings, he expressed strong views about Medicare's regulatory overload. "Patients and providers alike are fed up with excessive and complex paperwork . . . Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses and other health professionals out of the program," he said. It is important to note that the regulatory burden is a contributing factor to the health care staff shortage the United States is experiencing—nurses, doctors and technicians are leaving health care professions in pursuit of other opportunities.

Earlier this year, the AHA Board of Trustees formed a 30-member Advisory Committee on Regulatory Reform and Relief to address the problems that hospitals face in trying to comply with federal rules and regulations. To date, the AHA has identified five areas for process reform, and four instances for refinement of current regulations. Allow me to share these suggestions with you now.

PROCESS REFORMS

Improve coordination in the release of federal regulations. First, we urge the government to better coordinate the release of regulations. In 2000, hospitals received numerous complex regulations from the Health Care Financing Administration (HCFA), OSHA, HHS, EPA and FDA, several of which required sweeping changes to our information systems. For example, to implement prospective payment systems for Medicare skilled nursing care, home health care, outpatient care, and transfers of inpatients, hospitals have had to make significant changes to their patient data collection, coding and billing systems. This is in addition to other regulations hospitals are currently in the midst of implementing, such as uniform electronic transactions standards, privacy standards and prospective payment for rehabilitation services. Such extensive and frequent systems updates are especially troublesome for small and rural hospitals that have limited information systems staff.

We believe that the implementation of regulations should be better coordinated in and amongst the various federal agencies. To that end, we recommend enhancement of the duties of the Office of Information and Regulatory Management at the Office of Management and Budget to allow for the orderly release of regulations so that providers' administrative and information systems are not overwhelmed.

Allow providers their day in court. Hospitals must also be able to challenge in federal court any attempt by HHS to overstep its authority or to enforce questionable policy in the Medicare program without following established rulemaking procedures. Today, if hospitals wish to seek judicial review of a regulation, they must knowingly violate Medicare law and risk exclusion from the program. That's too high a price to pay for the opportunity to question rules that so fundamentally affect our operations. It's interesting to note that regulations promulgated by any other agency permit a challenge under the Administrative Procedures Act. Hospitals are not looking to bring every disagreement to court. However, the law requires that

HHS issue a regulation and act within certain parameters. When these procedures are not followed, hospitals deserve due process in court. Therefore, Congress should enact legislation to provide hospitals and other providers with a specific opportunity to appeal decisions made by HHS with respect to questionable Medicare policy.

Require MedPAC to include hospitals' compliance costs when recommending payment rates. The cost of caring for patients continues to increase as a result of complex regulations such as HIPAA and greater technological advances in such areas as pharmaceuticals and blood products. An AHA-commissioned study, looking at hospital costs alone, found that the cost of implementing HIPAA could be as much as $22.5 billion over five years, for three of the rule's proposed provisions. In addition, new advances in blood filtration are expected to increase the price of blood by 50 percent.

The costs incurred by hospitals to comply with federal regulations and standards are simply part of our costs to provide care to patients. Therefore, MedPAC should be required to annually aggregate the estimated impact of a regulation on providers' payments and costs, and to incorporate this aggregated impact into the Medicare inflationary market basket update.

Consult health care professionals on rule development. Early in the development process, regulatory agencies should consult those affected by a regulation—the caregivers—so practical implementation issues and problems can be identified and resolved before a particular regulatory approach is locked in. An example of this problem is last year's ambitious implementation schedule of the outpatient prospective payment system. Despite providers' warnings, late changes to the implementation caused updated software to be unavailable in time. Fiscal intermediaries (FIs) were then unable to process outpatient claims for more than six months. For Northwestern, this meant $2.3 million in late reimbursement.

To facilitate improved rule development, agencies should be required to publicly release databases, cost estimates, assumptions and methodologies at the time notice is given of a proposed rule. Regulated entities could then conduct their own studies and analyses, and possibly suggest alternate regulatory models that would be more appropriate. We fully support Secretary Thompson's recent recommendation that HCFA pilot test new regulatory measures for feasibility and workability before requiring them of providers nationwide.

Enact the Regulatory Fair Warning Act. Today's highly regulated health care environment demands that federal rules and regulations are issued in a timely manner, and made available and understood not just by those who are regulated by them, but also by those who enforce them. Passage of bipartisan legislation similar to the Regulatory Fair Warning Act, introduced by Rep. George Gekas (R–PA) in the 106th Congress and reported favorably by the House Judiciary Subcommittee on Commercial and Administrative Law, would help stop ambiguous and conflicting regulatory pronouncements. Specifically, the Regulatory Fair Warning Act would prevent federal agencies from penalizing businesses or entities for alleged violations if:

- the rule was not published in a public document;
- the agency did not give fair warning that a type of conduct is prohibited or required; or,
- the agency had already given specific guidance that contradicts an inspector's claim that the regulation had been violated.

CURRENT REGULATIONS IN NEED OF REFINEMENT

Streamline paperwork. Much time, effort and expense could be saved if paperwork requirements were streamlined. For example, patients must fill out the 25-question Medicare Secondary Payor (MSP) questionnaire every time they come to the hospital for recurring services, such as chemotherapy or blood work. Altering this requirement to require completion of the MSP every 90 days for recurring services would be a substantial improvement. We commend Rep. Saxby Chambliss (R–GA) for his efforts in convincing HCFA to no longer require a MSP questionnaire be completed for *every* outpatient rehabilitation therapy encounter. However, the agency has yet to implement this improvement and some FIs still require completion of the MSP.

In addition, hospitals to which doctors' offices forward specimens for laboratory analysis are required to contact a beneficiary whose specimen was submitted, and collect information about possible secondary insurance coverage. Beneficiaries often react with suspicion when contacted by a hospital lab asking them personal questions. They naturally assume that their physician is handling the lab tests. Independent labs are not required to collect this information. Hospital labs should be treated no different than independent laboratories providing the same service.

Fix the costly and needlessly burdensome HIPAA medical privacy regulation. Hospitals are encouraged by Secretary Thompson's decision to re-open the privacy rule for comments and urge him to suspend the effective date and fix the rule. We believe a *better* privacy rule would benefit patients and providers alike. Many provisions in the final rule and the aggressive implementation schedule were written without consideration of the impact on patient care and the high costs of compliance. As I mentioned earlier, an AHA-study looking at hospital costs alone, found that the cost of only three key provisions of the proposed rule could be as much as $22.5 billion over five years.

The AHA has long supported the development of uniform national privacy rules. However, HIPAA's privacy rule, as currently written, is overly burdensome and its implementation schedule too aggressive. We believe concerns about the rule's complexity, costs and implementation timetable must be addressed prior to the rule's effective date.

Emergency services needed to stabilize patients should not be denied payment. As a participating provider in the Medicare program, Northwestern is required to screen any individual who comes to the emergency department to determine whether that person has an emergency medical condition or is a woman in active labor and, if so, to stabilize him or her. To adequately screen and stabilize the patient, we often employ ancillary services that are routinely available to the emergency department. Medicare sometimes denies payment for the services furnished in the emergency department because they exceed the local medical review policies (LMRPs) or utilization guidelines for coverage and frequency established by the Medicare fiscal intermediaries. However, we are prohibited from billing beneficiaries for such services unless we notify patients in advance that the service may not be covered (advanced beneficiary notice). Conversely, we cannot notify patients in advance because the Inspector General interprets this advance notification of possible non-coverage as a delay in screening and stabilization. Hospitals, caught in a Catch-22, are often left with an unpaid bill for emergency care.

To reconcile these conflicting requirements, services furnished in the emergency department should be exempt from denials based on LMRPs, and Medicare should pay for all services necessary to screen and stabilize patients.

Limit data collection to what is necessary for payment and quality. Prospective payment systems should be simple, predictable and fair. Unfortunately, the patient assessment tools for skilled nursing, rehabilitation and home health are far from ideal. In fact, HCFA has devised three separate instruments, the Outcome and Assessment Information Set (OASIS), Minimum Data Set (MDS), and MDS–PAC, which collect much extraneous information, lack statistical reliability, and are extremely burdensome on hospitals. We concur with MedPAC's recommendation in its annual report to Congress (March 2000) that "the secretary should review all post-acute data collection requirements. Each item should have an explicit rationale, and only information needed for accurate billing, risk adjustment, or quality measurement should be required."

COMPLIANCE COSTS ARE HIGH

Complying with this growing mountain of rules and regulations comes with a high administrative price tag.

At Northwestern Memorial, we take corporate compliance seriously. We have committed a great deal of time and resources to ensure that we follow state and federal regulations. We have a corporate compliance department headed by a corporate compliance officer, who is also an experienced health care attorney. The hospital's corporate compliance committee includes 10 senior officers who meet monthly to discuss regulatory changes and compliance initiatives. We have an internal audit department with a staff of six, who actively focus an increasing amount of time on Medicare-related compliance issues. Northwestern employs several outside consultants to help us prepare for review by HCFA and other agencies. In addition, we have numerous internal cross-functional task forces dedicated to ensuring compliance with regulations covering the Emergency Medical Treatment and Active Labor Act (EMTALA), coding, laboratory tests, patient observation and employee education, among others.

Besides the known expense of time and resources, burdensome regulations incur hidden costs—a prime example being the toll they take on employee morale. People choose to work at hospitals because they want to help others. The current regulatory environment buries dedicated employees in bureaucratic paperwork. In today's tight job market and shrinking caregiver workforce, we face employee exodus to jobs that involve less red tape and hold the potential for greater job satisfaction. Constantly training and educating new staff in the intricacies of these burdensome regulations is another hidden cost that hospitals must bear.

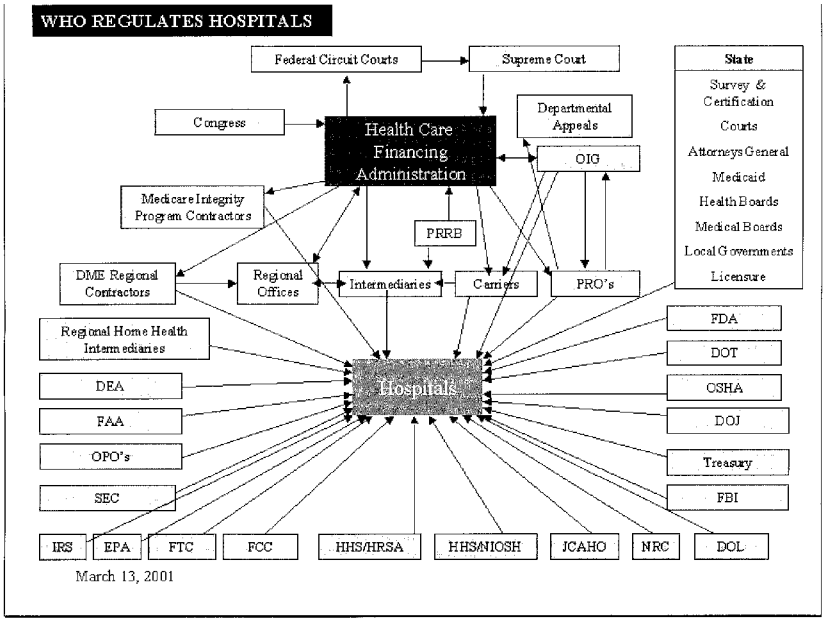
CONCLUSION

Hospitals' first priority is to provide high-quality care to our patients. Many regulations contribute to our efforts to provide quality patient care, but others simply drain resources away from that goal, placing a financial strain on providers.

Madam Chairman, we all agree the health care industry should be regulated. There are valid reasons why HCFA, the Joint Commission on Accreditation of Healthcare Organizations, the IRS and OSHA should monitor hospitals' activities. However, the strain of 30 or more organizations issuing thousands and thousands of pages of often conflicting and complex rules, instructions and laws is hurting the health of our nation's hospitals. There is no coordination among agencies that regulate providers, and rules appear to be issued in a vacuum with no regard to the fiscal consequences of compliance and the impact on our daily operations.

Though most of the examples I have given today come from Northwestern Memorial's experience, I speak for hospitals across the country, large or small. The AHA is ready and willing to continue our work with HHS, HCFA and other agencies to improve the way rules and regulations are promulgated and implemented. We pledge to do all we can to help make the regulatory system work better not just for hospitals and health systems, but also for the patients and communities we serve. But we need the assistance of the regulatory agencies and Congress to achieve this goal.

I thank the Committee again for the opportunity to describe the regulatory difficulties hospitals face. I welcome any questions you may have.



Chairwoman JOHNSON. Thank you very much, Mr. Mecklenburg. Ms. Ousley.

STATEMENT OF MARY K. OUSLEY, SENIOR VICE PRESIDENT, HEALTH SERVICES, MARRIOTT SENIOR LIVING SERVICES, BETHESDA, MARYLAND, ON BEHALF OF AMERICAN HEALTH CARE ASSOCIATION

Ms. OUSLEY. Good morning, Madam Chairman and Members of the Subcommittee. My name is Mary Ousley, and I am here today

on behalf of the American Health Care Association. I have been in the caregiving profession for nearly three decades. I am a registered nurse and a licensed nursing facility administrator.

I would like to commend you, Madam Chairman, on your vision for long-term care and for taking the time to know our profession and the care needs of the beneficiaries we serve.

I have worked both formally and informally with the Health Care Administration for many years, representing the long-term care profession. I am not here to bash HCFA. I consider the individuals that I have worked with to be not only my colleagues but also my friends.

However, there is a storm approach long-term care. We have a demographic crisis brewing, and we need to address that today. The baby boomers are retiring, the supply of care givers is dwindling, and recruitment has become virtually impossible.

Financially, nursing facilities are treading water. We are facing dual fronts with government financing care at less than cost and a staffing crisis of epidemic proportions. A primary contributor to this crisis is the regulatory oversight system. The system demoralizes care givers, burdens them with endless paperwork, and perhaps far, far more importantly, affords the long-term care professional very little respect for their hard work and dedication to the seniors of America.

I am not here today to ask for less government. I am here to ask for smarter, more accountable government.

We all know that however well intended this system for oversight for nursing facilities has been, it has failed to measure or improve quality in our Nation's nursing facilities. What was originally envisioned by the Institute of Medicine in 1986 to be residence-centered, outcome-oriented, and consistent, there is little resemblance today with what care givers deal with.

What has evolved is a regulatory system that is subjective, process oriented, a snapshot that focuses on punishment. After three decades in this profession, I can absolutely tell you that we cannot punish our way to improvement. We can only improve if we do that internally and we do it collaboratively.

Let me be clear about one thing. Chronic poor providers, if they are unable or unwilling to meet the standards, should be terminated from the program. But with such a failed system, how can we know what is the right action?

The questions before us are: What is the role of government in quality? And what reforms would garner the most meaningful improvements?

Number one, we believe that the Health Care Financing Administration must adopt new technologies that create an objective system that provides useful, real-time, accurate information to consumers and providers alike. Such technologies are being used today by health care providers to improve our quality of care. The bottom line is, as quality measurement has improved, HCFA's inspection system has stagnated.

I would like to highlight a few specific recommendations. Number one, as we move forward, allow and create a collaborative system so providers and regulators can work together. Investigators and surveyors must respect the parameters of clinical practice for

both physicians and nurses. Prevent HCFA from closing nurse aide training programs unless the deficiencies are tied directly to those programs. And implement a fair and impartial system of appeals that will dispose of grievances in an equitable way, quickly impose citations that are merited, and do away with those that are not. Allow additional care givers that can demonstrate competency to perform such tasks, such as feeding and hydration, to meet the needs of residents under the direction of a registered nurse. And please stop the punitive approach that is driving care givers and professionals out of long-term care and help us facilitate a system back to what was originally envisioned of residence-centered.

Second, as we look to the future, I think that the Health Care Financing Administration should grant waivers for States that have innovative ways to improve better oversight.

My third recommendation for reform is broader restructuring and, yes, focusing on resources. We do not believe that the Health Care Financing Administration today has all the resources that they need to get the job done as they are expected to do. And we believe as we move forward that it is imperative that we move toward one primary objective: that policy and oversight of providers be housed together with a distinct philosophy of partnership.

I have confidence that as we all work together in this new spirit of partnership, we can establish a fresh start and provide positive dialog with the interests of patients always first.

Thank you very much for the opportunity to testify.

[The prepared statement of Ms. Ousley follows:]

Statement of Mary K. Ousley, Senior Vice President, Health Services, Marriott Senior Living Services, Bethesda, Maryland, on behalf of American Health Care Association

Good morning Madam Chairman, and Members of the subcommittee. Thank you for inviting me here today to provide perspective on reform of the Health Care Financing Administration. I am honored to be here.

My name is Mary Ousley, and I am here today on behalf of the American Health Care Association. The American Health Care Association is a non-profit association representing more than 12,000 non-profit and for-profit skilled nursing, assisted living, subacute facilities, and facilities treating the developmentally disabled nationwide.

Let me briefly tell you about myself. I have been in the caregiving profession for nearly three decades. I am a registered nurse, a licensed administrator, and someone with first-hand experience on the front lines of caregiving. I am not here to beat up on HCFA. I have worked with them both informally and formally, in many capacities, and on many issues. However, it is critical that we enlist them as partners in serving the beneficiaries through a more active role in quality improvement.

I would like to commend you, Madam Chairman, on your vision for long term care, and for taking the time in the last few years to roll up your sleeves and get to know the intricacies of the care needs—and care environment—of our nation's frail, elderly and disabled population.

There is a storm approaching in long term care. We have a demographic crisis brewing that, if not addressed today, will severely threaten the quality and availability of care for the baby boomers who are now entering retirement. While this generational bubble begins to strain the long term care system, the supply of caregivers dwindles to crisis levels, and the oversight system serves to promote distrust of providers, demoralizes caregivers, and scares families.

Financially, nursing homes are treading water. We appreciate the Medicare PPS adjustments you made in BIPA last year because these adjustments are providing some stability to our Medicare patients. But it is imperative to note that nearly 70% of our residents are Medicaid beneficiaries, and that is where our real financial trouble lies.

You spoke eloquently a few short month's ago about the state of caregiving in this country, and your words have been appreciated by those hard working women who

perform a very difficult and demanding job. You said, "We're going to drive people out of the caregiving environment—because they came there to give care, not to do paperwork."

All I can say is, how right you were. We are facing a staffing crisis of epidemic proportions in every part of the United States. Turnover rates in our profession are more than 80%. Recruitment is nearly impossible. This crisis is compounded exponentially by a regulatory system that forces caregivers to focus an extraordinary amount of time on cumbersome paperwork and complex, confusing regulatory requirements.

This burdensome system is having a negative impact on patient care by driving good providers out of the business. Caregivers who enter this profession today quickly find themselves spending more time on paperwork describing their care, and justifying their actions on behalf of patients—than on actually delivering care.

I am not here today to ask for *less* government—I am here today to ask for *smarter,* more *accountable* government—government that works in the best interest of promoting and maintaining quality care for beneficiaries.

Since the Institute of Medicine (IOM) study in 1986 and the Nursing Home Reform Act of 1987 (OBRA '87), nursing facilities' daily operations have been inextricably linked to the Health Care Financing Administration (HCFA). The system of oversight that exists today—though well-intended—grew like a vine, and evolved into an ineffective bureaucracy.

The result of this evolution is that what was originally envisioned by the IOM to be a resident-centered, outcome-oriented, consistent system of oversight, was implemented in a manner that meets none of those criteria, and in many cases, does just the opposite.

Today, providers face a system of oversight that is an entirely subjective, process-oriented snapshot inspection system that focuses on punishment—not quality improvement. This system bears very little resemblance to what OBRA '87 envisioned.

The current system is susceptible to political forces, and providers are caught in the crossfire. The result of the current political climate is a type of "catch-22" scenario, in which a low number of citations is interpreted as poor oversight, while a high number of citations are seen as poor care. Clearly the incentive for inspectors is to cite more deficiencies.

The subjectivity of the survey system makes it unpredictable. This means that no provider, even if they have done everything correctly, can predict whether they will receive citations on any given inspection. This helps explain the wide variation in the charts attached to my testimony.

The Institute of Medicine (IOM) in their December 2000 report "*Improving the Quality of Long Term Care,*" discovered that "forty concurrent surveys in ten states found that state surveyors were inconsistent in detecting problems related to outcomes of care . . .", and that "At the same time, states surveyors also cited some facilities for deficiencies that appeared to be a function of their high prevalence of seriously impaired residents rather than poor quality care." In our view, a system that consistently fails to measure quality has little hope of improving it.

Let me again be very clear about one point: We are not talking about *less* regulation, we are talking about *better*, more *intelligent* regulation.

We need regulation that holds, as its ultimate goal, the improvement of care quality we provide to our frail, elderly and disabled patients. We absolutely believe that the underlying concepts in OBRA'87 are sound. Yet, we as providers know that it has been the implementation and evolution of that statute— through HCFA regulation and related policy— that has missed the mark.

Dr. William Scanlon of the GAO, when asked by Senator Grassley last September if the quality of the surveys and the data derived from them is reliable enough to make judgements about the level of quality provided in nursing homes, answered: "I am afraid it is not."

Over four years ago, HCFA itself, when writing about the same subjective inspection system used in hospitals wrote, ". . . there are no data supporting the link between structure and process requirements, and positive patient outcomes. The combination of process-oriented requirements with an enforcement approach that focuses on identifying providers that do not have the required structures and procedures in place, no longer represents the best available method for assessing and improving hospital quality of care."

I would ask then, how could it represent the best available method for assessing and improving nursing home quality of care?

So, the questions before us are: What is the role of government in quality? What reforms would garner the most meaningful improvements? And, how can we ensure these reforms will provide continuous improvement in quality of care while protecting residents?

First, let me state that chronic poor performers that are unwilling or unable to improve the level of quality they provide should be closed. But this is extremely hard to judge because as the GAO testified, our oversight system does not provide a reliable measure of quality, only compliance with process requirements. It also does not reward excellence in caregiving with incentives to providers that achieve great outcomes.

HCFA must adapt to new technologies that create an objective system that provides useful, accurate information to consumers and providers alike.

In many states, the oversight bodies that contract with HCFA to inspect nursing homes have applied for waivers from HCFA to use modern technology in quality measurement, to use outcome measures, or provide a collaborative approach to quality improvement. Unfortunately, all of these waivers have been denied.

The American Health Care Association (AHCA) has also worked toward meaningful improvement of the oversight system for years. We have developed software that gives providers information on their performance on key "quality indicators" (QIs) measured against national and local benchmarks. As opposed to the current snapshot, this system monitors actual resident conditions continuously over time. We have also developed customer satisfaction tools that measure residents' and families satisfaction with the care received.

However, these efforts have been stymied by HCFA's refusal to share the aggregate data (MDS) that each provider transmits to them electronically every month. Members of this subcommittee have called HCFA asking them to provide these data to facilities to improve quality internally. We have even filed a Freedom of Information Act (FOIA) suit to get this quality information, with no response. This makes little sense, and is emblematic of the overall problem where HCFA can not move, and retards quality improvement.

The bottom line is that as quality measurement technology has *advanced*, and HCFA's inspection system has stagnated—As a result it has become out of date, a more subjective and more punitive system.

It is imperative that the focus of HCFA oversight be changed to one of quality improvement in which government becomes a true stakeholder in improved quality for beneficiaries.

We urge you to adopt three types of reform of nursing home oversight:

One is making the much-needed incremental changes in the current regulatory system.

The second is to allow the regulators in the states to make advances in oversight without facing certain denial by Washington—to approve state waivers.

The third is broader restructuring of the role and responsibilities—and resources—of the HCFA. Yes, we believe they do not have adequate resources or training to do what is expected of them adequately.

With regard to the incremental improvements to the current system, the following are key areas in which minor changes could be made that would improve the quality of regulation, and also the quality of care we can provide. Below are 10 recommended steps:

1. Allow Collaboration—Create a collaborative system so providers and regulators can work together to address problems. In such a system, providers would retain responsibility to fix problems, but surveyors would play a supportive role to help providers achieve improvements. Currently, when surveyors find a problem, they are not allowed to discuss possible causes, provide technical assistance, or to suggest solutions. This "no collaboration" policy is an obstacle to ongoing improvements in quality. This is directly opposite of the approach taken with other providers such as clinical laboratories. **Solution:** Guidance must be given to inspectors through the *State Operations Manual (SOM)* to encourage collaboration and compliance-assistance toward quality improvement.

2. Allow providers to follow physician orders—All too often, providers are cited for deficiencies for simply following the orders of the residents' physician. Nursing home inspectors, who are rarely physicians and do not have medical training, often cite providers for giving medication as prescribed, but that the inspector might not understand is appropriate and, in the physician's judgement, is in the best interest of the patient. This is the only instance in health care where less-skilled personnel are allowed to second guess the orders of physicians, and nursing home care providers get punished. This system has forced providers to choose between government fines and the well being of those for whom they care. Most of the time, they pay the fine and protect the resident, but this system must be changed. Providers need to be allowed to follow the patients' doctor's orders without fear of citation.

3. Prevent HCFA from closing Nurse Aide Training Programs—We are currently operating in a severe shortage of nursing home workers. This shortage is predicted to rapidly escalate until there are far fewer caregivers than needed. In this environment, HCFA is terminating the in-house nurse aide training programs for facilities with certain deficiencies or enforcement actions (even if completely unrelated to the training programs themselves). Clearly this "punishment" only hampers the providers' ability to fix the problem and hire and train adequate staff to improve quality. Termination of Nurse aide training must only be an option when there is a deficiency directly related to the training program itself.

4. Implement a fair and timely appeals process—Currently, providers who want to dispute citations they believe have been issued in error first appeal to the agency that issued the citation. This process is not objective, and more often than not, a decision is rendered against the facility. Next, they must go through an administrative process that takes, on average, 1 year and 2 months. If appealed further, the next level, the Departmental Appeals Board (DAB) takes, on average, 1 year and 6 months. We must establish a fast and impartial system of appeal that will dispose of grievances in an equitable way, quickly impose citations that are merited, and dismiss those that are not.

5. Enlist Resident Assistants—Allow additional caregivers to help meet resident's daily needs. Currently, HCFA allows untrained volunteers to perform nursing-related tasks, but the paid staff of the facility can not help dress, feed, or even push a wheelchair (even under direct RN supervision) unless trained to become a full CNA. During this severe shortage of caregivers, and amid concern about nutrition and hydration, we need every caring hand we can find to help meet resident needs. Legislation is being drafted by Members of this Committee to address this problem through a demonstration program, and we look forward to working with you to pass this into law.

6. Remove disincentives to improving facilities—Allow new owners to improve facilities without threats of closure due to previous problems. Today, a new owner who purchases a troubled facility inherits the track record, fines, enforcement penalties, and the termination status of the previous owner. In some cases, facilities have been closed within months of the takeover due to compliance problems that were cited before the turnover. This policy discourages companies from taking over problem homes and improving care. The government should work towards improving care for residents—not prevent it. A positive step forward would be to allow a new owner to start with a chance to improve care.

7. Spend fine money improving care for residents—Funds collected from nursing facilities through fines for care problems should be spent on fixing the problem, not sitting in state and federal coffers ready to be diverted to other purposes. In the last 2½ years, funds collected from nursing facilities by states alone amounted to over $20 million—and this does not include a large amount of federal fines. The overwhelming majority sits in state coffers and is not spent on the improvement of care. This is a significant amount of money to take from the facilities that need it most, and unconscionable to allow it to go unused for care improvement. The federal government should mandate that fines collected from troubled facilities be spent improving care in those facilities. HCFA must review and find appropriate citation levels for fines. At what level is correction less desirable than punishment?

8. Prevent mandatory termination—Current law dictates that if a facility has been cited for substantial deficiencies, the clock starts running, and they must be found in compliance within six months or face mandatory termination of their Medicare certification. This may sound reasonable, but the effect has been that homes fix all problems cited in the initial survey, but have very minor new deficiencies in follow-up surveys—for which they are terminated. Most homes cannot remain open without being paid, and therefore residents are forced to give up their home. The statute must be changed to allow providers and regulators to consider other options for the residents' benefit, and to give residents and their families more voice in those decisions.

9. Prevent the labeling of Chains—It is inappropriate to label all facilities that have common ownership as poor performers just because of the shortcomings of one facility. This is misleading to consumers and in no way fosters care improvement. "Guilt by association" should not be tolerated, nor allowed.

With regard to the second issue, I can be brief and keep it simple. The oversight system works best when people closest to the beneficiary have a stake in the decision making process. HCFA does have the authority to grant Medicaid waivers to states, and should approve good waivers. HCFA should also be granted similar au-

thority for oversight of dually-certified providers who serve Medicare beneficiaries as well.

Lastly, in terms of broader HCFA restructuring, we feel it is imperative that any new structures put in place be targeted toward achieving two major goals. The first is that policy and oversight for providers of care be housed together, but with a distinct philosophy of partnership. That government be a real stakeholder, accountable with providers and dedicated to working collaboratively to improve quality for beneficiaries.

The second major goal must be that the continuum of long term care be made more seamless so that the mass of baby boomers needing benefits can access services in a clear, rational manner. As the needs of seniors shifts the benefits should follow the individual without excessive paperwork and hand-offs between regulators.

In the final analysis Madam Chairman, it is imperative that the HCFA of the future have the resources and the structure to meet the needs of the millions of retiring seniors as the system meets the challenge of this demographic boom.

I have confidence that government and health care providers seek the same goal of ensuring quality care. With a new Administration, new leadership at HHS, HCFA, and even right here on this Committee, we look forward to establishing a fresh start, and a new, positive dialogue in which caregiver and regulator alike always puts the interests of patients first.

Thank you.

Figure 1-1: Average Deficiencies per Facility by Region

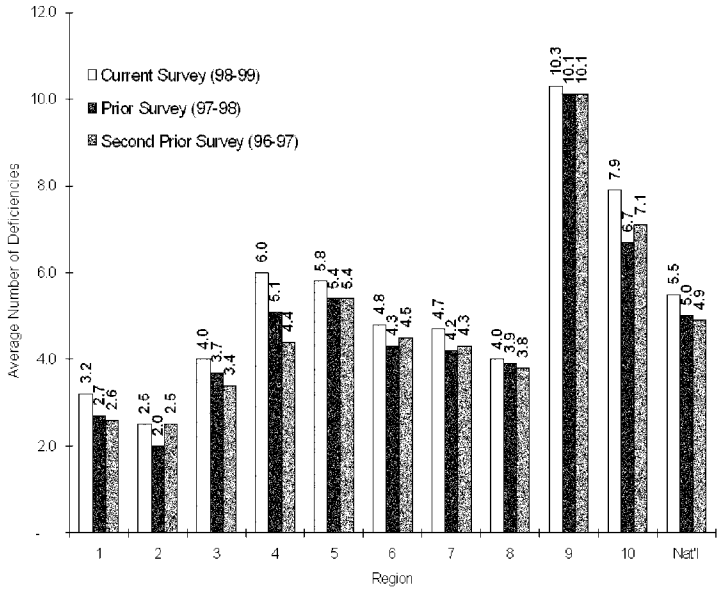
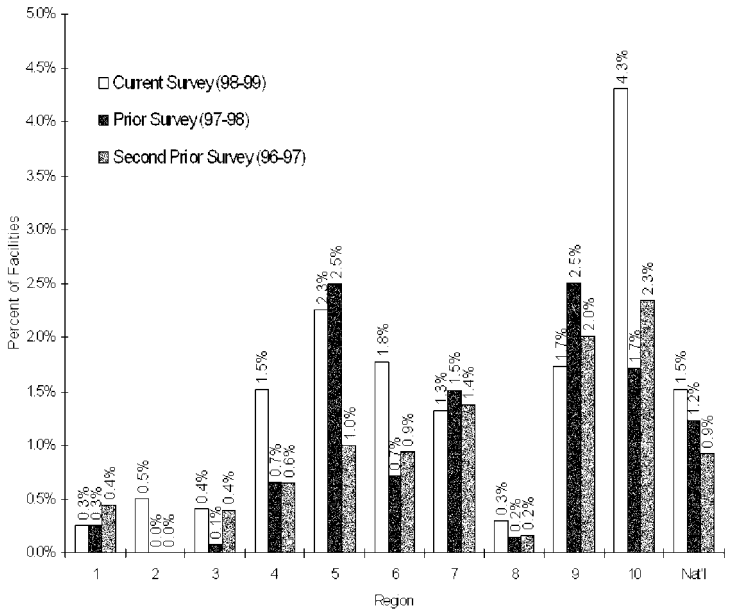


Figure 6-1: Immediate Jeopardy Rates by Region



Chairwoman JOHNSON. Thank you very much.
Ms. Wilson.

STATEMENT OF SUSAN WILSON, R.N., M.P.H., VICE PRESIDENT, CLINICAL OPERATIONS, AND CHIEF OPERATING OFFICER, VISITING NURSE ASSOCIATION OF CENTRAL CONNECTICUT, INC., NEW BRITAIN, CONNECTICUT; PRESIDENT, BOARD OF DIRECTORS, CONNECTICUT ASSOCIATION FOR HOME CARE; AND MEMBER, NATIONAL ASSOCIATION FOR HOME CARE

Ms. WILSON. Thank you, Madam Chairman, Representative Stark, and Committee members, for inviting me to present testimony today on behalf of Medicare beneficiaries and their home health providers. I am Susan Wilson, vice president of clinical operations for VNA of Central Connecticut, president of Board of Directors for the Connecticut Association for Home Care, and a Member of the National Association for Home Care.

In preparing for this testimony, we provided you with extensive written testimony in reference to the issues that face us today. If you refer to Attachment 1, it references the 8,000 pages of regulation under which home care is presently working, which was published just between June 1999 and March of this year. It primarily addresses the two most significant regulations impacting home health care today: the Outcome Assessment Information Set, or

OASIS, and the implementation of the prospective payment system.

I would like to just highlight a few areas, one of which, obviously, is the overall concern for the prospective payment system. The stringent payment limits that we experienced under an interim payment system resulted in the closure of approximately 3,400 agencies, and NAHC's preliminary PPS reveals that 45 percent of the remaining agencies are now reporting losses and difficulty in billing. It is understandable that with any new system there are going to be problems; however, the extent of the problems have created a huge impact on cash flow and an overwhelming environment of frustration. We literally have requested hundreds of clarifications from HCFA in reference to the regulations, and essentially they have remained unresolved.

Under PPS, we are mandated to refer to a common working file which was intended to provide us with information regarding the beneficiaries and the benefits they have utilized. It is, however, cumbersome to use, as some providers do not have access to the common working file, and the information that is there is frequently difficult to access, untimely, and inaccurate.

Home health agencies also have difficulty in processing claims. When subject to medical review, they may be denied in part or in full, and HCFA has issued no instructions for what we are to do with partial denials. Also, there are errors which occur, human errors which occur in the processing of claims, and it can take up to an additional 30 days to resolve these, if not more.

Also, beneficiaries are now receiving Medicare summary notices which explain the changes; however, we found that they often overstate the information by as much as 10 times. Notices have been received in which the sum of the episodic payment and the charges are lumped together, giving the appearance that the home health agency has been overcharging or has been overpaid. Although HCFA is in the process of correcting this information, there is no plan to suspend these notices.

Just as the beneficiaries receive notice, we also receive a notice called a remittance advice report. They are fraught with errors and are often incomprehensible, leaving the reports of little value to the providers.

Finally, the case mix adjustment system which is presently used is difficult to use, at best, and found to be slightly better than 30 percent accurate. Changes are definitely needed in this to reflect more in terms of clinical care and clinical factors rather than the service provision itself.

In my own agency, we have had the great fortune of having a highly skilled staff that provide acute clinical interventions and also extensive coordination to the community. I bring to your attention an example of a 102-year-old woman in our community who had pressure ulcers due to an ill-fitting brace. Our intervention was requested twice a day, and the related supplies were extensive. Today, that wound is healing, the family has once again resumed the majority of her care, and inpatient care has been avoided. However, the average cost of supplies was $680 per episode, although we were only reimbursed approximately $50. The agency sustained an average loss on a total reimbursement of $1,410.

We have provided you with a list of recommendations that would help in most of these regards. I do bring to your attention in particular the elimination of the mandatory 15-percent cut.

There are other issues which we face: an extensive assessment form, which in combination can be upward of 20 pages and duplicative in nature. The other issue which we face has just come upon us: the home health advanced beneficiary notice. This is primarily intended for duly eligible clients. We have found that HCFA failed to provide accurate instruction in a timely manner. It has been very costly for agencies to provide, the forms are confusing, and, in particular, we are asked to provide this information and submit claims on services that we know full well are not provided, for example, home health aide services only. We also have to deal with medical claims reviews, technical denials, and sampling methodology.

In conclusion, on behalf of the National and Connecticut Association for Home Care, we recognize the workload that HCFA presently faces, as we all do. However, it also indicates longstanding operational weaknesses, but we look forward to working with the Committee and with HCFA to help resolve these and would hope in the future that we can work together. I am deeply honored today by the opportunity to represent not only the work of home care providers throughout the Nation but, more importantly, the interests and concerns of the sick, the frail, and the elderly. And I thank you once again, Madam Chairman, and the Committee.

[The prepared statement of Ms. Wilson follows:]

Statement of Susan Wilson, R.N., M.P.H., Vice President, Clinical Operations, and Chief Operating Officer, Visiting Nurse Association of Central Connecticut, Inc., New Britain, Connecticut; President, Board of Directors, Connecticut Association for Home Care; and Member, National Association for Home Care

Thank you, Madam Chairman, Representative Stark, Committee members, for inviting me to present testimony on ways to bring regulatory relief to beneficiaries and providers and restructure the Health Care Financing Administration (HCFA). My name is Susan Wilson. I am Vice President of Clinical Operations and Chief Operating Officer of the Visiting Nurse Association (VNA) of Central Connecticut. I am also the President of the Board of Directors of the Connecticut Association for Home Care (CAHC), the voice of homecare in Connecticut, and a member of the National Association for Home Care (NAHC).

NAHC is the largest national organization representing home health care providers, hospices, and home care aide organizations. Among NAHC's nearly 6,000-member organizations is every type of home care agency, including nonprofit agencies like the VNA, for-profit chains, public and hospital-based agencies and free-standing agencies. CAHC represents 61 providers, delivering greater than 75 percent of all home health and hospice services provided in the state.

Home health care providers that participate in Medicare are required to be knowledgeable of and comply with a vast number of statutes, regulations and policies, including Medicare coverage rules, reimbursement guidelines, and quality of care standards. However, for over the last two years, this burden has increased with a proliferation of new requirements.

In preparing for this hearing, NAHC has compiled many of the regulatory directives governing the Medicare home health program. These include the Medicare Conditions of Participation, coverage rules, standards for payment and appeals process (all found in Title 42, Code of Federal Regulations); Interpretive Guidelines (HCFA Publication 7, Appendix B); Home Health Agency Medicare Manual (HCFA Publication 11); as well as numerous HCFA Program Memoranda and Transmittals. We have included for your review a listing of these regulations and notices comprising more than 8,100 pages of instructions (Attachment 1). The majority of the listings published between the time period of June 19, 1999–March 5, 2001 principally address two most significant regulations impacting home health agencies—

the Outcome and Assessment Information Set (OASIS) for home health and the implementation of the home care prospective payment system (PPS).

In addition to the regulations and policies imposed by HCFA, home health agencies (HHAs) must comply with all other applicable federal, state and local laws and regulations. Some examples of the federal laws include:

- Occupational Safety and Health Administration (OSHA) standards for:
- protection against illness due to bloodborne pathogens;
- prevention of needlesticks;
- prevention of transmission of tuberculosis; and
- recording of work-related injuries and illnesses.
- Department of Health and Human Services (HHS) standards for:
- Health Insurance Portability and Accountability Act of 1996;
- Culturally and Linguistically Appropriate Services; and
- Limited English Proficiency Guidelines.
- Food and Drug Administration (FDA) standards for:
- Medical devices.

For the purposes of this written testimony, I will highlight several Medicare regulations and policies that impact the home care provider's ability to deliver efficient patient care. These include the requirements associated with PPS, OASIS, Home Health Advance Beneficiary Notice (HHABN) and demand billing, medical claims review, appeal of technical denials, sampling procedures for post-payment and audit reviews, branch office designation, and Medicare cost reporting.

REGULATORY BURDENS

A. PPS

Under the Balanced Budget Act of 1997 (BBA), Congress mandated a number of dramatic changes in the Medicare home health benefit, including requiring that home health move to a PPS, and imposed an interim payment system (IPS) until PPS could be put in place. The stringent payment limits under IPS, which were in place from October 1997 through September 2000, reduced home health outlays far more than expected, resulting in widespread home health agency closures (approximately 3,400) and problems for beneficiaries in obtaining access to care. The implementation of PPS represented a dramatic change in billing and payments procedures for home health agencies under Medicare. Now, when a home health agency admits a patient for services, the agency submits a request for anticipated payment, or RAP, to Medicare and receives a portion of the full payment for the 60-day PPS episode. At the conclusion of the episode of care, the HHA submits a final claim to Medicare and receives the remainder of the episode payment. Payment is based upon a series of OASIS assessment questions, which categorize a patient into one of 80 categories that are intended to reflect differences in care needs.

While Congress has made several significant BBA modifications, many agencies around the country continue to feel the financial constraints imposed by the BBA coupled with the administrative adjustments required for adaptation to the PPS.

NAHC's preliminary PPS survey of HHAs found that about 45 percent of the agencies are reporting losses and difficulty with billing their regional home health intermediary (RHHI), resulting in cash flow problems. Although it is understandable that some problems would occur in a new system, the extent of the problems has created an overwhelming environment of frustration and increased stress within the HHAs. At the same time, HHAs are experiencing record difficulty in recruiting and retaining staff needed to adequately serve the growing population of disabled and elderly patients. Financially burdened HHAs are hard-pressed to compete with other employers that offer better wages, better benefits, lighter workloads, and better hours.

HCFA has worked with the home care community to facilitate the implementation of these new regulations and policies through meetings, conference calls, Web site postings and list serves. However, due to the breadth of these changes over the past two years, these efforts have not been sufficient to ensure a smooth transition. NAHC, state home care associations and HHAs have had to request literally hundreds of clarifications from HCFA since the implementation of PPS. These clarifications pertain to several areas, including information systems, common working file, billing codes, claims review issues, explanation of benefits to beneficiaries, payment remittances, and case-mix adjustment.

Common Working File (CWF)

The (CWF) is a database that allows agencies to access information about the enrollment status of Medicare beneficiaries and their utilization of Medicare benefits. It is an important component of the Medicare reimbursement system for home health agencies because PPS bundles payment for all services related to home care

during an episode of coverage. In order to avoid duplicate billing, it is necessary that all providers of services have access to the CWF and that the CWF is actively updated. HCFA envisioned the CWF would provide accurate, up-to-the-minute information about Medicare beneficiaries, but there are problems. For example:

—When a Medicare beneficiary is discharged with services completed from an HHA prior to the 60th day of an episode, the CWF may still incorrectly show them as being under a home health plan of care thus preventing other providers (such as another HHA, medical supplier or outpatient therapy provider) from being paid for services provided during the 60-day period.

—Other providers whose services should never be considered bundled under the home health PPS rate have had claims rejected due to a combination of instructional errors and system errors.

—It takes about 10 days for the CWF, which primarily responds to regionalized queries, to verify a beneficiary's admission status from the full national database.

—Certain providers and suppliers have no access to the CWF. As a result, providers and suppliers report avoiding home care patients for fear of claims denials.

Claims Processing and Review

HCFA has been diligent in its efforts to work with home health agencies to resolve claims processing problems. In addition, HCFA has developed new procedures for medical review under PPS. Nonetheless, a number of problems continue to negatively impact cash flow.

—When claims are subject to medical review, they may be denied in full or in part. HCFA has issued no instructions for partial denials under PPS and some providers report claims being held in suspense.

—Although HCFA reports that a fix is under way, RAPs submitted by an agency that provided the initial care to a patient have been rejected when the patient transfers to another agency, and the second agency happens to bill first.

—When a provider makes a clerical error in the beneficiary's Health Insurance Claim (HIC) number, payments can be delayed for an additional 30 days in order for the erroneous information to be purged from the system.

Medicare Summary Notice Over Billing Errors

The Medicare Summary Notice (MSN), also known as an explanation of benefits, is issued to Medicare beneficiaries every month explaining charges to Medicare. The MSN is required to provide information about services and charges. However, the current MSNs overstate charge information by as much as 10 times the actual charges. Although HCFA is in the process of correcting MSN information, there is no plan to suspend the erroneous notices, causing beneficiaries to complain about excessive charges.

Some specific problems with MSNs are:

—Issuing an MSN after a single visit to the beneficiary, based on a RAP submission. These MSNs include charge information for a full episode payment.

—MSNs for final claims that erroneously report payments as the sum of episodic payments and charges, giving the appearance that the HHA has either overcharged or been overpaid by Medicare.

—MSNs include nonsensical statements and single-line listings of all services, making them cumbersome and difficult to understand.

Remittance Advice Errors

The remittance advice (RA) was designed to provide detailed accounts receivable information on Medicare payments and adjustments. Since the implementation of PPS, HCFA altered the RA in order to accommodate the changes in payment methodology. HCFA has been working on correcting remittance advice information but providers and fiscal intermediaries alike are still having problems using the RA to reconcile payments.

—Intermediaries have instructed HHAs to manually track payments since the first payments under PPS but this is time consuming and is not an adequate solution. Manual tracking does not allow agencies to determine how much they have been paid for individual patients or what amounts have been withheld and for what reasons.

—There is no indication that HCFA has a plan to address the remittance advice problems that occurred in the first six months of PPS.

At the Visiting Nurse Association of Central Connecticut (VNACC), we have found that the problems with remittance advices are further compounded because our intermediary has told us that it can adjust the RAP despite the calculated case-mix grouper. The RAP is then not reconciled until the final payment.

Case-Mix Adjustment

The home health PPS base rate is inadequate because of the budget neutrality requirement compounded by a case-mix adjuster system that needs refinement. The budget neutrality requirement for the first year of PPS artificially lowers PPS payment levels by requiring that they be based upon outlays for home health under the disastrous interim payment system. As a result, there is widespread concern that existing payment levels will fall short of agencies' actual expenditures in serving patients. The PPS includes an 80-category system of case-mix adjuster groupings (Home Health Resource Group or HHRG) that serves as the basis of determining the episode payment. The system utilizes selected OASIS data elements and features three domains, clinical/functional/service utilization and therapy needs. The reliability of the case-mix adjuster in explaining the variations in resource use by patients is slightly better than 30 percent.

There are a number of refinements that need to be made to the case-mix adjuster.

—More work must be done on diagnostic issues. Although the case-mix research only identified three diagnostic conditions (orthopedic, neurologic and diabetes), significantly impacting costs, more research is needed on other historically high-cost conditions, such as congestive heart failure, cancer and stroke.

—Co-morbidities have not been taken into account. For instance, a patient with diabetes, hypertension, and end-stage renal disease, is much sicker than a patient with just diabetes. Also, a stroke patient with Alzheimer's requires much more care than a patient whose only condition is a stroke.

—Caregiver availability is not included in the case-mix system.

—HCFA did not identify sufficient clinical factors, which resulted in use of proxy information, such as number of therapy visits and use of services prior to home health admission.

—Medical supplies, which can be very costly depending upon the medical condition and supply needs of the patient, are not case-mix adjusted. Instead, each episodic payment contains approximately $50 for medical supplies, regardless of patient needs.

—PPS requires that home health agencies provide all supplies to the beneficiary during an episode of care, regardless of whether they are on the plan of care or needed by home health agency staff to carry out the plan of care. Many of these supplies were used by the patient prior to initiation of home health services, resulting in a disruption between the patient and the prior medical supplier.

Following are some examples of case-mix and supply concerns faced by the VNACC:

The population served by VNACC is older and generally lives alone or with a caring spouse who suffers from an equal number of frailties. It is not unusual to admit a client with five (5) or more co-morbid conditions, all which significantly impact their well being, their safety and the intervention required by staff to meet professional standards of care. Under the present system of case-mix groupings, it is the primary diagnosis alone that adjusts the level of reimbursement. Many of our clients have other primary diagnoses, such as congestive heart failure, hypertension, chronic obstructive lung disease and atrial fibrillation, as co-morbidities. Because these diagnoses are not in those three diagnostic categories that produce higher reimbursement in the case mix system, the reimbursement rate is not adequate to meet the high costs of their care.

In addition, VNACC provides care to a demographically older population. Due to the provision of highly intensive, skilled clinical interventions and the extensive coordination of community resources, this agency is very successful in maintaining our older citizens in the comfort of their home rather than in an inpatient setting. One such example is a 102-year-old woman and her 74-year-old daughter, both of whom required extensive and prolonged intervention. Due to pressure ulcers induced by an ill-fitting brace, our intervention was requested initially two times a day and the related supplies were extensive. Today, that wound is healing, the family has once again resumed the majority of her care, and inpatient care was avoided. On average, the cost of supplies was $680.60 per episode and the agency sustained an average loss on the total reimbursement of $1,410.04 per episode.

This client's 74-year-old daughter is also a client of this agency. Her story is similar. While caring for her mother, this agency also cared for her. Under the PPS system, the financial loss to this agency was $1,934.22 inclusive of $395.03 in supplies alone.

Recently, our agency admitted an elderly woman, status-post total hip replacement. Her plan of care for rehabilitation required the intervention of a physical therapist only. In addition to her recent surgery, this woman had also had a colostomy several years prior. She was totally and proudly independent in her colostomy

care. While her additional health care needs were recognized and addressed, no further intervention was required by the staff of VNACC. Under the present system of reimbursement, however, this agency became financially responsible for her ostomy supplies throughout the course of the rehabilitation plan of care.

Legislative and Administrative Recommendations

Congress should safeguard the viability of the home health PPS by:

1. Directing HCFA to continually update the CWF and make this data available to all health care providers on an expedited basis.
2. Directing HCFA to maintain a listing of outstanding PPS problems/issues complete with anticipated fixes for publication on their Web site and on NAHC's home health list serve.
3. Establishing expedited payment schedules for Medicare home health services such that initial episode payments to agencies are equal to 90 percent of the anticipated episode reimbursement amount and exempt home health agencies from the 14-day payment floor.
4. Directing HCFA to fix the errors on the Medicare remittance advice.
5. Ensuring an equitable PPS with an adequate case-mix adjuster by requiring ongoing, in-depth study and appropriate adjustments as necessary.
6. Developing a case-mix methodology to account for variation in costs of medical supplies.
7. Restricting the ability of HCFA to modify payment rates and revise the PPS case-mix adjustment system so as to prohibit any adjustments without adequate advance notice.
8. Ensuring continued care access for high-cost and medically underserved patients under PPS by monitoring the adequacy of payments, adjusting overall home health outlays as needed, and developing a more adequate system of outlier payments.
9. Limiting the responsibility of the HHA for medical supplies to those that directly relate to the patient's current treatment plan.
10. Reimbursing agencies for costs incurred in complying with regulatory and legislative requirements that were not included in the initial calculation of the PPS rates.
11. Requiring HCFA to develop criteria for case-mix adjustment corrections on a prospective basis through public rulemaking, as authorized under the Benefits Improvement and Protection Act of 2000 (BIPA).
12. Restoring the full market-basket updates for home health services that were reduced under BBA and the fiscal year 1999 omnibus appropriations measure.
13. Eliminating the mandatory 15 percent cut, in home health reimbursement scheduled for October 1, 2001, and pass legislation introduced by Senator Susan Collins (R–ME) and Representative Wes Watkins (R–OK) the "Home Health Payment Fairness Act of 2001" (S.326 and H.R.975).

B. The Outcome and Assessment Information Set (OASIS)

In July 1999, HCFA implemented mandatory use of a uniform patient assessment instrument, OASIS, for all patients served by home health agencies participating in Medicare. Under the Medicare home PPS, episodic (60-day) payments include $4.32 for ongoing agency OASIS expenses, including telephone, computer hardware, editing and auditing data entry, and supplies. During fiscal year 2001, an additional $5.50 is also added to the episodic rate for adapting OASIS forms to PPS use. The HCFA OASIS User's Manual consists of 700 pages of instructions.

This assessment instrument is required to be used for all patients regardless of payor source. While there are valid reasons to use a uniform patient assessment instrument, the extensive administrative responsibilities with OASIS must be streamlined to reduce costs, increase direct patient care time, and improve staff satisfaction and retention. HCFA has now indicated that it will be issuing to home health agencies patient-identifiable, adverse event reports and report cards on the agencies. This planned action raises numerous concerns relative to patient privacy and report accuracy. Home health agencies have had limited time to adjust to the OASIS method of patient assessment and uses of the report. Further, the use of a first generation adverse event report, which is not case-mix adjusted, is occurring without adequate training of providers and the state surveyors who will use these reports to survey agencies.

Recently the General Accounting Office (GAO) published a report, "Medicare Home Health Care: OASIS Data, Use, Cost, and Policy Implication, (GAO–01–205) which was mandated by the Medicare, Medicaid, and SCHIP Refinement Act of 1999. GAO found that use of the OASIS has made documentation of home health patient information more consistent, while adding approximately 40 minutes to the

start-of-care assessment. GAO also reported that previous studies did not capture the additional 50 minutes per OASIS needed to check and edit collected data, enter and transmit the information electronically, and train new staff. Eighty-four percent of agency survey respondents disclosed that they provide, on average, eight hours of training for newly hired staff. The GAO thinks, however, that agencies receive adequate compensation for these activities. In their opinion, the episode payment "could provide an ample cushion for many agencies, which can be used to offset the costs associated with the OASIS mandate."

With respect to privacy concerns, GAO stated that, while HCFA's policies and procedures regarding disclosure of personally identifiable information were generally consistent with the Privacy Act, they found weaknesses in HCFA's implementation of them. Among their concerns were some agencies failures to clearly inform beneficiaries of the purposes for which their information may be disclosed and failure to routinely monitor contractors and researchers use of the information. Further, GAO found little or no oversight of how effectively the state agencies and third-party payors are maintaining the privacy of OASIS information.

While the report correctly notes an underestimation of the burden of OASIS, the GAO conclusion regarding adequate financing for OASIS is based on an incorrect understanding of PPS rates. The GAO neglects to acknowledge that, while payment rates are based on 1998 utilization, those payments are reduced significantly to comply with the "budget neutrality" requirement in place during the transition to the PPS, which reduced the base payment rate by approximately 25 percent. This oversight leaves the public and policymakers with a mistaken impression regarding the level of reimbursement provided under the PPS. Furthermore, with respect to the GAO OASIS survey, the costs of newly instituted requirements, such as additional assessments beyond those required prior to OASIS, are not taken into account. These new requirements have added significant costs to agencies as they continue to comply with the burdensome and paper intensive OASIS mandate.

The VNACC incurred the following costs, which have not been recognized, other than data entry costs, in the PPS payment rate:

Oasis Training Costs exceeded $9,000.00 for classroom training alone. This does not include the 4 month preparation and implementation by administrative staff, the individual conferencing and joint home visits after orientation to assure staff competency in completing the assessment and ongoing education and updates.

External Printing Costs = $15,000.00. Note: When revisions were made to the assessment tools in preparation for PPS, all existing stock needed to be destroyed and new tools set and printed.

Scanners/Software/Computers = $18,000.00

OASIS Data Entry Personnel Salaries = $25,000.00

OASIS Clinical Reviewer Salary— $47,000.00

Additional non-billable visits to complete OASIS assessments = 228

Legislative and Administrative Recommendations

1. Congress should appropriately compensate providers to cover the full cost of OASIS data collection and reporting of Medicare home health skilled patients.

2. Congress should amend the Medicare Conditions of Participation for Home Health and eliminate the requirement to collect OASIS data on non-Medicare patients.

3. HCFA should provide training in the use of adverse event and outcomes reports for quality improvements and focus on a supportive, rather than a punitive, approach.

4. HCFA should strengthen its oversight of state agencies and third-party payors' privacy maintenance of OASIS information.

C. Home Health Advanced Beneficiary Notices

Formal written notice is required to advise Medicare beneficiaries when the home health services they need will not be covered under Medicare, either in whole or in part. After several false starts, the Home Health Advance Beneficiary Notice (HHABN) was implemented on March 1, 2001. The Medicare Conditions of Participation for home health mandate that agencies notify the patient, orally and in writing, about changes in Medicare coverage. The HHABN is HCFA's mandatory form.

When a beneficiary is given a HHABN notifying them of non-coverage, the beneficiary has three options: (1) the patient wants the specified home health services, agrees to be fully responsible for payment, and asks for an official Medicare decision (demand bill); (2) the patient does not want to receive the service; or (3) the patient wants home health services, agrees to be responsible for payment but does not want the HHA to submit a demand bill.

A HHA must submit a RAP when a patient requests that a demand bill be filed with Medicare. Medicare pays the RAP even though the HHA considers the care to be non-covered. Under PPS, a demand bill can only be submitted at the end of a 60-day episode of care. Some state Medicaid agencies have suggested that the HHABN must be given every subsequent 60 days. Further, third party payers, such as Medicaid or another insurance, refuse to pay until Medicare makes a payment determination. This is a particular problem in the New England states. This process for making the initial determination takes a minimum of 90 days, partly due to the fact that a determination cannot be requested until the end of a 60-day episode or discharge of the patient. In those states where the Medicaid agencies have taken an aggressive approach to Medicare payment, the process will take longer because the states exercise their appeal rights, including requests for reconsideration and administrative law judge hearings. This process could take an additional 60 days to two years. While Medicaid exercises its appeal rights, the home health agency receives no payment for the care provided, since Medicare recoups the RAP payment upon determinations of non-coverage.

The financial implications for beneficiaries and agencies could be enormous. Beneficiaries who do not have Medicaid or other insurance must pay out-of-pocket for the services. Home health agencies must continue to provide care they believe to be non-covered. By the time the HHA receives Medicare's official determination, the beneficiary may have already moved into a second, or third, episode of care.

Following are related HHABN issues and unresolved problems:

—The process imposes an additional paperwork burden on HHAs, which must complete Medicare paperwork for patients who, in fact, are not eligible for Medicare services or Medicare payment.

—Intermediaries initially issued incorrect instructions to providers resulting in the development of HHABN forms that could not be used, and confusion regarding the scope of the notification process.

—Although HHABN requirements were implemented March 1, 2001, there are still many unresolved concerns, including: (a) whether the HHABN must be provided to patients receiving only personal care; (b) whether the HHABN must be provided every 60 days to ongoing patients; and (c) whether beneficiary-requested demand bills must be submitted on an ongoing, 60-day cycle.

—If HHAs are directed to complete the notice every 60-days for ongoing patients, agencies will have to complete additional paperwork (e.g., discharge OASIS and start of care OASIS forms) to discharge the patient from Medicaid and readmit them to Medicare every 60 days. For VNACC, the two OASIS forms that would be completed comprise 28 pages of documentation and 183 repetitive questions.

—Cash flow will be significantly impacted since the pre-demand bill RAP payment will be recouped and, in many cases, the HHA cannot pursue Medicaid payment until an official denial is obtained from Medicare.

—During the time that a beneficiary's coverage determination is under consideration by the intermediary, other providers such as outpatient therapy providers and medical supply vendors will have their claims rejected by Medicare B.

—In addition, some state Medicaid agencies will refuse to pay for medical supplies until the official Medicare coverage determination is obtained, because of the consolidated billing requirement under PPS.

The VNACC found that HCFA failed to provide accurate instruction in a timely manner, creating an environment that makes providers prone to errors. These can be very costly, because agencies will be liable if proper notice is not given. The process and forms are confusing to Medicare beneficiaries, particularly in regard to their failure to include other payer options, such as Medicaid. Other payers may exercise the option to appeal adverse Medicare determinations to the highest level. In Connecticut, due to our experience with Medicaid third party liability (TPL) recovery efforts, we know the delay to reach an administrative law judge (ALJ) could take a year or more. Due to the delays in getting a determination, and then pursuing the appeals process, along with the medical supply issues, many providers in Connecticut are considering whether they can afford to provide services to the Medicaid population. In addition to the reduction of 32 (24%) of the agencies in Connecticut, this creates a serious shortage for the clients.

Legislative and Administrative Recommendations

1. HCFA should clarify and simplify the HHABN and demand billing notice procedures and allow for a single notice.

2. HCFA should, in an effort to decrease the paperwork burden on health care providers, get states to honor single notices.

3. HCFA should clarify expeditiously the outstanding issues and questions from the HHAs.

4. HCFA should allow HHAs to submit a final claim for determination immediately after delivery of at least one visit rather than at the end of the episode.

D. Medical Claims Review

Home health providers are experiencing increasing difficulties in processing claims through the RHHIs for services provided to Medicare beneficiaries. Problems cited by agencies include increased inappropriate and excessive random and focused medical reviews, medical review inconsistencies, and technical denials.

A wide variety of inconsistencies exist in payment decisions by the RHHIs reviewing medical claims. Differences in interpretation of homebound, technical requirements, and medical necessity requirements have resulted in confusion among many home care providers. In addition, local medical review policies (LMRP) are often more restrictive than the coverage policy dictates, complicating coverage decisions further.

Given the current financial uncertainties related to intensified audits and disallowances and inconsistent medical reviews, coupled with the PPS billing problems, thousands of Medicare claims are currently in dispute or on appeal. This has created severe cash flow problems for many providers. Agencies are under severe financial hardships when payments are delayed weeks or months while under review and appeal.

Reduced payment levels have a direct impact on agency ability to respond to mandatory documentation and claims compliance. The costs to comply with Medicare regulations are consuming a greater portion of the PPS base payment rate. In order to keep losses to a minimum while meeting increased compliance pressures, HHAs must implement more sophisticated information systems that can adapt to the ever-changing regulatory environment. The need for systems upgrades to capture accurate data *once* for use by multiple users while protecting the confidentiality and security of patient information is acutely needed within HHAs. The long term viability of HHAs hinges on their ability to file accurate and timely claims, treatment plans, and outcome documentation.

At the VNACC, the business staff has shared that the increased level of medical review and the financial constraints on agencies are compounded by the difficulty in accessing intermediary staff, poor response time (as long as two weeks), and conflicting information from the intermediary. In addition, at a recent meeting between the intermediary and Connecticut agencies, we were told that several errors in the system have not been resolved. However, HHAs are responsible for tracking claims and payments manually, because the intermediary is unable to do it at this time. This would not be accepted in reverse. When providers are mandated to comply, no excuses are tolerated.

Last April, the VNACC was notified that a focused medical review of 30 records resulted in the denial of 20 home visits. The penalty was a 30% prepayment review for a full quarter. Approximately 150 records were selected for review every month. We had to copy each page of documentation, mail them to the intermediary and wait for their determination. No payment was received until each record was reviewed and any appeal process finalized. During our ongoing communication with the intermediary, their office made 18 errors ranging from sending lists of client denials and copies of final determinations belonging to other agencies, to claiming denial of visits previously reviewed and approved by their own medical review department. Our denials were reduced to 4 nursing and 4 home health aide visits, but we remained on the 30% prepayment review.

Legislative and Administrative Recommendations

1. Congress should reform the home care provider's claim review process by passing legislation that contains the following principles:

—Time limits should be imposed on intermediaries for review of claims.

—Additional Development Requests (ADRs) should be coordinated within the intermediary systems to avoid duplication.

—HHAs should be provided with the standards by which the intermediary initiates and discontinues focused medical review.

—Use of prepayment review should happen only after a provider has demonstrated non-compliance.

—Successful appeal determinations should be factored into decisions on continuing focused medical review.

—Sampling should be used only as a last resort.

2. Congress should authorize HHAs to utilize PPS payments in a flexible manner in order to achieve system efficiencies without adverse consequences relative to payment, coverage, and compliance with the Conditions of Participation.

3. Congress should enact legislation that reforms the claim audit process and sets standards for providers that would diminish extensive prepayment claim reviews.

4. Congress should enact a temporary "technology" pass-through to upgrade and modernize HHAs information systems.

5. Congress should enact the "Medicare Education and Regulatory Fairness Act of 2001" introduced by Senator Frank Murkowski (R–AK) and Representative Pat Toomey (R–PA) (S.452 and H.R.868).

E. Appeal of Technical Denials

Home health care benefits under Medicare involve a combination of technical and substantive requirements. For example, as a substantive requirement, a patient must be homebound in order to be entitled to benefits. A technical requirement includes that the patient's physician must certify, in writing, that the patient meets the homebound requirement. However, if the certification is not signed and dated prior to the billing for coverage, a claim denial is issued. While the technical error can easily be corrected, HCFA forces both types of denials into the time consuming and expensive appeals process. This delays payment by at least three months and as much as a year and a half in some cases.

The VNACC has found such excessive scrutiny of technical errors to be costly, both in financial terms, as well as in administrative and staff time. The repeated duplication of mountains of paper only scratches the surface. It is difficult enough to hire staff to meet the needs of the community, much less dedicate staff to the preparation of all of the documents necessary to appeal technical denials caused by simple, clerical errors.

Legislative And Administrative Recommendations

1. HCFA should reject the technically non-compliant claims, but allow for resubmission when the claim is technically appropriate. Such approach would continue to encourage compliance while significantly reducing administrative burdens.

2. Congress should require HCFA to allow physician assistants (PAs) and nurse practitioners (NPs) to certify and make changes to home health care plans. PAs and NPs are oftentimes more familiar with a patient's case and more readily available than physicians to expedite the processing of paperwork, ensuring that home health agencies will be reimbursed in a timely manner and that care to the beneficiary and cash flow to providers will not be interrupted.

F. Statistical Sampling Methodology For Post-Payment Audit and Review

In March 1999, HCFA published an RHHI manual update outlining new procedures for comprehensive medical review using statistical sampling (Transmittal Number 1770). The updated instructions provide details for conducting comprehensive medical reviews, medical review audits, and for statistical sampling and overpayment projections.

The use of sampling procedures involves the RHHI identifying a specific portion of claims from among an agency's claims submitted during a specified period of time. The proportion of denied claims in the sample would be extrapolated to all claims for the period, resulting in denial of claims that were never reviewed individually.

Sampling imposes significant risks to agencies and eliminates some providers' appeal rights. Under HCFA's sampling policy, the overpayments projected through the claims reviews are recouped by Medicare prior to any rights of appeals. Since the projection can involve millions of dollars, home health agencies are unlikely to survive long enough to access the appeals process. Appeals are important because reversals of claims have routinely exceeded 80% over the years.

The HCFA Region V Associate Regional Administrator registered a protest alleging that the statistical methodology used is invalid and irresponsible. This claim is supported by the Region V statistician and the statistical consultant to the Department of Justice in Chicago. Documents have been submitted to this committee regarding this allegation. With an improper sampling methodology, the risk of erroneous overpayment projection is dramatically heightened.

HCFA has rejected the majority of recommendations made by home care providers to stop sampling and overpayment projections. In addition to opposing the use of statistical sampling, NAHC objects to the manner in which HCFA implemented this policy. At a minimum, policy changes of this nature should be subject to public review and comment, as required under the Administrative Procedures Act, before it is finalized. NAHC recommends that HCFA suspend its instructions to the intermediaries on statistical sampling of home health claims until appropriate modifications are made in policy.

In March of 1998, the VNACC was randomly selected for a financial Medicare audit. We were told in advance that several auditors would remain in our office for

five days to scrutinize all aspects of our financial record as they relate to our cost report. We asked if clinical records would be audited as well, and were told no. One hour before the financial auditors were expected, two clinical surveyors arrived and announced their intention to remain for three days to review records and meet with clients. We provide the clinical records from their pre-determined list. Home visits to randomly selected clients revealed that we had properly exercised the regulatory provisions for home care. We were commended for the quality of care we provided. However, the surveyors did announce that three visits, from the hundred reviewed, would be denied. In their opinion, two home health aide visits represented more homemaking activity than personal care. The third visit was clearly a human, billing error. The actual total of these home visits was less than $90.00. Medicare however extrapolated this figure "to the universe of claims" and demanded a $5,000.00 repayment, for which we had no recourse.

Legislative and Administrative Recommendations

1. HCFA should develop a sampling regulation through public notice and comment.
2. HCFA should use sampling only as a last resort and only with statistically supportable methods.
3. HCFA should not undertake recovery of payments until all appeals have been exhausted.

G. Branch Office Designation

HCFA has established new criteria for branch offices that emphasize the distance of the branch locations from the parent without reasonable consideration of the parent entity's actual supervisory capabilities. The policy does not recognize the use of modern methods of communication such as faxes, telephones, pagers and telecommunications that are used by every other business in the country as acceptable methods of communications and supervision. HCFA's branch office policies are contrary to regulatory reform initiatives and the proposed conditions of participation which espouse the need to care. In many cases, agencies have closed branch offices because of the added costs of complying with the conflicting and unnecessarily restrictive branch office policies, producing access problems for beneficiaries. NAHC drafted a petition for rulemaking on behalf of Medicare-certified home health agencies, requesting HCFA to institute a new rulemaking procedure and establish a single set of national criteria for defining "branch office" of a home health agency under the Medicare program. After two years, HCFA has failed to respond to this rulemaking petition. Last year the Congress prohibited use of time or distance as sole criteria for determining branch office designation. Unfortunately, that falls short of what is needed.

Legislative and Administrative Recommendations

Congress should amend the definition of branch office by:

1. Recognizing that technological advances provide efficient and effective ways to "distance-manage" branch offices and workstations.
2. Eliminating the criteria of time and distance for designating branch offices.

H. Medicare Cost Reporting

The onset of the Medicare home health prospective payment system on October 1, 2000 did not end cost reporting responsibilities for home health agencies and audits of cost reports. It will be several years before cost reimbursement reaches its effective end as there are thousands of home health agencies still subject to cost report audits and cost disallowances. It is reasonable to assume that it will be three to five years before most of these issues are eliminated.

Cost reporting has long been a contentious area between the Medicare program and affected health care providers. Differences regarding the interpretation of cost reimbursement principles have existed for years. At the same time, the cost reporting and audit process has imposed needless administrative burdens on home health agencies' directing operational expenditures away from patient care and into paperwork. These administrative burdens continue today with home health transitioning to PPS since HCFA has chosen to continue their requirement for cost reporting even in the absence of cost reimbursement.

Listed below are the most notable of unnecessary administrative burdens.

—After nearly six months into PPS, HCFA has yet to finalize a revised cost report and instructions. However, the proposed revisions require that home health agencies maintain significantly different statistical information compared to past years without providing any notice prior to the fiscal year that such information would be required. As such, home health agencies run the risk of providing unreliable data or need to retroactively construct a database to satisfy the cost reporting demands.

—The proposed revisions to the cost report provide for the use of inconsistent standards regarding the rule that providers are paid the lesser of their costs or charges. Under this proposed revision, aggregate costs are determined on a full twelve-month basis while customary charges are based on the charges imposed only during the portion of the year during which Medicare cost reimbursement applies. As a result, home health agencies may face retroactive payment disallowances that were unpredictable and unforeseeable.

—Auditors from Medicare intermediaries are requiring some home health agencies to produce complete financial records that are under common ownership or control with the home health agency. These demands are made despite the fact that the home health agency has no financial transactions or shared operations with the other organizations. Medicare law requires access to the financial records of related organizations that do business with the home health agency. However, there is no law requiring access to these records where there is no business relationship.

—The audit process often leads to demands that home health agencies produce documentation that is not specifically required by the Medicare program. For example, home health agencies have been requested to produce time and function logs for staff in 15-minute increments even though the job description for the staff squarely fits within Medicare allowable cost standards. These documentation demands have forced home health agencies to immediately create an expensive record keeping system.

Legislative and Administrative Recommendations

Congress should reduce the administrative burdens placed on home health agencies at cost reporting process by:

1. Directing HCFA to utilize pre-existing statistical reporting standards to support revisions in the home health cost reporting process. Any changes in required data should be made prospectively.
2. Directing HCFA to utilize a consistent standard for the calculation and application of the lower of cost or charges rule during the transition from cost reimbursement to PPS.
3. Eliminate the inappropriate demands for documentation to support reimbursement claims by requiring fiscal intermediaries to adhere to professional auditing standards and generally acceptable accounting principles.
4. Restricting HCFA's ability to demand financial records from commonly-owned or controlled organizations that do not have financial transactions with a Medicare home health agency.

Conclusion

The comments of the National Association for Home Care and the Connecticut Association for Home Care, as set forth above, should not be construed as critical of the Health Care Financing Administration or its hard working staff. Instead, NAHC and CAHC offer these comments with constructive intent and the recognition that HCFA has been overwhelmed with an unprecedented workload that began with the dramatic reforms of the Balanced Budget Act of 1997 and continued since that point. Many of the concerns expressed herein could be alleviated if HCFA were provided with sufficient resources. However, there are others that indicate long-standing operational weaknesses within HCFA relating to the performance of in-depth impact analyses and full consideration of alternative approaches prior to the implementation of new policies and procedures.

HCFA has routinely opened its doors to suggestions from NAHC and CAHC. We hope that HCFA's recognition of the value of provider input can be maintained, if not enhanced, over the coming years. NAHC and CAHC look forward to the opportunity to work with the Subcommittee and with HCFA personnel to eliminate unnecessary administrative burdens and alleviate necessary ones where acceptable, but more efficient alternatives exist to accomplish the same policy goals.

Supplemental Statement

This statement supplements testimony given on March 15, 2001, by Susan Wilson of the Visiting Nurse Association of Central Connecticut, Inc. on behalf of the National Association for Home Care at a hearing before the Subcommittee on Health of the House Ways and Means Committee. Chairwoman Nancy Johnson has requested the submission of this statement in response to the testimony and supplemental statement of Toby S. Edelman of the Center for Medicare Advocacy regarding its efforts to pursue Medicare payment on behalf of the state Medicaid program.

MEDICARE: MAXIMIZATION: CAUGHT BETWEEN TWO PAYORS

The National Association for Home Care takes no issue with the bona fide beneficiary-related advocacy provided by the Center for Medicare Advocacy in Connecticut. However, NAHC disputes the claim of the Center for Medicare Advocacy that it, as well as its client, Connecticut's Department of Social Services, have undertaken reasonable efforts to avoid the use of costly, time-consuming, and paperwork-intensive methods of pursuing Medicare payment on behalf of Medicaid-eligible recipients of home health services in Connecticut. Instead, the 15-year history of the so-called "Medicare maximization effort" in the state of Connecticut demonstrates a dominant interest in continuing to pursue Medicare payment through retroactive demands for claim submission and high volumes of appeals. The inefficiencies of this method of pursuing potential payment from the Medicare program fails to serve any patient related interest and only leads to higher administrative costs that are borne by patients, providers of services, and the Medicaid and Medicare programs.

In its supplemental statement, the Center for Medicare Advocacy (CMA) touts its success in securing over $133 million from the Medicare program as a recovery of funds originally paid by Connecticut's Medicaid program for home health services since 1988. It neglects to offer any reference as to the costs of the efforts, including the costs of the state, Medicare, and the home health agencies. It is NAHC's understanding that the Medicare program expends significant administrative monies to process demand bills, reconsideration appeals and administrative law judge hearings. For example, NAHC believes that each reconsideration costs approximately $300 and each hearing approximately $1000 to process from beginning to end. For home health agencies, the costs of patient chart compilation, review, and copying to respond to the demand bills of Connecticut Medicaid ranges from $50 to $100 for each billing period. These costs, as well as the state's own internal and contracted costs must equal several millions of dollars each year.

At the same time, the Center references that "Connecticut's activities to obtain proper Medicare for dually eligible clients have always included efforts to obtain appropriate benefits in the first instance." However, if there were a true interest in avoiding unnecessary Medicaid payments, the Medicare maximization efforts of demand bills and appeals should be gradually shrinking over the past 13 years. Instead, the state of Connecticut and its contractor, the Center for Medicare Advocacy, continue to push high levels of demand bills months after Medicaid payment has been made, file hundreds of administrative appeals each year, and initiate litigation to establish the state's role as a party in interest in the Medicare appeals process.

In contrast, home health agencies in Connecticut have attempted to advance alternative, more efficient methods of insuring that Medicare meets its responsibility as the primary payor of services, with Medicaid as a payor of last resort. It must be understood, that home health agencies in Connecticut generally consider that the level of Medicare payment for services rendered is preferable to the payment rates made for the services under Medicaid. Home health agencies have no financial or operational interest in receiving Medicaid payment over Medicare. The recent implementation of Medicare home health prospective payment (PPS) adds further complications since Medicaid maintains a per service payment method in contrast to the 60-day episodic payment under Medicare PPS. In addition, the current nursing shortage is exacerbated by diverting clinical resources to paperwork. Home health agencies have a strong interest in avoiding unnecessary administrative burdens that in no way improve access to care or the quality of services.

In reality, home health agencies in Connecticut are simply victims in a fight between two huge bureaucracies, each of which may have an interest in shifting responsibility for necessary home health services to the other. Home health agencies have not voluntarily chosen to take on the nearly impossible task of distinguishing Medicare-covered home health services from that care covered under the state Medicare program. The role of an informal Medicare coverage decisionmaker has been forced upon home health agencies with the threat that the home health agency could be liable for the cost of care whenever it fails to determine that care, before it is provided, is outside of Medicare coverage. Through the so-called limitation on liability provision of Medicare law, 42 USC § 1395pp, the Health Care Financing Administration has created a system which shifts the financial liability for the cost of home health services to the provider in most circumstances where Medicare is billed for non-covered care. Using ambiguous Medicare coverage standards that are inconsistently applied within the Medicare intermediaries, the home health agency must notify the patient that care is noncovered by Medicare before the services are rendered or end up assuming the liability for the cost of care. In such circumstances, the home health agency will receive no payment from Medicare and is prohibited from billing the patient or other third-party payors. With the current retrospective

review method by Medicaid, home health agencies face double jeopardy—service costs without payment from Medicare or Medicaid.

It is hoped that with the recent changes in Medicare's criteria for determining homebound status, as contained in the Benefit Improvement and Protection Act of 2000 (BIPA), that some of the difficulties experienced with this confusing concept will be reduced. For example, under BIPA, Medicare patients regularly receiving adult day facilities services may retain homebound status. Prior to BIPA these patients were generally disqualified from Medicare home health services coverage as a result of their absences from the home. CMA had successfully appealed such cases on behalf of Medicaid. However, these appeals did not alter the standard applied by Medicare on its initial review of claims. Home health agencies are caught between a Medicare program that rejects the claims and a Medicaid program that pursues them.

THE INEFFICIENT DEMAND BILLING/APPEAL PROCESS

In the event where a dual eligible Medicare/Medicaid beneficiary receives home health services paid under the state Medicaid program, Medicare payment is pursued through a process known as "demand billing." This process entails a retrospective demand from the state Medicaid program to submit individual Medicare claims on behalf of the dual eligible beneficiaries. Where that demand bill claim is not fully paid by Medicare, an appeals process is utilized. That process involves three administrative appeals steps and the opportunity for a federal district court review. In circumstances where Medicare coverage is awarded, the state recoups Medicaid payment directly from the provider of services, which then receives the appropriate Medicare payment. As a result of the timing of the process, home health agencies are often required to submit revised annual cost reports to Medicare and await settlement of the cost report before payment is made.

The demand bill process for home health agencies encompasses the preparation of Medicare claims for multiple time periods for each beneficiary, extensive medical records review, a high volume of document copying and transmittal, and the management of a complex accounting and financial system to properly reconcile retroactive Medicare with earlier Medicaid payments. When a claim proceeds into the appeals process, the workload magnifies as duplicative documentation requests are issued at each stage.

A central feature in the demand bill process is the new Home Health Advance Beneficiary Notice (ABN). While NAHC fully supports timely and appropriate Medicare coverage notices, the integration of the ABN with the state's Medicare maximization efforts has fostered improper payments, confused patients and providers, and increased paperwork. The ABN may work with patients that have no potential payer source other than Medicare, but it doesn't fit for a patient that has access to continued care and payment under Medicaid.

In the 13 years in which the state of Connecticut has pursued Medicare maximization on home health services through the Center for Medicare Advocacy, the process has been essentially unchanged. In the beginning, the Center for Medicare Advocacy made large-scale requests for demand billings to home health agencies at certain points in the year while also pursuing a high volume of administrative appeals. A semblance of a claim selection process was utilized by the Center for Medicare Advocacy based upon the dollar amount involved and the volume of services provided to the patient. In most respects, that same system is in place today. While the efforts have recovered significant Medicare payments for the state Medicaid program, no advances have been made in reducing the administrative burden or preventing a Medicare disallowance in the first instance.

RECOMMENDATIONS

Over the years, home health agencies in Connecticut have made numerous recommendations as to steps that could be undertaken to significantly reduce the administrative burden related to dually-eligible patients. These recommendations require cooperation between the Health Care Financing Administration and the state Medicaid program. Most can be undertaken under current authority. However, there may be a need for legislative change to authorize some of the recommendations. These recommendations include:

1. Eliminate the threat of shifted liability for a provider of services on dual-eligible Medicare/Medicaid beneficiaries. In these circumstances, there is no question as to the necessity of the services to the patient, only the identity of the payor source.

2. Provide front-end billing of dual-eligibles to the Medicare program with any residual claims transmitted from Medicare to Medicaid. This process would require structured and expedited time frames for claims processing in order to maintain reasonable cash flow for home health agencies. To reduce the volume

of dual eligible claims submitted in this process, selection criteria established by the state Medicare program could be utilized to pre-screen claims.

3. Establish a reconciliation process between Medicare and Medicaid relative to any disputed claims. Through this process, a sample of the claims in dispute would be appealed and a financial reconciliation occurs between Medicare and Medicaid. The home health agencies need not be part of the appeals process except for the potential of providing a copy of the patient's record. There would be no cost report adjustments or shuffling of payments between the provider, Medicare, and Medicaid. The process would be similar to the subvention method utilized to reconcile VA and Medicare obligations.

4. In Connecticut, those Medicaid services authorized through the state's case management contractor would be excluded from the process because they would involve a pre-screening to determine whether the plan of care is, in full, or in part, covered under the Medicare program.

In summary, NAHC supports an efficient and accurate process which properly assigns payment responsibility to Medicare or Medicaid. However, the concerns with the Medicare maximization efforts is that they rely upon inefficient, burdensome, and costly processes that do not include preventative action and instead utilize a system designed for individual claims to pursue a high volume of disputes. The home health community continues to recommend that a new process be established to address these mass payment disputes as distinct from that process originally intended to address the small number of circumstances where an individual beneficiary requests the submission of a demand bill.

[The attachments are being retained in the Committee files.]

Chairwoman JOHNSON. I thank the panel for your testimony and for the speed with which you were able to move through the highlights. Indeed, I hope the Members of the Committee will take time to read these papers in detail because they are very thoughtful. They do focus on very real, practical problems that I think we really must tend to.

Dr. Corlin, I wanted to mention that the inspector general believes that the bill that you support introduced by Representative Toomey would undermine his ability to eliminate fraud. How do you respond to that?

Dr. CORLIN. We are aware of that interpretation, and we are a bit surprised by it. Nothing could be further from the truth, Madam Chairman.

In any case where fraud is suspected or alleged, that would have to be referred immediately to the OIG, as it is now, and would not be different in any way, shape, or form from the present situation.

Our concerns and the reason we support this legislation are to deal with how inadvertent billing errors are dealt with. We want fraud to be dealt with just as vigorously as it is now and would not impede the OIG in any way in anything they do in a fraud investigation.

Chairwoman JOHNSON. Dr. Corlin, when an inspector general comes into a physician's office, do they differentiate between billing errors that represent an undercoding and billing errors that represent an overcoding?

Dr. CORLIN. Initially, not at all. And what was happening is that assessments were being made based just on overpayments rather than the net of overpayments and underpayments.

Now, at least there is some net charge based on the two, but it just strikes me that if I was an investigator and I went in and I saw a pattern where most of the bills were correct but some of

them were wrong, and if all of them were wrong in the positive direction, I would have some real suspicions. But if all of them were wrong and there was a pattern of some being overbilled and some being underbilled, if that is fraud, that is the dumbest fraud I have ever seen in my life. And to me, that should be evidence of the fact that there are problems in lack of education and inefficiency in the billing process, not a deliberate attempt to defraud.

Chairwoman JOHNSON. I don't remember quite how long it took for the inspector general to realize that he needed to offset underpayments and overpayments, but it did take a couple of years. I just want to put on the record the experience of a physician in one of my small towns who had the inspector general come in, and he found $1,742 in overcharges. But through Medicare's methodology, this resulted in a demand to repay $74,000.

So there is a methodological problem there with the way they move from the problems that they have seen and the conclusion that they come to. There also is, I think, just for the Committee's knowledge, no way that a physician can even challenge a single review of a case and say to the overseer, the inspector general's person, that actually this is what the case really was, challenge his interpretation of that case. He really has to abdicate his right. As this doctor says, "I had to choose to either abdicate my rights of appeal and other due process protections, or challenge the Medicare to an adversarial conflict on their turf by their rules."

So there are some significant problems here.

Dr. CORLIN. Madam Chair, we agree absolutely and have seen horror show after horror show take place. One group, if I may give an instance——

Chairwoman JOHNSON. Actually, I don't want to take too much time as chairman, so I would appreciate it if I could just move on to the others.

I just want to mention that I was interested that Northwestern added 26 full-time employees this year solely to comply with new regulations. True?

Mr. MECKLENBURG. That is correct. We added 16 additional utilization review staff and 10 additional billing coders this year, primarily for HIPAA and outpatient payment coding.

Chairwoman JOHNSON. And then I would like to ask Ms. Ousley to comment just very briefly, because I would like to ask Ms. Wilson to comment very briefly.

On this issue of the turnover rates in the nursing homes, I know it is almost impossible to recruit new nurses, but this turnover rate, you say, of 80 percent, is that unusual? How many years ago was it that you had a lower turnover rate? And what have been the changes that have caused this?

Ms. OUSLEY. It is unusual and it is growing by unbelievable dimensions today. And as I said, I do believe that it is related very much to the atmosphere in which we are asking our nurses to work. They, again, are afforded so very little respect, and as I indicated, the oversight process that the nurses go through is just almost unbelievable.

There is such a demand for write it down, write it down, document it, that they are getting so frustrated that they absolutely

cannot do what they were trained to do, their profession, to provide the care for residents.

A personal example. In one of my facilities just a few weeks ago during the survey process, two of the nursing supervisors—and this is a facility that has been essentially deficiency-free for the last 20 years. One of the nursing supervisors actually got physically sick in the middle of the survey and said, "I have to go home." Another nursing supervisor said, "When it is over, I am done. I can't stay here anymore. I can't go through this again. We work too hard to have to deal with this."

Both those nurses, thank goodness, are still with us today because it is a good and it is a stable community, and the administrator was able to convince them. But that is the type of thing that is happening that is driving good, caring people out of this profession. And I firmly believe that is one of the reasons that it is increasing.

Chairwoman JOHNSON. This is a very big issue, the change that has happened in the survey and certification process over the last 5 or 6 years, and I urge members to go visit their nursing homes and talk to the people who have been through these surveys, talk about what the impact has been on the quality of care of this kind of survey versus the kind of survey work we were doing in a more collaborative environment a few years ago. You can only really get the flavor of the change. There is no question in my mind but that it is forcing people out of the business.

Ms. Wilson, let me just ask you—and thank you for your detailed testimony. It was extremely useful. But one of the things that disturbed me the most is that Congress mandated that there be a case mix adjuster. Now, in your testimony, you mentioned that comorbidities were not taken into account. Could you just describe to us what impact this had? And then save just 1 minute to also describe what kinds of cases some to you that couldn't possibly be covered by Medicare, and yet you have to go through this time-consuming process that results in a delay for service payment of at least 2 months, and often as much as year. So just would you comment on that comorbidity issue? Because it is astounding to me that this would not have been built into case mix adjustment.

Ms. WILSON. On the issue of comorbidities, when the OASIS data set is completed—and at the start of care, OASIS assessment is comprised of about 83 separate questions. One of the very small factors is, in fact, the diagnosis. There are only three primary diagnoses, which pertains to orthopedics, neurological issues, and diabetes, which are drivers of a differentiation in reimbursement.

Having a population in New Britain which is an older population, our agency primarily serves an older population. Of course, we see people with comorbidities: congestive heart failure, chronic obstructive lung disease, et cetera. It requires intensive intervention on the part of the clinicians. We have to organize many community resources, and obviously all of those factors impact the individual's safety and well-being.

The cost in time and money is astronomical. However, it has absolutely no impact on the cost of reimbursement. Only if, in fact, a primary diagnosis of diabetes, an orthopedic, or a neurological diagnosis were primary would that have any impact whatsoever.

Chairwoman JOHNSON. So the bottom line is that there is very little relationship between the cost of care that senior needs and actually your reimbursement level?

Ms. WILSON. Correct.

Chairwoman JOHNSON. Let me move on now and not go to the other question and give Mr. Stark an opportunity.

Mr. STARK. Thank you, Madam Chair. Just a couple of issues here because I need a little more data from some of our witnesses.

I think, Dr. Corlin, you indicated—and we are going to have a little difference, I suspect—in the testimony today that Medicare's rules and policies are driving physicians from the program.

Now, what we are finding, for example, is that in every State except Missouri, the participating physician rate is higher in 2000 than it was in 1999; MedPAC did a study of physicians, and they found, in questioning physicians about the difficulty of finding a referral, that only 4 percent of the physicians said it was very difficult to find a referral for a Medicare patient, but 3.7 percent had the same difficulties finding referrals for privately insured patients. So there is almost no difference in finding a referral for a Medicare patient. If we were driving the docs out, one would suspect that it would show up there.

By the way, this is a 1999 survey; there is another one in the works. When they surveyed physicians about their attitudes about Medicare and comparisons to Medicaid—which I think is probably the worst in terms of physicians' preference-fee-for-service, PPOs, and private HMOs, Medicare does pretty well. In other words, 54 percent felt that the billing paperwork was a very serious problem for patients served by HMOs, and only 29 percent gave this answer for Medicare. So one could say Medicare is doing better than private HMOs, which should not come as any surprise because the physicians have been supporting our efforts to get the Patient's Bill of Rights passed. That has sort of fallen off.

Dr. CORLIN. No, sir, it has not.

Mr. STARK. OK, good. But what I guess I am saying is that, while I am perfectly willing to urge my colleagues to move efficiently and to improve Medicare, I think it is fair to say Medicare is—in your own practice, I will bet you—one of the two best or least hassling payers you have got. And I find this is true from many physicians. In Connecticut, for example, the AMA affiliate there is suing Aetna for paying claims slowly.

Now, let's say that a doctor's practice grosses 2 million bucks. That is before it pays all the nurses and rent and everything else. We pay—we, being HCFA-clean claims in 30 days. You are lucky if you could tell me with a straight face that managed care plans pay you in under 120 days.

I am suggesting that you get to float a half a million bucks with us that you are not getting out of these other plans. And if you can earn 6 or 8 or 10 percent on that. You don't do so badly. Again, I am not suggesting that we can't improve, but I think you have got to compare us to the others. I don't think, Doctor, that you would ask me to turn Medicare over to Aetna without any change in regulation and let them pay you under their plan for all your patients. I just think that you would probably have trouble getting re-elected as president. I might have trouble getting re-elected——

Dr. CORLIN. I am only allowed to serve one term, sir.

[Laughter.]

Mr. STARK. Don't mention that to the good folks in the 13th District of California, please.

There is no business operation—and that is what HCFA is—that can't stand improvement and doesn't need constant revision to see that we are using current technology. In fact, we are offering you a buck off, I think, if you will file electronically. Maybe we should charge you a buck—you being your group and other participating doctors—if you don't file electronically to urge you to get out and buy that laptop and help us be more efficient.

There are a lot of ways we can cooperate, but the MERFA may very well completely eliminate any ability to enforce our laws and regulations. It is not the way to go. And I would urge you to—which is unlike previously, 10 years ago with the AMA—continue to be in the tent with us as we write any improved legislation, and I think we can go a long way together.

But, please, you know, for a lot of the guys who work hard, this argument 135,000 pages of regulations is baloney. We have counted them. There are about 35,000, which is maybe too many, but it isn't 135,000. That number came from Mayo, who have refused to send us any documentation of where it came from. But, believe me, I want to stay out of the Mayo Clinic if they can't tell the difference between 135,000 and 35,000, or when they read my cholesterol level, I am going to have a real problem.

So thank you for your organization's support to stop smoking, to get kids insured, to reform managed care. But remember that one of the complaints you have that are fixed in the Patients' Bill of Rights is that you get paid by the private insurers on time. At least we do that. We may come back after you later, and maybe we have to change that. But be careful what you wish for. It could come to pass. And I look forward to working with you.

Now, if I have misstated any of your position or the difference—if you want to shed any light on the difference in our statistics, please do. Sorry, Madam Chair.

Dr. CORLIN. Thank you, Mr. Stark——

Chairwoman JOHNSON. Dr. Corlin, if you will be quite brief, as the red light is already on.

Dr. CORLIN. Yes, I will. I would be pleased to respond.

We are not here today to talk about specifically just payment issues. I can tell you that in virtually every community in which I speak, there are at least one or two of the senior internists who have said, "I have had it with the kind of audit process that they have put me through, and I am not going to see Medicare patients anymore," and that is a shame.

I would like to respond by giving two very, very brief responses which focus on our concerns today, and one has to do with a six-person group dealing in one subspecialty with internal medicine. And I have seven lines that I want to read you about what they went through. They are recognized in the entire area in which they practice as being the most high-quality group in that specialty.

The carrier audited 80 claims from their practice—this is six doctors in a very active practice—and demanded all the supporting documentation within 45 days, which they sent. The carrier then

extrapolated from those 80 claims and said that that practice owed somewhere between $99,000 and $285,000, and they would accept the $99,000, but it had to be paid within 30 days, and they had to admit liability.

Also, if they wanted to try to get an extended payment system, they would have to provide financial documents that they were turned down for loans at the bank in order to do it.

The physicians appealed the audit finding after paying the $99,000, with interest, and 3 years later after the initial audit was done, the administrative law judge held that the carrier was wrong and that there was no overpayment and ordered their $99,000 returned to them, without interest.

The other issue we find ourselves in is we are told repeatedly that if you contact the carrier and ask a question and get an answer, you can only rely on that answer if you are subsequently audited, as we did it the way the carrier told us, if you are given a written confirmation of the answer. We are never able to get those.

I would love to be able to tell you that I can go to 300 physicians around the country, ask them to ask the same question of their carrier 10 times each over 3 months, and get 3,000 answers the same. I suspect we would have 1,200 different answers to that same question.

Help us with those issues, and the financial factors that we are concerned about will not be as great.

Mr. STARK. And just a follow on, Madam Chair, a quick comment. We have about 50 different carriers across the country. They are not government employees. Generally, they are Blue Cross or Aetna employees who contract with the Government, and each one has a different set of standards. And we recognize that as do you. This is not "the government." This is 50 different contractors. It is like dealing with 50 different banks around the country chasing you for your visa card bill. And we and HCFA recognize that we don't have common computers.

I mean, I could go on——

Chairwoman JOHNSON. Mr. Stark, we do need——

Mr. STARK. The Chair knows this——

Dr. CORLIN. HCFA, when they say they can't control the carriers——

Chairwoman JOHNSON. I believe the whole point of this hearing is to get this kind of problem on the record, because while in the old days you might be able to tolerate it, now with the incredibly complex cases, the variety of diagnostic treatment and technologies, you cannot put people through this and expect them to participate in the program, and we really have an obligation to hear this and deal with is constructively. Mr. McCrery.

Mr. MCCRERY. Thank you.

I think Mr. Stark does raise a legitimate question, though, and I would like for you, Dr. Corlin, and maybe Mr. Mecklenburg to elaborate.

What is the difference in paperwork requirements or the burden of compliance between HCFA and Medicare and the private sector in your private-pay patients? Dr. Corlin?

Dr. CORLIN. Thank you, Mr. McCrery. It is all across the board with the private payers. Some are very good and respond very

quickly and are very efficient. Others, the situation is terrible. And I think probably if you want to characterize managed care, the best thing you can say is if you have seen one managed care plan, you have seen one managed care plan. Some of them work through a delegated model, either fee-for-service or capitation, and work very efficiently with minimal disruption to the practice. We are fortunate in our community that that is the way we work. I have never had a circumstance where I have had to do anything more, if I got a rejection, than call and speak to a medical director over the phone and got it taken care of very quickly. I am talking about authorization, not payment. And many of ours in our own practice are capitated. Some are not. We are much more fortunate than some. It ranges from very good to very bad.

The Medicare payments themselves, the payment system, at least for physicians, is not the problem. We are not complaining that there is slow pay for Medicare.

Now, we had in southern California 4 months of slow pay, and many physicians didn't get paid at all for 3 months when they switched from one intermediary to another. That is a specific issue. It is not likely to happen again.

But our concern is we want the auditing process that it is the carriers that do to be efficient, appropriate, and businesslike. I would love to be able to come back here near the end of my presidency and congratulate you for making HCFA the Nordstrom of Government agencies.

Mr. MECKLENBURG. Mr. McCrery, I would concur with the assessment that we have problems with most of our payers in terms of slow pay, burdensome requirements, added paperwork. I think in terms of Medicare and Medicaid, in our own organization right now we have had two major impacts by example: one, implementation of new outpatient payment regulations that have been very difficult for us to get to a completed and clean claim; second, we have had a change in intermediaries, which has already been discussed, with dramatically different paperwork requirements, dramatically different interpretations of Medicare payment restrictions, that have led to dramatic increases in receivables and in our allowance for bad debts.

Mr. MCCRERY. Well, generally, though, can you help me with my question, which is: How does the burden of complying with Medicare compare with the burden of complying with the private sector in general?

Dr. CORLIN. That burden is much, much worse in the standpoint of having——

Mr. MCCRERY. What burden is worse?

Dr. CORLIN. The burden regarding Medicare.

Mr. MCCRERY. Is worse than the private sector?

Dr. CORLIN. It is much worse based upon the uncertainty and inexactitude of knowing what to do. At least with managed care plans, whether we like it or not, we know exactly what has to be done. And if we call and ask a question, chances are we are going to get the same answer time after time. We may not like the consistency, but there is consistency and we know the rules.

There are circumstances in dealing with the Medicare intermediaries where the rules are confusing, the wording is confusing,

and when we call we get different answers without the substantiation.

Mr. MCCRERY. So you disagree with Mr. Stark's characterization that the private sector is just as bad as Medicare in terms of the burden it places on you for paperwork and compliance?

Dr. CORLIN. Absolutely. With regard to those aspects of it, I do.

Mr. MCCRERY. Mr. Mecklenburg, how about hospitals?

Mr. MECKLENBURG. I would agree with that conclusion. If I can give you one simple example of a difference between Medicare and many of our other payers, every time a Medicare patient receives service, we are required to ask a series of questions about secondary payers. It has 25 questions on it. We have to ask it every single time a patient receives services, whether it is a physician service or a laboratory test. That is not only a burden for our personnel——

Mr. MCCRERY. Private payers don't require that.

Mr. MECKLENBURG. Not this kind of questioning. The first question I have to ask a patient every time is: Are you receiving black lung benefits and will services being performed be paid by black lung? A patient that is seeing us every couple weeks for a lab test gets very tired of answering that question.

Mr. MCCRERY. Well, Madam Chair, evidently these witnesses, who are from the health care sector, disagree with the information that Mr. Stark provided us. Maybe we should ask Mr. Stark to provide some witnesses to substantiate the claims that he is making so we could clear this up.

Mr. STARK. If the gentleman would yield?

Mr. MCCRERY. Sure.

Mr. STARK. Most of that comes from MedPAC, and we will hear from them, and they are doing another study. So I think that is right on. We should find out. We will have MedPAC as a witness later.

Mr. MCCRERY. Good.

Ms. WILSON. May I add a comment in reference to your question as it pertains to home care?

Mr. MCCRERY. Sure.

Ms. WILSON. Certainly in terms of the private sector, we definitely have our problems, and there is definitely a financial burden that comes with contracts at substandard pay rates, et cetera. However, when it comes to the coverage, very often, as has been said, we can call, we can discuss what the situation is, and seek some resolution. There is also a very clear process in terms of appeal, and we have utilized that.

One example that we have had with our agency is that the fiscal intermediary routinely does focused medical reviews, and we are not aware of when those are taking place. In April 1999, we were notified that our agency had undergone a focused medical review of 30 records which resulted in—now, 30 records can total hundreds and hundreds and hundreds of visits. It resulted in a denial of 20 home visits. The penalty was a 30 percent prepayment review for a full quarter, which is going to total about 450 records for our agency.

What that meant was we needed to copy each and every record, send it to the intermediary, have it reviewed, wait for their deter-

mination, appeal if necessary. This is a process that goes on for weeks, months, and sometimes could last for a year or more.

However, during that process, what we found was that the intermediary made 18 errors ranging from sending lists of client denials and copies of final determinations belonging to other agencies to claiming denial of visits previously reviewed and already approved by their own medical review department. When this was clarified, what they originally said was 20 home visits was actually a total of eight. However, we still were subjected to the 30 percent prepayment review. There was no getting away from that process.

That I don't believe would have occurred with the private sector.

Ms. OUSLEY. If I could also add, just on behalf of the nursing facilities——

Chairwoman JOHNSON. Very brief, Ms. Ousley. That red light is on.

Ms. OUSLEY. For Medicare, for us, in justifying the 44 category claims requires, again, tremendous documentation, and like my colleagues, with review many times comes numerous denials for paperwork reasons.

Chairwoman JOHNSON. Thank you very much. Mr. Kleczka.

Mr. KLECZKA. Thank you, Madam Chair.

Mr. Mecklenburg, the form that you refer to that has to be asked of every patient coming into the hospital, is that a verbalized form or is it given to the patient and you just check the various questions?

Mr. MECKLENBURG. Depending on the patient, it may be done either way.

Mr. KLECZKA. But for the most part, it is given to them and they will just go and check it off? Then also there is another form: Do you use insulin? Are you allergic to anything? Have you seen a doctor? You know, that type of info is also requested, right?

Mr. MECKLENBURG. Yes, there is a variety of information——

Mr. KLECZKA. All right. So on the 25 questions, that is probably just given to the patient and they check yes or no, and so that, you know, isn't an overly—I think the presentation here is overly exaggerated on that.

Madam Chair, I think it is important that we look at the regulatory burden of the program. I know full well there are 40 million-plus people getting the services of the program. So, naturally, it is going to be somewhat cumbersome. But to blame all the woes in the medical profession on the regulations of the Medicare program I think is going a little above and beyond where we should be going today. The only thing I haven't heard from this panel is blaming the recent demise of the stock market on the Medicare burdens, but that may come maybe from the second panel, Gail.

Nevertheless, the point I wanted to make is if, in fact, we are going to talk about the issue, I think we better get some facts straight and start with the database that we somewhat agree with. And I think Mr. Stark brought up the fact that there are not 132,000 pages of regulation. That sounds good to the public, and they will scratch their head and say, oh, my gosh, we have got to do something about it. But I am told by the former HCFA Administrator Nancy Ann DeParle that the actual pages, including the

manuals, comes out to be about 35,000 pages, which is no small number but, nevertheless, a lot less than 132,000.

Do you agree with that, Mr. Mecklenburg, or not?

Mr. MECKLENBURG. I don't know that I do agree with that, but I would be happy to get back to you on that.

Mr. MCCRERY. Where did the 132,000 come from?

Mr. MECKLENBURG. I think as Mr. Stark said, it came from a study at the Mayo Clinic.

Mr. MCCRERY. OK. And are you aware that Nancy Ann DeParle wrote the Mayo Clinic to ask for justification, which they never responded to?

Mr. MECKLENBURG. Not until——

Mr. MCCRERY. It is nice to use the number, but I would just make sure we use it with some accuracy.

Dr. Corlin, you indicated a recent situation with your practice, we had to do some paperwork before attending to the patient. I can't find that in your printed statement. Could you just re-relate that to the Committee real quick?

Dr. CORLIN. The circumstance occurred that—and it was Tuesday night. It was one of the three hemorrhaging patients that I got called to see. It was someone who had been in the intensive care unit for several days, and because of the requirements to have each and every physician who sees the patient put documentation that is unnecessary and repetitive, instead of about four or five pages of progress notes, there were 33 pages of progress notes. Simply to find out what had gone on with that patient in the last 72 hours, those had to be read before I could——

Mr. MCCRERY. But the inference was that you were filling out this paperwork while the patient was bleeding. Was that——

Dr. CORLIN. No, no. I didn't say that. I was called in and I had to go over that patient's chart. Prior to a couple of years ago, the same amount of medical information would have all been on the chart in probably four or five or six pages. Now it is over 30 pages.

I would invite you, if you ever come to Southern California, I will take you on rounds with me for a day, and we can go through some of the charts, after I cover the patient's name for their confidentiality, and you can——

Mr. MCCRERY. And you are saying those numerous pages are because of the Medicare rules and regulations?

Dr. CORLIN. Absolutely.

Chairwoman JOHNSON. If the gentleman will yield?

Mr. MCCRERY. Sure.

Chairwoman JOHNSON. We will provide you with a list that the Mayo Clinic actually did of Medicare regulations and supporting documents.

Mr. MCCRERY. OK.

Chairwoman JOHNSON. And all of the coding books and those kinds of things that are absolutely essential, plus the laws, and that 137,000 does come from that study.

Mr. MCCRERY. OK. Well, I haven't seen that, and I would like to take a gander at it. But I am told there are 900 pages of statutes, so Congress is not bashful by any stretch. To implement those statutes, there are 1,700 pages of Medicare regulations, and then we do have some HCFA program manuals, and that totals about

32,000. And I am told that is the sum and substance of the Medicare regs that you folks have to adhere to.

But, again, Madam Chair, it is something we should look at. But to blame all the woes, including nursing shortages, on the paperwork I think is a real stretch. I have a niece who is an RN—in fact, I have a couple nieces who are RNs back in Milwaukee, and one is a critical care RN. And the shortage there is a shortage in the nursing profession and not paperwork. And when these nurses have to mandatorily work either another half shift or another full shift at the expense of the family, that gets pretty burdensome. And that is not a Medicare problem.

So I think what we have to do as a nation and possibly as a Congress is look into the actual nursing shortage, which is, I think, more dominant than paperwork having nurses quit the business.

Thanks.

Chairwoman JOHNSON. I think certainly our goal here in this hearing is not to claim that the change of administrative burden is the whole problem or solving it the whole answer. But it is important, and it is the first time in my experience—and I have been on this Subcommittee for 12 years—that we have ever had a panel like this. It is the first time, I think, that we have ever faced the dimension of problems and, therefore, needed to have this. So it isn't the whole answer, but it certainly is one of our obligations to deal with, Jerry. I didn't mean to imply that it was the only thing. But I think their testimony does help you to see that it is an element in the nursing——

Mr. KLECZKA. Madam Chair, again, I agree with you for the most part that it is something we should look at. The program is getting bigger, and it is going to double in size in our lifetime. But to blame everything in the world on HCFA, I am just not ready to do that.

Chairwoman JOHNSON. I would hope that you would take from this—go visit your nursing homes, go visit doctors who——

Mr. KLECZKA. Oh, I am there all the time.

Chairwoman JOHNSON. Talk with them firsthand. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Madam Chair, and thank you for your leadership in this area. If anything needs to be changed, it is the overregulation of HCFA.

I wish my good friend from California, Mr. Stark, were still here. I would remind him that the Mayo Clinic is recognized as one of the foremost medical centers in the world by virtually everyone in medicine, and I certainly respect and take seriously their concerns with regard to overregulation by HCFA and the overly burdensome, cumbersome Medicare regulations. I meet ever week, virtually, with health care providers in Minnesota. I am home every week. And I hear virtually every time about the crushing paperwork burden imposed on providers by HCFA, as has been testified to here today, duplicative documents, redundant forms that are unnecessary to treat patients, unnecessary for quality health care. Too many providers are spending too much time struggling with paperwork rather than treating patients, and it is time, I believe, to introduce common sense into the HCFA bureaucracy; 130,000 pages of rules and regulations are clearly excessive.

For the first 6 or 8 years I was in office, the IRS managed to garner the most complaints among my constituents. Over the last several years, it has certainly been HCFA.

I just was at a nursing home several weeks ago where the administrator explained to me they just hired two new nurses to do nothing but fill out forms. Two new nurses that could be helping patients, working on health care issues, to do nothing but fill out Medicare forms.

This regulatory burden is unacceptable. Certainly it is necessary to have a reasonable level of documentation to prevent fraud, to improve patient care, but it is time, Madam Chair, for HCFA to start focusing on working with patients, working with the health care industry in a collaborative way, rather than working against health providers in an adversarial way. And from your testimony and from the firsthand accounts of providers in Minnesota in my district, it is certainly the consensus, if not the unanimous feeling, of my providers that they are burdened, overly so, by paperwork. And certainly they corroborate your testimony today, every one of you, despite what some of my friends who sometimes—and they are my friends on the other side. Sometimes I think they are operating on a different planet. I couldn't believe what I was hearing, and I wish they were still here to respond.

But I want to thank you, all four of you here, for telling it like it is. Congress needs to hear from you who are operating in the real world and who deal with patients, who represent the best in providers, and I appreciate your coming forward and being helpful to this Committee, because this Committee is very serious about changing the overly bureaucratic, overly burdensome regulatory scheme, regulatory regime of HCFA. This must change because the current regime is totally unacceptable to quality and cost-effective health care. As you suggest, too many people are being driven out of health care because of HCFA.

Let me just ask Mr. Mecklenburg, if I could, do you have any idea—have you quantified this? What percentage of administrative staffs employed in hospitals today deal for the most part, for most of their time, with Medicare reimbursement issues and regulations? Can you estimate the number or the percentage and/or the cost of the Medicare regulations?

Mr. MECKLENBURG. I don't know that I can give you that number. I would be happy to try and find that for you and get back to you.

I would just go back to my testimony. In my organization alone, which is a large teaching hospital, we can identify specifically 100 employees—that ranges from utilization review coordinators, billing coders, corporate complaint staff, internal auditors, various billing folks—that are full-time in compliance. That does not include the staff nurse, the management staff who spend some part of their day. So it is a significant amount of the effort. And what is unfortunate, I think what you can look at, if you are looking at a hospital like mine or many others across the country, if you look at where staff have been added over the years, the high proportion has been made in administrative services, mostly to comply with regulation.

Mr. RAMSTAD. Just like the two nurses just hired by that Dakota County, Minnesota, facility to do nothing but paperwork.

Mr. MECKLENBURG. That is correct.

Mr. RAMSTAD. Thank you again. I see my time has expired. Thank you, Madam Chair.

Chairwoman JOHNSON. Thank you.

I am going to recognize Mr. McDermott, and you see people leaving because we have a vote on. I, too, am going to go and vote, but after Mr. McDermott questions, it is my hope that one of the other Members who has not had a chance to question will have returned so we can proceed promptly and move on to the next panel. Mr. McDermott.

Mr. MCDERMOTT. It is kind of a weird experience sitting up here by myself, nobody listening to what I ask.

[Laughter.]

Mr. MCDERMOTT. In listening to this debate here today, one could come down only, it seems like, in extremes, on one side or the other. Either there is an enormous amount of fraud, waste, and abuse out there, and, by God, we are going to find it; or else we are all doing just fine, and why are you being so intrusive. As a practitioner myself, I can feel for what that is like.

I have a couple of questions that I have been thinking about. One is, it seems to me that in 1995 HCFA put out some rules for evaluation and management documentation guidelines, and they barely got those in, and then in 1997 we started with another provision, and in 1998 another set of rules came out, and we are doing it again.

It seems to me that one of the problems may well be that we haven't taken the time to let anything settle in and for people to actually figure out how it works. But I was reading in the MedPAC recommendations where they suggest that HCFA should pilot test documentation guidelines for evaluation and management services before their implementation and/or pilot test any alternative method.

It seems to me that that is partly what is missing here. I was in medicine when we put on the DRG system. It just came out of nowhere, boom. And it was a research tool at Rutgers or some place, and they were looking for something in the Congress on how to deal with costs, so, bang, that is the answer.

When you do it to the whole system without testing, it seems to me that there is a real problem, and I wonder if my perception is correct. And if it is, what kind of pilot test do you think would give HCFA the capacity to figure out what they want to know without running over the doctor-patient relationship and setting the IG at encouraging senior citizens to call in when you find somebody who has mis-paid a bill?

We have created an atmosphere in medicine which I don't—and in health care in general. It is also with hospitals and with home health and so forth, and in nursing homes, that I don't think is a very healthy one. I don't think it is good for the patients.

I wonder what kind of pilot testing you think, starting with you, Dr. Corlin, and perhaps others have some ideas.

Dr. CORLIN. Thank you, Dr. McDermott. And I very much appreciate your comments and that kind of an attitude. I think it is a

thing that we look forward to working with and cooperating with. And unlike Mr. Kleczka's comments, we are not blaming everything in the world on this. HCFA does a lot of things very, very well, but it does some things not well and some things that we think are really counterproductive. And we would like to see those things corrected so that there can be better focusing of HCFA's resources as to where the problems are.

With regard to the specific question you ask, first, I think there has to be the realization that, whatever the regulations are, while there has to be clear uniformity and equality in how they are applied, there also has to be a realization that in dealing with medical practices and in patients, this is not a one-size-fits-all situation.

We would like to see one pilot done in a teaching setting where you have physicians in training supervised by staff physicians, to see what kind of requirements are appropriate there.

We would like to see one pilot done in a far rural setting where there are much more limited resources, both on the practitioners there and the patients having fewer resources in terms of do I go to this practitioner or that practitioner or the other practitioner. They may only have one source that they can go to, and we would like to see one setting done there.

We would like to see one pilot done which is the result of a peer-reviewed development, almost a clinical vignette setting: Is this the right way to get the documentation?

I think there has to be the realization that while the public and the Government clearly have the right to say we need to prove that when something is billed for it was actually done, by the same token the patients and the physicians have the right to say, you know, this is not just an accounting exercise where you do double-entry bookkeeping and make sure the numbers add up. It has to be relevant to the medical practice, it has to be clinically appropriate, and it has to not interfere with what the patients need.

We would love to be able to sit down out of the glare of lights and cameras and say: How can we work out these pilot studies? And let's put them into working for a while and have people who are, you know, disinterested and are not biased on either side evaluate the results and see what we come up with.

Mr. MCDERMOTT. Did I misunderstand? Did not the AMA and HCFA work together in putting these E&M criteria together or this classification together?

Dr. CORLIN. The AMA urged a lot of the classification and criteria to be developed. We did not work with the development of a lot of the overly burdensome ones. And in many cases, we will come forth and I believe—I am going to have to check with staff because I was not personally involved with that. We may well have been involved in requesting some of the general category to be addressed, but were not involved in the development of the details.

Now, many of the specialty societies put forth individual items for it, and we coordinated some of that. But we were most distressed, particularly with the 1997 guidelines, because of how clinically inappropriate they were in comparison with what has to be on the chart meeting HCFA's requirements versus what has to be

on the chart to document good medical care that is easily retrievable the next time that chart is picked up.

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

Mr. MCDERMOTT. Would you extend it for just 1 second?

Mr. CRANE. All right. One second. One thousand one.

Mr. MCDERMOTT. One of the cases that—the fraud and abuse initiative started in 1998, and an example used as an unsupported service for physician payment was "a routine physical exam." And to put that into the improper payments implies it is bad or fraudulent. How do we get around that? I mean, the IG says he is looking for improper payments.

Dr. CORLIN. I think, sir, that right now there is a reasonably good understanding on everybody's part as to what fraud is. When fraud occurs, fall on them like a ton of bricks, and we will be there clapping. No question about it.

Beyond that, there are the inadvertent billing errors that occur by people who they or their office staff may not know the proper way to do it, and then there is a third thing, which I think, Dr. McDermott, gets to the point you raise, which is the coverage issue. If a routine physical is not a covered benefit—and I am a gastroenterologist; up until July 1st, when, fortunately, it will change—routine colonoscopy may not be a covered benefit, if it is done, if it is needed by the patient for good medical care, if it is documented that it was done but it is not a covered benefit, then simply reject that as not being a covered benefit, send back an EOB saying it is not a covered benefit, and the issue is done with. That is a different category of situation.

Mr. MCDERMOTT. Did I understand, then, they wouldn't have paid for the routine physical exam?

Dr. CORLIN. They shouldn't have. Whether they did or not may be another matter.

Mr. MCDERMOTT. Is there any way it could have gotten paid for? I mean, it would seem to me that the intermediary would have a screen that said any time that comes up, no.

Dr. CORLIN. Well, they probably do and I hope they do. And, again, being a gastroenterologist, let me get back to one example that has caused a lot of confusion in people's minds with regard to the issue of screening colonoscopy, which has gotten a lot more publicity because of Katie Couric and the tragedy of her husband. In the long run, it is going to help people enormously.

People consider screening colonoscopies and don't know what it really means. That doesn't mean a patient who has had, say, an episode of rectal bleeding and comes in to a doctor. That is not a screening test. That is in regard to a specific symptom. A screening test is somebody who is completely healthy, who has no family history of colon cancer, who says I am 50 and I want the test just because I think it is good to have it when I am 50, good medical care says, yes, that is right. Is that a covered benefit of any given program? That is another issue completely, and we would—you know, the coverage issues are the coverage issues. But that is just for screening, not for when someone has symptoms, and one of the difficulties we have had—and I am sure Mr. Mecklenburg can relate the same thing—is confusion in the part of a lot of reviewers' minds of care given on a truly screening or surveillance basis as

opposed to the same care given in response to someone who has some history or symptoms that indicate it is specifically necessary.

Mr. MCDERMOTT. If a patient—I am stretching my——

Mr. CRANE. Two seconds.

Mr. MCDERMOTT. Two seconds. With respect to a patient who would come in and say, "I feel bad and I don't know what it is, I just don't feel right," you would so a physical exam. Would that be considered a routine physical exam?

Dr. CORLIN. To my way of thinking, no. A routine exam of any sort, whether it be a general physical, a colonoscopy, a mammogram, a Pap smear, this is something that someone says I am well, I have learned either from my physician or from the media, or whatever, that it is good to have this test every so often, and I want to have mine to be sure I don't have a problem, that is routine screening.

When a patient comes in with any symptoms, that is not routine screening anymore.

Mr. MCDERMOTT. Thank you.

Chairwoman JOHNSON. Mr. Crane.

Mr. CRANE. Thank you, Madam Chairman.

Dr. Corlin, just last week the Office of Inspector General reported that nearly $12 billion in Medicare spending was lost last year to improper payments. And while this represents a welcome improvement over the previous years, it remains unacceptably high.

The OIG has claimed that this bill substantially undermines the program's integrity. How do you respond to that assertion?

Dr. CORLIN. First, let me say that I agree with your initial statements. We are glad the amount is down, it is still far too high, and would support any reasonable efforts to get it even lower. We would disagree with the OIG's conclusion because nothing in this bill would in any way deter or interfere with the investigation of suspected fraud, whether that is the most blatant of fraudulent billings or even—there are certain provisions in the bill that would say if the physician or the practice brings forth concerns about claims that may have been paid improperly, that they cannot be held accountable on fraud for that since they brought it forth.

The OIG complained that, well, the physician could just take all their bills for the year, bring them forth, and say, gee, I may have done it wrongly, can you help me, get the advantage of the float, the way Mr. Stark described it, and immunize themselves on all their claims. That is not true because that pattern of behavior in itself is fraudulent. That clause is given to the physician who finds in an occasional case or, gee, in this one code I just realized I may have been billing it wrong, and I want to get it corrected.

We in no way want to do anything to limit their investigation or prosecution of fraud when it occurs. And if there is anything in this bill that inadvertently would have that result, we would look forward to be supportive of changing language to see to it that that doesn't occur.

Mr. CRANE. And, I don't know, Gary, should I call you "Mr. President"?

Mr. MECKLENBURG. Whatever you wish, Mr. Crane.

Mr. CRANE. All right. You mentioned several burdensome operational processes that hospitals are required to do by Medicare. Do other payers, private insurance companies or HMOs, ask you to do the same task but in a less onerous way? And if so, could you elaborate a little?

Mr. MECKLENBURG. I think as we talked a little bit before, I think the requirements of each payer can be highly variable. That is another operational problem that we have of inconsistency in the forms, in the data, in the way that we must submit claims.

I would submit that the regulations that come from Medicare and Medicaid are often longer, more onerous, more subject to interpretation perhaps by a variety of people than we experience with most of our payers.

Mr. CRANE. In your testimony, you suggest that hospitals must be able to challenge in Federal court any attempt by HHS to overstep its authority or to enforce questionable policy. Could you please tell us specifically what you are referring to and what sort of questionable Medicare policy have you encountered? And why should your provider seek legal rather than regulatory or legislative remedies?

Mr. MECKLENBURG. The problem that we have with this part of the Medicare regulations is that, in order for us to exhaust the administrative processes under Medicare, we have to first be in violation of the Medicare rules or law. And if we are in violation, then we risk being banned from participation in the program. We certainly think that that is not the proper way for us to go about determining whether or not a specific rule or a specific regulation is appropriate or inappropriate inside the law. So we simply think we ought to have the opportunity from time to time to be able to challenge in a due process sense what has been proposed.

Mr. CRANE. Thank you for your testimony, and I yield back the balance of my time, Madam Chairman.

Chairwoman JOHNSON. Thank you very much, Mr. Crane. Miss—Mrs. Thurman from Florida. Sorry about that.

Mrs. THURMAN. It is OK. It has already been a long morning.

I want to add my thanks to the chairwoman for bringing this particular issue to the forefront, because we have all seen this to be a problem.

Dr. Corlin, one of the interesting things, though, that I did notice in one of the responses was that you mentioned that you had gone from about six pages to 33 pages in the last 5 to 6 years. Was that correct? In the paperwork that you were doing?

Dr. CORLIN. Actually, it is probably a more recent timeframe. It is probably within about the last 3 or 4 years.

Mrs. THURMAN. So we could actually say that some of this has coincided with the major changes that have been happening here in Congress through the BBA, the buybacks, and then again over the last couple of years where these regulations have actually gone up.

Dr. CORLIN. I think probably related to the 1997 HCFA regulations. If there is any one point that they are key to, it is probably more the 1997 E&M guidelines than anything else, yes.

Mrs. THURMAN. One of the things that I would just caution with this Committee is that we have just also done one this last year,

again, and, you know, it is probably apropos that we are talking about this now, because there is probably going to be a whole other set of guidelines out there that potentially will also have an impact on what you are doing, plus the information I know that we are asking from all of the providers now because we, you know, stopped some of the things that have been put in place so that we could gather additional information, so that we could make a better decision on how we might implement any of that. I mean, I think that is true.

So the question that I would ask all of you then is: In the time that we have gone through these transitions, have you used the process of, you know, when the rules are set out there, and are you using the process to give your comments on review as to where you think there are problems? And if you can, can you cite some of those for us so that we can find out potentially from this Committee what has happened to those rule suggestions and how they have been implemented that have not been, you know, what you might have put down as the providers?

Mr. MECKLENBURG. I think we consistently comment on various rules and regulations that come out, and we would be happy to provide you back with very specific examples of where we have done so and where we believe the outcome hasn't been appropriate.

Ms. OUSLEY. Certainly, we spend a lot of time commenting on the rules and regulations as it pertains to nursing facilities. One of the issues that we have faced over these last several years, especially with the implementation of the Medicare prospective payment system for nursing facilities, is that we essentially implemented the system with an interim final rule. So it can be said that we were actually flying the airplane as it was being built. So as we would train our nurse aides, train others on exactly what would be required, as we were getting them trained and getting one process implemented, then the process would start to change. So that was very, very difficult, and it really has contributed tremendously to the burdens and some of the issues that we have talked about today.

HCFA certainly listened to our comments and worked with us to try to accomplish all of that under a very short time frame, but it was very, very difficult to accomplish.

Mrs. THURMAN. But they also were given directive by the Congress——

Ms. OUSLEY. Correct.

Mrs. THURMAN. To, in fact, do certain things to have an outcome, which has created—even with the comments sometimes, you know, was maybe not the outcome that you wanted, but certainly might have been the outcome that Congress wanted, I would suggest.

Ms. Wilson, I want to say that you all do have an awful lot of paperwork, and I think probably of all of the areas that beneficiaries see that, more is from your particular area of the visiting nurses or home health care, because I can tell you from just sitting down with my mother, you know, up here and then in Florida, I did the same paperwork ten times. There was no difference. And I was just transferring her from, you know, here to there, and, you know, you do 2, 3 hours as the caregiver to the person who is going

to be responsible for taking care of them in your home. And I found that just incredibly——

Ms. WILSON. Well, thank you for mentioning that, because not only am I an administrator of a home health agency, I am also a daughter and a daughter-in-law of aging parents, and it has been astronomical to sit down and try to explain what it is that we are presenting.

One of the common complaints that we have from our clients is that there are too many questions, there are too many papers, I have to sign my name too many times, and I don't know what I am signing.

Mrs. THURMAN. And I heard that from your nurses as well, and they have said to me, if you could do one thing, do that. However, in saying all of that, the other thing that I would ask from all of you is, you know, part of the problem that I think has come to our attention and one of the problems that we face is that at the same time that all of these issues were going on, we were having Operation Trust out there, we had all of this fraudulent activity just recently in Florida under Medicaid. We have now found payments that, you know, could average up to as much as $10 million in the Medicaid fund because people who have died have actually still—Medicaid is still being billed for them.

So I think one of the things that, as we go through any of these changes, is that you have to understand I believe from our side over here that we are also responsible for the dollars that are coming in and that are being spent. You are taxpayers. You understand that. And over the years it has been our responsibility to hold that accountability and to make sure those things aren't happening. And we constantly see from every organization, from all of our constituents, saying I know there is fraud, you know, I have been here, I have done that, we have started programs. And so we are, you know, trying to be helpful, but on the same side of it, we are the protectors of the taxpayers' dollars, and they demand a certain amount of accountability from us to show that we are not allowing these kinds of actions to take place.

Ms. WILSON. May I comment in reference to that? I absolutely agree with you. I do believe that there needs to be oversight. I do believe that there needs to be protection. I absolutely believe that regulations that are in place are there for a purpose.

We did go through a period of time where certainly fraud and abuse was on the front page of every single newspaper in the country. However, in speaking particularly about the Northeast, many of the surveys that were done, the audits that were done, found very, very little. However, agencies continue to be under scrutiny.

Our agency alone, within a period of 18 months, had 12 to 13 different surveys. Every single one of them came out perfectly clean. We turned around and the next proverbial knock would be at the door.

I had one of the staff people say that it got to the point where, while we absolutely agree with zero tolerance as far as fraud and abuse is concerned, that we are now in a system where the best is never enough and everything you do is suspect. And that the staff find intolerable.

Mrs. THURMAN. If I could just say, Madam Chairman, one of the things that I would think that, as Secretary Thompson said yesterday, that we certainly needed to be giving more money to HCFA, that one of the things that I think that we should look into—and I don't want to mandate anything more to HCFA, but is to look at what is happening in the training aspects of both those that are going out to inspect and those that are doing the coding.

I remember in the early 1980s when every government agency started going on computers, and we spent all this money on computers, but we spent no money on training. So a lot of the computers would sit there because people couldn't use them. And I think we have got a similar situation going on here, and maybe we should be putting a moratorium on any kind of regulations until we can figure out where we are today.

Chairwoman JOHNSON. Thanks very much, Congresswoman Thurman. I thank the panel very much for your excellent testimony and for your patience in answering questions.

We will move on to the next panel now: Toby Edelman, attorney for the Center for Medicare Advocacy; George Grob, the Deputy Inspector General, the Office of the Inspector General; and Bob Moffit, the director of Domestic Policy Studies at the Heritage Foundation; and the Honorable Gail Wilensky, Project HOPE.

As is our usual procedure, you will each have 5 minutes, and then we will turn to questions. As soon as you are ready, Ms. Edelman, if you will proceed.

STATEMENT OF TOBY S. EDELMAN, ATTORNEY, HEALTHCARE RIGHTS PROJECT, CENTER FOR MEDICARE ADVOCACY, INC., AND MEMBER, BOARD OF DIRECTORS, NATIONAL CITIZENS' COALITION FOR NURSING HOME REFORM

Ms. EDELMAN. Good morning. I am Toby Edelman, an attorney with the Center for Medicare Advocacy, and a Member of the Board of Directors of the National Citizens' Coalition for Nursing Home Reform. Thank you for the invitation to testify on behalf of Medicare beneficiaries and their advocates. I would like to summarize my written testimony and three points and then elaborate briefly on each of them.

First, Medicare beneficiaries and advocates view HCFA's rules and the regulatory process somewhat differently from the providers who have testified this morning. We see the rules promulgated by HCFA as helping to assure that beneficiaries have full access to high-quality health care.

Second, we know that law and regulations can work. In the area of nursing homes, the nursing home reform law and Federal rules have improved the quality of care for residents in some important respects. The good care practices mandated by the reform law and rules are also cost-effective and save Medicare dollars.

We have seen other examples where HCFA's rules and guidelines are criticized by providers, including this morning the home health advanced beneficiary notice. But these give beneficiaries important information that helps them get the health care they need and are entitled to receive under Medicare.

Third, we believe that HCFA is often overly deferential to the health care industries it regulates and that beneficiaries can be seriously harmed as a result.

Medicare beneficiaries see the rulemaking process, at its best, as both open and highly democratic. The process allows all sectors of the public to participate, to express their views, and to be heard. Beneficiaries as well as providers can influence HCFA's rules and guidelines. The rulemaking process also requires HCFA to respond to these public comments and to explain its rationale in making regulatory decisions.

The reform law enacted in 1987 and its implementation by HCFA are a clear example of how law and regulation work effectively. They established a high level of care as the Federal standard and helped improve the quality of care for residents.

The reform law was based in large part on good practices that had been tried and proven effective in States and facilities, and I would like to discuss just two of the practices this morning: reduction in the use of restraints and resident assessment.

When the law was enacted, nursing practice and the nursing home industry in general believed that restraints would protect residents from injuries and falls. As a result, in the late 1980s an estimated 41 percent of all residents in the country were physically restrained. The reform law changed that paradigm. Based on practices of facilities that had demonstrated that removing restraints was a better and safer way to provide care, Congress and HCFA made restraint reduction a priority concern. In 1999, only 11.2 percent of residents were physically restrained.

The Institute of Medicine report on long-term care that was issued earlier this year called restraint reduction "the greatest improvement in nursing home care." And the Institute of Medicine credited HCFA's regulations and oversight for this tremendous improvement. Being restraint-free is better for residents and it is cheaper for government payers.

The second example is the requirement from the law that all facilities assess residents using a comprehensive, standardized, reproducible assessment instrument. The minimum data set, or MDS, was developed by HCFA through an intensive public process that involved all sectors of long-term care, and I would add parenthetically that, although the nursing home reform law explicitly authorizes States to develop their own assessment instrument, all States in the country have chosen to use the MDS process that HCFA developed.

An evaluation in 1996 found that MDS improved care outcomes for residents. There were more positive outcomes—more residents had hearing aids; more of them were involved in meaningful activities—and fewer negative outcomes—fewer residents had catheters, for example.

Not only was care better, it cost less. Hospitalizations were reduced by 26 percent, reflecting an annual estimated savings to the Medicare Program of $2 billion in hospital costs in 1992 alone.

As I describe in my written testimony, clinical staff and administrators continue to resist using the MDS and have complained about it, even as they acknowledge that it gave them better information about residents and helped them provide better care.

Despite improvements, we know that serious and unconscionable care problems remain in too many nursing homes. Many of these problems were documented by Senators Grassley and Breaux in the extraordinary series of hearings they held in the Senate Special Committee on Aging between July 1998 and September of last year. But these hearings also demonstrated that the care problems resulted primarily from lack of strong public enforcement of the care standards and not from the statutory and regulatory standards themselves. And the recent IOM report agreed with this analysis.

I would like to turn briefly to my third point, that HCFA is too timid in exercising its rulemaking authority and overly deferential to health care providers. In the nursing home area, HCFA at first had difficulty implementing the strong enforcement approach of the reform law in the face of fierce and aggressive opposition by the industry. The weak enforcement system initially established by HCFA's guidelines tolerated high levels of facility non-compliance with care standards. The General Accounting Office reported in July 1998 that 99 percent of facilities that had deficiencies were not subject to any remedy at all. The GAO called this an amnesty program for providers and said they were given a chance to correct their problems.

The weak enforcement of the care standards was a major cause of the care crisis that Senators Grassley and Breaux's hearings vividly documented. Strong congressional oversight and the administration's nursing home initiative have now helped redirect the agency's approach to enforcement to some extent. The enforcement system is now more consistent with Federal law and more likely to achieve its purposes of assuring correction of deficiencies, sustained compliance by facilities, and, of course, most important, high quality of care for residents.

Nevertheless, many beneficiaries have been hurt by what the GAO described as the lax and overly tolerant enforcement system that HCFA at first created in deference to the industry.

I would just like to say something very briefly about benefits of other HCFA rules beyond nursing home care. This morning we heard criticism of the new home health advanced beneficiary notice, which requires home health agencies to use a standard form in notifying beneficiaries when they believe the Medicare Program will not cover particular home health benefits. I have three comments about that.

First, this requirement is not new. HCFA has required home health agencies to provide beneficiaries with notice of non-coverage since at least 1975. What is new is the requirement that home health agencies use a form specified by HCFA.

But the second point is that home health agencies had been informed in advance that HCFA intended to mandate use of the HHABNs, and they have been fully involved in the regulatory process since September 1999 in developing that form.

Finally, and I think most importantly, receiving notice about non-coverage of care is critical to beneficiaries. Once beneficiaries receive such a notice, they can require that their home health provider submit what is called a demand bill to the Medicare Program. This is the first step in the appeals process. But even at this early

step, more than half the beneficiaries who submit demand bills win their claims and get coverage for home health care from the Medicare program. In other words, the home health agencies were wrong in more than half the cases in saying that the services needed by beneficiaries would not be covered by Medicare. The HCFA-mandated notice from the provider and the demand——

Chairwoman JOHNSON. If you would please conclude?

Ms. EDELMAN. Yes, thank you. That——

Chairwoman JOHNSON. I know how important this is to you, and we will get back to it in the question period.

Ms. EDELMAN. Yes, well, thank you very much. The final point about this is that this notice helps beneficiaries pursue their right to Medicare coverage, and without the notice and without the system, beneficiaries would not receive the Medicare coverage of home health care that Congress intended.

Thank you very much.

[The prepared statement of Ms. Edelman follows:]

Statement of Toby S. Edelman, Attorney, Healthcare Rights Project, Center for Medicare Advocacy, Inc., and Member, Board of Directors, National Citizens' Coalition for Nursing Home Reform

INTRODUCTION

Good morning. I am Toby Edelman, an attorney with the Healthcare Rights Project of the Center for Medicare Advocacy, Inc. and a member of the Board of Directors of the National Citizens' Coalition for Nursing Home Reform. Thank you for the invitation to testify before the Subcommittee on behalf of Medicare beneficiaries and their advocates.

OVERVIEW

Rules promulgated by the Health Care Financing Administration to implement federal Medicare legislation have helped to assure that Medicare beneficiaries have access to high quality health care. In the area of nursing homes, the nursing home reform law and federal rules have improved aspects of quality of care for residents. In addition, the good care practices mandated by the reform law and rules are cost-effective and save Medicare dollars.

However, while HCFA can and does play an important role in protecting beneficiaries' access to high quality care, too often, the agency is timid and overly deferential to the health care industries it regulates. Beneficiaries can be harmed as a consequence.

THE PURPOSE OF THE MEDICARE PROGRAM IS TO PROVIDE HEALTH CARE SERVICES TO BENEFICIARIES, NOT PAYMENTS TO HEALTH CARE PROVIDERS

Congress enacted the Medicare program in order to provide health care benefits to older people and people with disabilities. Courts have repeatedly recognized and stated that the program is designed for beneficiaries, not providers. *Home Health Services, Inc. v. Currie*, 531 F. Supp. 476, 479 (D.S.C. 1982), *aff'd* 706 F.2d 497 (4th Cir. 1983) ("[T]he statute was obviously not enacted primarily for the benefit of the provider of services, but rather for the recipients of medical care benefits."); *Gartman v. Secretary of the United States Department of Health and Human Services*, 633 F. Supp. 671, 679 (E.D.N.Y. 1986); *Mays v. Hospital Authority of Henry County*, 582 F. Supp. 425 (N.D. Ga. 1984).

THE ADMINISTRATIVE RULEMAKING PROCESS ENABLES BENEFICIARIES AS WELL AS HEALTH CARE PROVIDERS TO PRESENT ISSUES AND CONCERNS TO THE HEALTH CARE FINANCING ADMINISTRATION

Due to the complexity of health care programs and the expertise needed to administer them, Congress delegates responsibility to the Department of Health and Human Services to provide the details for its legislative enactments. The Health Care Financing Administration is the component within the Department that has expertise and is given the authority to implement the Medicare statute. HCFA

meets its duty to implement federal legislation, including Medicare, through a public rulemaking process.

While the rulemaking process is lengthy and time-consuming, it is also, at its best, both open and highly democratic. The rulemaking process allows all sectors of the public to express their views and to be heard. Beneficiaries and their advocates, as well as health care providers, participate in the rulemaking process in order to bring their experiences and concerns to the attention of HCFA. Through their comments on rules, they explain the impact of rules on all segments of the public and offer suggestions to improve or strengthen rules to achieve their statutory goals. When HCFA publishes final rules, it is required to respond to these public comments and to explain its rationale in making regulatory decisions. HCFA is publicly accountable for its decisions.

MEDICARE BENEFICIARIES AND THEIR ADVOCATES SEE RULES AND THE RULEMAKING PROCESS AS HELPING TO ASSURE BENEFICIARIES' FULL ACCESS TO HIGH QUALITY HEALTH CARE

While providers may see various aspects of the laws and rules as burdensome and excessive, beneficiaries often view these same laws and rules quite differently. Beneficiaries see the laws and rules as establishing a system that protects their rights and interests in receiving full access to high quality health care.

NURSING HOME CARE

The nursing home reform law enacted by Congress in December 1987 and its implementation by HCFA are a clear example of how law and regulation work effectively both to establish a high level of care as the federal standard of care and to help improve the actual quality of care that residents receive. I follow nursing home law closely, having spent nearly 25 years advocating on nursing home issues on behalf of residents, particularly Medicare and Medicaid beneficiaries.

The 1987 reform law was the most comprehensive revision to federal nursing home law since the Medicare and Medicaid programs were enacted in the 1960s. Congress based the detailed legislation on a series of hearings in 1987 in the three committees with legislative responsibility for the Medicare and Medicaid programs; on the 1986 report of the Institute of Medicine, *Improving the Quality of Care in Nursing Homes*, which itself was the result of several years of exhaustive research; and on recommendations of the Campaign for Quality Care, an *ad hoc* coalition of nursing home provider associations, health care professionals working in nursing homes, and residents' advocates, convened by the National Citizens' Coalition for Nursing Home Reform to identify areas of consensus about how best to translate the IoM's recommendations into federal law.

The nursing home reform law was based in large part on good practices that had been tried and proven effective in states. Requiring the training of nurse aides (who provide the majority of direct care to residents) and comprehensive assessment and care planning, guaranteeing residents' rights, and authorizing a broad range of intermediate sanctions that survey agencies could impose against facilities that failed to meet care standards were among the innovations of the legislation. These good practices involved both the care practices that nursing homes had developed and used with success as well as survey and enforcement practices that states had successfully used. The reform law made these good practices mandatory for all states and all facilities that chose to participate in the Medicare and Medicaid programs.

The Law and Implementing Regulations Promulgated by HCFA Have Promised Residents High Quality of Care and Have Led to Some Significant Improvements in Care.

The nursing home reform law and regulations and guidelines published by HCFA to implement the law have led to demonstrable improvements in the care that residents receive. While the series of hearings held by Senators Charles Grassley and John Breaux in the Senate Special Committee on Aging, between July 1998 and September 2000, documented that grave and unconscionable problems remain in the quality of care provided by too many nursing homes, the hearings demonstrated that these problems result primarily from the lack of strong public enforcement of the care standards, not from the statutory and regulatory standards themselves.[1]

The Reform Law Required Reduction in the Use of Physical and Chemical Restraints.

The requirement to reduce the use of physical and chemical restraints was based on good care practices in some nursing homes that had reduced or entirely elimi-

---

[1] The Institute of Medicine's 2001 report *Improving the Quality of Long-Term Care* also identified "serious deficiencies" in assessment and enforcement of care standards as the cause of continuing serious care problems in nursing homes. Institute of Medicine, *Improving the Quality of Long-Term Care,* 251 (2001) [hereafter IoM, *Improving the Quality of Long-Term Care*].

nated restraints. At the time the law was enacted, however, a more common view in the nursing profession and the nursing home industry was that restraints would protect residents from injuries and falls. As a consequence, in the late 1980s, an estimated 41% of all residents were physically restrained.[2]

The reform law adopted the best practice from the restraint-free movement (which recognized that restraints in fact caused more injuries to residents than restraint-free care), changed the paradigm of care on a national scale, and led to a reduction in restraint use for residents. The most recent national data indicate that in 1999, 11.2% of residents were restrained.[3] Freeing residents from restraints was documented to be not only better from residents' perspective, but also a less costly way of providing care.

As Joani Latimer, a nursing home residents' advocate, wrote in the Journal of the American Society on Aging, "good law takes everyone to a higher standard."[4] The reform law set a new standard regarding restraints. When the New York-based Commonwealth Fund supported a project several years ago on restraint reduction in nursing homes, project staff asked facility staff why they participated in the research. Many answered that since the reform law now required reduction of restraints and facilities would be evaluated by the survey agency by this different standard of care, they were motivated to learn how to comply with the new rules most effectively. The project gave them that opportunity.

In a report issued this year, the Institute of Medicine attributed the reduction in the use of physical and chemical restraints nationwide, which it called "the greatest improvement in nursing home care,"[5] to the requirements of the reform law:

> [M]any facilities have successfully reduced the inappropriate use of physical and chemical restraints. The focus of increased regulatory scrutiny on these two areas of care was a major contributing factor in reductions in both of these.[6]

Reducing the use of restraints is good care; it is also a less expensive way to provide care to residents.[7]

The new survey process that was put in place in July 1999 included six new investigative protocols addressing adverse drug reactions, pressure sores/ulcers, hydration, unintended weight loss, dining and food service, and sufficient nursing services.[8] With the restraint experience as a model, it can be hoped and expected that the new regulatory attention on these care areas will also lead to improvements in care outcomes for residents.

The Reform Law Required Standardized Resident Assessments.

Another beneficial aspect of the 1987 reform law was the requirement that all facilities assess residents using a comprehensive, standardized, reproducible assessment instrument. The assessment would identify "potentially treatable or reversible causes of functional impairment" and would be used to plan each resident's care in the individualized care-planning process.[9]

The new resident assessment instrument, known as the minimum data set, or MDS, was developed through an intensive public process that involved all sectors of long-term care and included extensive testing. Although the nursing home reform law explicitly permitted states to develop their own assessment instruments, all states have chosen to use the assessment instrument and process that were developed by HCFA.

An evaluation of the impact of the MDS in 1996 found that the new assessment process improved care outcomes for residents. The study found, among other changes:

- "a 24 percent increase in the accuracy and comprehensiveness of information in the residents' nursing home records."

---

[2] *Id.* 79.

[3] Charlene Harrington, et al, *Nursing Facilities, Staffing, Residents, and Facility Deficiencies, 1993 Through 1999*, 85 (Oct. 2000), at http://www.hcfa.gov/medicaid/nursingfac/nursfac99.pdf.

[4] Joani Latimer, "The Essential Role of Regulation to Assure Quality in Long-Term Care," *Generations*, Vol. XXI, No. 4, 13 (Winter 1997–1998) [hereafter Latimer, "The Essential Role of Regulation"].

[5] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 79.

[6] *Id.* 77.

[7] Charles D. Phillips, Hawes, C., and Fries, B., "Reducing the Use of Physical Restraints in Nursing Homes: Will It Increase Costs?" *American Journal of Public Health, Vol.* 83, 342–348 (Mar. 1993).

[8] HCFA, Transmittal No. 10 (Jul. 1999). The survey protocol is at http://www.hcfa.gov/pubforms/pub07pdf/part-07.pdf.

[9] Charles D. Phillips, Hawes, C., Mor, V., Fries, B.E., and Morris, J.N., "Geriatric Assessment in Nursing Homes in the United States: Impact of a National Program," *Generations* (Journal of the American Society on Aging), Vol. XXI, No. 4, 15, 16 (Winter 1997–1998) [hereafter Phillips, "Geriatric Assessment"].

• "a 17 percent increase in the number of problems that are addressed in residents' care plans."

• "a 30 percent increase in the use of hearing aids for persons with hearing difficulty."

• "a 27 percent increase in the use of behavior management programs for residents who wander, display physical aggression, or resist nursing care."

• "Residents with bowel incontinence were almost twice as likely to receive a toileting program."

• "a 29 percent decrease in the use of indwelling urinary catheters."

• "a 28 percent decrease in the proportion of residents with little or no activity."[10]

The increase in positive care outcomes and decline in negative care outcomes that resulted from implementation of the MDS had a price tag—they saved Medicare dollars. Providing good care to residents and more accurately identifying and meeting residents' care needs also led to reduced instances of hospitalization. Dr. Catherine Hawes reported that introduction of the MDS led to a 26% reduction in hospitalization of residents, resulting in an annual estimated savings to the Medicare program of two billion dollars in hospital costs in 1992 alone.[11]

While use of the MDS led to an increase in positive health outcomes for residents and, at the same time, significantly reduced costs to the Medicare program, administrators and nurses who were questioned about the MDS reported mixed feelings about the new assessment tool. Dr. Charles Phillips, et al., reported that 43% of clinical staff were "resistant" to using the MDS and that 68% of administrators complained about the "excessive paperwork burden."[12]

However, a majority of both administrators and nursing directors agreed that the RAI had positive effects on quality: some 59 percent of nursing directors reported that the RAI improved the quality of residents' clinical assessments, 69 percent that their staff's assessment of residents' functional status improved, and 75 percent acknowledged that the RAI was more useful than the assessment system used in the past. Finally, 78 percent of nurses reported that the RAI improved their ability to detect clinically meaningful changes in resident functioning.[13]

Health care providers may find fault with regulations even when they recognize the improved health care for beneficiaries (and cost savings to the Medicare program) that result.

ACCESS TO CARE

Some of the Medicare regulations that health care providers complain about are intended to assure that beneficiaries receive the health care benefits that Congress mandated.

In the area of home health care, for example, home health agencies have recently been critical of the home health advance beneficiary notice (HHABN) issued by HCFA through a program memorandum. Effective March 1, 2001, HCFA requires home health agencies to use a standard form to notify beneficiaries when they believe that the Medicare program will not cover particular home health benefits. This substantive requirement is not new. In fact, HCFA has required home health agencies to provide beneficiaries with notices under these types of circumstances since at least 1975. The recent program memorandum is different from prior notices only in its specification of the actual language that home health agencies must use in the HHABNs that they give to beneficiaries to advise them of their rights under the Medicare law.

Home health agencies were well-informed in advance that HCFA intended to mandate use of the HHABNs and were fully involved in the process. The model notice was issued through the Paperwork Reduction Act process, which requires public comment and review by the Office of Management and Budget. Beginning in September 1999, transmittals and draft notices were issued and withdrawn several times, in large part, in response to comments from home health agencies. OMB and HCFA held a public hearing in July 2000, in which representatives of the home health industry actively participated and expressed their concerns about the burden imposed by the HHABNs.

Receiving notices about non-coverage of care is critical to beneficiaries, however, and outweighs the minimal burden imposed by using a standard notice form. Beneficiaries who are able and willing to pay for home health services can do so after

---

[10] Catherine Hawes, "Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA 1987," 6–8 (Commonwealth Fund, Dec. 1996).

[11] *Id.* 8.

[12] Phillips, "Geriatric Assessment," *supra* note 9, 16.

[13] *Id.* 16–17.

receiving a notice of non-coverage from their home health agency. If they choose, they can also require their home health provider to submit what is called a "demand bill" to the Medicare program. Once the Fiscal Intermediary receives a demand bill, it makes a formal determination whether a particular home health service is covered by the Medicare program.

Beneficiaries who request that a home health agency submit a demand bill are often successful in getting Medicare coverage of their home health services. According to HCFA data, between 1994 and the first three months of 1998, beneficiaries who had demand bills submitted on their behalf were fully or partially successful at the initial claims stage in getting home care coverage in 50.2% of the cases.[14]

Without the HCFA-mandated notice from the provider and the demand bill process that enables them to request that Fiscal Intermediaries review their health care needs, beneficiaries would be unable to pursue their rights to receive their statutory entitlement to home health care under the Medicare program. As the court said in *Healey v. Shalala*, "A demand bill is the key to the administrative process."[15]

A second example illustrates the importance of the Medicare program's providing information to beneficiaries about their rights under the Medicare statute. A recent report by the Office of Inspector General recommends that HCFA "educate beneficiaries on the options and consequences of assigned and non-assigned claims and purchasing medical equipment and supplies from participating and non-participating suppliers."[16]

Under Part B of the Medicare program, suppliers of medical equipment may choose to submit assigned or non-assigned claims. For assigned claims, where suppliers agree to accept the amount allowed by Medicare as payment in full, Medicare pays 80% of the allowed amount and the beneficiary pays 20% of the allowed amount (plus any outstanding deductible). For non-assigned claims, Medicare pays 80% of the allowed amount, but sets no limit on the charge that the supplier may charge the beneficiary. The beneficiary must pay all the supplier's charges after Medicare pays its amount. Balance billing is the term used to define "the portion of the charge in excess of the Medicare allowed amount."[17] Suppliers may also "participate" in Medicare or not. Participating suppliers submit assigned claims for all items and services provided to beneficiaries; non-participating suppliers submit either assigned or non-assigned claims to Medicare, decided on a case-by-case basis.

The Inspector General's recent report indicated that Medicare beneficiaries paid $41 million above the Medicare-allowed amounts for equipment and supplies and that most beneficiaries are unaware of the cost implications of purchasing equipment and supplies from participating and non-participating suppliers.[18] Informing beneficiaries about the cost implications of their purchases could help beneficiaries reduce their health care costs. Since non-participating suppliers are unlikely to advise beneficiaries that they could purchase the same supplies for less money elsewhere, only the government is likely to inform beneficiaries of their rights under the Medicare law.

QUALITY OF HEALTH CARE

Rules and regulatory systems also require and promote high quality of care for beneficiaries. This purpose of the regulatory system is also of critical importance to beneficiaries.

Ms. Latimer reports that regulation is necessary in the health care area, particularly in long-term care, because market forces may be unable, alone, to assure high quality of care for beneficiaries.[19] The factors that may make the marketplace work as a mechanism assuring high quality of products are largely absent in health care. Health care consumers may be inadequately informed; may have little choice among health care providers (because of insurance limitations or provider discrimination against program beneficiaries); and may be required to make decisions at a hurried, stressful time. Moreover, the consequences of their decisions often cannot be reversed. People can choose to buy a different television set if the one they buy breaks. Similar opportunities are unlikely in health care. Health care that is denied or inadequately provided may not be able to be fixed or corrected.

---

[14] *Healey v. Shalala*, 2000 WL 303439, at 4, 68 Social Security Reporter Service 212 (D.Conn. Feb. 11, 2000). This statistic does not include beneficiaries who were successful in getting coverage at later stages of the appeals process.

[15] *Id.*

[16] Office of Inspector General, Department of Health and Human Services, *Balance Billing for Medical Equipment and Supplies*, ii, OEI–07–99–00510 (Jan. 2001).

[17] *Id.* i.

[18] *Id.* i–ii.

[19] Latimer, "The Essential Role of Regulation," *supra* note 4, 10.

The Institute of Medicine's 1986 report on nursing home quality rejected reliance solely on market forces to improve the quality of long-term care:

> [H]istorical experience hardly supports an optimistic judgment about the effects on quality of care of allowing market forces to exert the primary influence over nursing home behavior. Nursing homes were essentially unregulated in most states prior to the late 1960s. Their operations were governed almost entirely by market forces, and the quality of care was appalling.[20]

As noted above, the IoM's report was the blueprint for the nursing home reform law that Congress enacted in December 1987. Fifteen years later, the Institute of Medicine reiterated its support for a regulatory model to assure quality in long-term care.[21]

The value of a regulatory system to assure quality of care for nursing home residents was also firmly recognized by the California Supreme Court. In a 1997 decision, the Court recognized that regulatory systems are intended to prevent avoidable bad outcomes for residents: "the very purpose of the statutory scheme" is "preventing injury from occurring." [22]

Public support for regulation of nursing homes to address quality continues. The *New England Journal of Medicine* reported this month that a strong majority of Republican voters (57%) and Democratic voters (68%) in 2000 supported increasing regulation of nursing home quality.[23]

AT TIMES, HCFA HAS BEEN TOO TIMID IN EXERCISING ITS RULEMAKING AUTHORITY AND OVERLY DEFERENTIAL TO THE HEALTH CARE PROVIDERS IT REGULATES

Although Medicare beneficiaries and their advocates recognize HCFA's ability to implement federal legislation in ways that improve access and quality of care, we are concerned that the agency at times defers excessively to the health care providers it regulates.

In the nursing home area, HCFA had difficulty implementing the strong enforcement approach of the nursing home reform law in the face of fierce and aggressive opposition by the nursing home industry. The weak enforcement system initially established by HCFA's guidelines tolerated high levels of facility non-compliance with federal standards of care, leading to the care crisis that Senator Grassley's and Senator Breaux's hearings vividly documented. Strong Congressional oversight and the Administration's Nursing Home Initiative have now redirected the agency's approach to enforcement, making it more consistent with the law and more likely to achieve its goals of assuring correction of deficiencies and sustained compliance by facilities.

While beneficiaries and their advocates would not disagree that HCFA has experienced problems and delays in implementing federal legislation, we would contend that some of the agency's difficulties result from the increased numbers of mandates from Congress and inadequate resources to meet those mandates. HCFA and the state regulatory agencies need more money to do their jobs well. HCFA should not be asked to do more work with insufficient funding and then be criticized for not doing it well. The agency needs adequate financial support to do its work.

HCFA underwent an extensive reorganization just a few years ago. Another reorganization would consume considerable agency resources without sufficient benefit. Any organizational structure is always inherently artificial to some extent because of the agency's extensive and overlapping areas of responsibility. What is needed is good coordination within the agency and adequate support for the staff who work there.

Thank you for the opportunity to appear before you today.

SUPPLEMENTAL STATEMENT

This statement supplements testimony given on March 15, 2001 by Toby S. Edelman of the Center for Medicare Advocacy, Inc. (the Center) on behalf of Medicare beneficiaries and their advocates. At the hearing, Chairwoman Nancy Johnson expressed considerable dissatisfaction with the work of the Center. The Chairwoman's comments reflected a misunderstanding of the Center's work on behalf of Medicare beneficiaries and Connecticut's Department of Social Services and about the Medicare demand bill process. Since the Center was not allowed an opportunity

---

[20] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes* 5 (Mar. 1986).

[21] IoM, *Improving the Quality of Long-Term Care*, *supra* note 1, 141.

[22] *California Association of Health Facilities v. Department of Health Services,* 16 Cal.4th 284, 940 P.2d 323, 336, 65 Cal. Rptr.2d 872, 885 (1997).

[23] "Health Policy 2001: The Implications of the 2000 Election," *The New England Journal of Medicine*, Vol. 344, No. 9, 679, 681 (Mar. 1, 2001).

at the hearing to respond to the Chairwoman's concerns, this Supplemental Statement is submitted to explain both the work of the Center in Connecticut and the Medicare demand bill process.

About the Center for Medicare Advocacy

Since 1986, the Center for Medicare Advocacy has been providing legal assistance and education on behalf of Medicare beneficiaries and their community. Our work is focused on frail elderly people, individuals who are disabled or chronically ill, and those who need Medicare coverage in order to receive home care, long-term care, and rehabilitative services. The Center's goals are to:

- Increase proper Medicare coverage, and, therefore, access to health care, for beneficiaries who are most vulnerable and most in danger of unfair Medicare denials;
- Promote the ability of Medicare beneficiaries themselves and those who care about them to advocate effectively for proper Medicare coverage.

Our Medicare advocacy services, which are available at no cost to all Connecticut residents, include a toll-free telephone line, dozens of educational and self-help materials, brochures, manuals, and training and legal support for Connecticut's "CHOICES" health insurance and assistance program. Each quarter our attorneys, paralegals, and nurses respond to approximately 2,000 calls from Medicare beneficiaries, their family members, and the community. We staff the toll-free line each day from 9:00 a.m. until 5:00 p.m. and provide assistance ranging from information to advocacy materials to direct legal representation.

The Center offers information and training sessions throughout the state for older people, health care providers, case managers, Area Agencies on Aging staff, advocates, and others in the Connecticut elder network. On many occasions, we have responded to requests from members of the Connecticut Congressional delegation to participate in health fairs and to provide assistance to constituents on questions involving Medicare-covered services.

The Center produces two quarterly newsletters, the *Center News* and the *Healthcare Rights Review*, and maintains a web site at www.medicareadvocacy.org. Last quarter alone, we had 15,450 "visitors" to the web site and 12,113 requests for printed information.

In 1997 the Center was recognized by the Health Care Financing Administration (HCFA) for its Medicare advocacy when it received HCFA's *Beneficiary Service Certificate of Merit* award. In March 2001, the Connecticut General Assembly issued an official citation commending the Center for its fifteen years of advocacy on behalf of Connecticut's elders and people with disabilities.

The Center is a small business located in northeastern Connecticut where we employ 23 Connecticut residents. The Center is staffed by attorneys, paralegals, nurses, computer experts, and administrative support personnel. Funding is secured largely from competitively-awarded contracts with the Connecticut Department of Social Services, and from writing, consulting, and training.

Work on Behalf of Medicare Beneficiaries Who Are Not Also Entitled to Medicaid

Pursuant to grants, won competitively from the Connecticut Department on Aging and its successor agency, the Department of Social Services, the Center designed a Medicare advocacy and education project, which we currently implement.

Through our Medicare Advocacy Project, from 1986 through February 2001, the Center responded to more than 69,910 WATS calls, formally opened 3,772 cases, and recovered more than $12,512,476 in previously-denied Medicare benefits. This work was all performed on behalf of individuals who are *not* entitled to Medicaid and who rely upon Medicare as their primary source of health insurance.

Work on Behalf of Dually-Eligible Medicare Beneficiaries

Since 1988, the Center has also worked with the State of Connecticut to assure that dually-eligible Connecticut residents have full access to the Medicare benefits to which they are legally entitled. By virtue of their low income, dually-eligible beneficiaries are entitled to Medicaid as well as to Medicare. Federal law makes Medicaid the payer of last resort and requires state Medicaid programs to assure that other payers, including Medicare, pay for health care services first. 42 U.S.C. § 1396a(a)(25)(A); 42 C.F.R. § 433.138.

Under contract with the State of Connecticut, the Center pursues Medicare coverage for certain skilled nursing facility, chronic disease hospital, and home health care services which were provided to dually-eligible beneficiaries and paid for by Medicaid. The Center chooses cases for Medicare appeals on the basis of a selection process that involves careful analysis of legal merit and medical facts. These cases are identified from a larger set of dually-eligible cases referred to the Center by the Department of Social Services. Another group of cases has been considered coverable by the providers and is submitted by them for Medicare coverage. The process for

home health care appeals was reviewed and approved by the United States District Court in Connecticut:

> . . . . Given the reversal rate to which the defendant [Secretary of the US Department of Health and Human Services] admits, . . . the steps taken by plaintiffs to ascertain liability meet the standard of "all reasonable measures." Therefore, plaintiffs are not barred from administrative review of these claims by reason of failure to abide by third party liability provisions of Medicaid.
>
> . . . Medicare must provide the administrative review necessary to determine ultimate liability . . ., if its providers choose not to submit claims for payment and if the state reasonably determines that there is a high likelihood their Medicare coverage was improperly denied.

DIM v. Shalala, CA No. 2:91CV00546, 25–26 (AHN) (D. Conn. 1994).

Connecticut's efforts to obtain proper coverage for dually-eligible beneficiaries have been extremely successful. Significantly, in the majority of cases, benefits are won at the initial stage of review, which is performed by the Fiscal Intermediary. From the inception of the Center's dually eligible work through February 28, 2001, the organization's Medicare appeal efforts have resulted in recovery of $162,246,776. These were funds originally paid by Connecticut's Medicaid program. Of this total, $133,277,840 are attributable to home health cases. According to figures from the Connecticut Department of Social Services, the sources of the favorable decisions resulting in these recoveries are as follows:

80% from Fiscal Intermediaries
20% from Administrative Law Judges

In addition, Connecticut's activities to obtain proper Medicare for dually-eligible clients have always included efforts to obtain appropriate benefits in the first instance. Through provider education, the advocacy programs described above, and the long-standing CHOICES program, the State of Connecticut and the Center have taken many steps to assure that Medicare meets its legal obligation to Connecticut's dually-eligible population. For example, in 2000–2001, the Center and the Department of Social Services provided three Medicare coverage training seminars, one for home health agencies and two for skilled nursing facility staff. Another seminar is scheduled for May 2001.

The ultimate goal of the Department's Medicare maximization efforts is to increase the number of cases properly submitted for Medicare initially, thereby reducing the need for a Medicare advocacy effort. It is our hope that training efforts and a history of successful appeals will serve to change provider claims submission practices. Since so many of the cases are covered at the Fiscal Intermediary review stages, providers should feel increasingly comfortable submitting similar cases for Medicare coverage themselves, making appeals in those cases unnecessary.

Connecticut's Medicare advocacy has meant very significant financial savings for the State's Medicaid program and has increased access to Medicare and to medically necessary care for Connecticut's elders and disabled citizens.

As in the past, the Center for Medicare Advocacy is ready to do all it can to provide training and to help increase the proper submission and initial coverage of meritorious claims for Medicare. When pursuing Medicare coverage remains necessary and appropriate, the Center will continue to make every effort to perform these tasks as effectively and efficiently as possible. We welcome the opportunity to work with providers and HCFA towards accomplishing these goals.

Demand bill process

The federal Medicare statute and implementing regulations require providers to give beneficiaries advance notice of non-coverage.

When a Medicare health care provider makes a determination that a particular home health service will not be covered by the Medicare program, the Medicare statute requires that the provider give the beneficiary notice. 42 U.S.C. § 1395bbb(a)(1)(A) (Medicare beneficiaries have "the right to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being . . .").

In implementation of the Medicare statute, HCFA requires that providers give beneficiaries advance notice of changes in care. 42 C.F.R. § 484.10(c)(1). The notice must be "fair and reasonable." *Healey v. Shalala*, 68 Soc. Sec. Rep. Ser. 212, 2000 WL 303439 (D.Conn. Feb. 11, 2000).

Official Medicare coverage decisions are made by Medicare's Fiscal Intermediaries and can only be made upon submission of claims, including demand bills.

Only a Medicare Fiscal Intermediary can decide whether a particular service is covered by the Medicare program; the provider's determination of non-coverage is not conclusive. However, in order for a Home Health Fiscal Intermediary to review

a home health care claim that the provider believes is not covered by the Medicare program, a bill must be submitted to the Intermediary.

Only health care providers can legally submit claims to Medicare for payment. Therefore, in order to obtain an official Medicare determination, beneficiaries must depend upon their health care providers to submit claims. Medicare regulations and policy require Medicare providers to submit claims and documentation when requested by a beneficiary. Beneficiaries are said to request submission of a "demand bill." The demand bill process is the vehicle that is used to obtain official review of beneficiary-initiated coverage and claims disputes.

A further limitation on the demand bill process is that beneficiaries can request that a demand bill be submitted to an Intermediary only if they pay for the health care service. Beneficiaries cannot appeal provider denials of coverage unless they first receive and pay for the health care service. Reimbursement to beneficiaries under the Medicare program is made only on a retrospective basis.

The requirement for health care providers to give beneficiaries advance notice of non-coverage, which informs them of the demand bill process, has existed since at least 1975.

Success rates are high when demand bills are submitted to Fiscal Intermediaries.

When demand bills are submitted to Fiscal Intermediaries, beneficiaries are often successful. According to data from the Health Care Financing Administration, between 1994 and the first three months of 1998, "the success (full or partial) rate for all demand bills submitted at the request of home health care beneficiaries was 50.2%." *Healey v. Shalala*, 68 Soc. Sec. Rep. Ser. 212, 2000 WL 303439, page 4 (D.Conn. Feb. 11, 2000), approved by the judge March 7, 2000.

Health care providers frequently fail to give beneficiaries advance notice of non-coverage.

Although the requirement for health care providers to give beneficiaries advance notice of non-coverage has existed for more than 25 years, the available evidence, from beneficiaries themselves, complaint logs, contact reports, and deficiency reports, indicates that providers frequently fail to give beneficiaries written advance notice and often give no notice at all.

Moreover, since beneficiaries must pay for the health care services in order to request submission of a demand bill, relatively few beneficiaries request that demand bills be submitted. Demand bills are a minuscule portion of claims processed for home health beneficiaries. From 1994 through 2000, demand bills represented less than one-half of one percent of claims submitted to Fiscal Intermediaries.

Successful litigation by the Center for Medicare Advocacy assures that Medicare beneficiaries receive notice of their right to have demand bills submitted on their behalf.

A nationwide class of homebound elderly and disabled Medicare beneficiaries, represented by the Center for Medicare Advocacy, the National Senior Citizens' Law Center, AARP, Greater Boston Legal Services, and Northern California Lawyers for Civil Justice, filed a lawsuit in 1998 alleging that beneficiaries did not receive meaningful notice and appeal rights when their home health care benefits were reduced or terminated. *Healey v. Shalala*, *supra.*

The court granted plaintiffs a declaratory judgment stating that

> . . . plaintiffs have a legal right to a written: "(1) pre-deprivation statement why the HHA believes Medicare may not or may no longer cover their services; (2) explanation of the circumstances in which a beneficiary has the right to have a demand bill submitted, and (3) disclosure of information regarding a patient's right to appeal . . ."

Id. 2.

The court also recognized that a "demand bill is the key to the administrative process." *Id.* 4.

The court declined to issue an injunction because the Secretary of the Department of Health and Human Services advised the court that she was "'in the process of developing and implementing mandatory notice language which all HHAs will be required to use and which will provide beneficiaries with all the information that even plaintiffs insist is required as a constitutional mandate.'" *Id.* 9.

The home health advance beneficiary notice (HHABN) clarifies health care providers' Medicare notice responsibilities and makes the specific text of the notice mandatory, but creates no new obligations on providers.

HCFA has been developing the mandatory notice language for the home health advance beneficiary notice (HHABN) since September 1999. Home health agencies have been fully involved in the public process of developing the text of the notice.

On September 29, 2000, HCFA published its proposed HHABNs in the Federal Register (65 Fed. Reg. 57,821). HCFA solicited public comments through the public process required by the Paperwork Reduction Act. On December 1, 2000, the Office of Management and Budget, exercising its authority under the Paperwork Reduction Act, approved the HHABNs.

During this period, HCFA also continued to affirm home health agencies' obligation to provide beneficiaries with advance notice of changes or termination of benefits. For example, on September 29, 2000, HCFA sent the Regional Home Health Intermediaries a memorandum clarifying that home health agencies remain obligated to provide advance beneficiary notices, including an explanation of the demand bill process as set forth in HCFA Program Memorandum Transmittals A–99–52 and A–99–54. HCFA provided additional clarification on this obligation at 65 Federal Register 58,858 (Oct. 6, 2000).

Conclusion

The Center has a 15-year history providing effective assistance and representation to Medicare beneficiaries in Connecticut and nationwide. The demand bill process is the method that enables Medicare beneficiaries to receive appropriate Medicare coverage of their health care services.

Chairwoman JOHNSON. Mr. Grob.

STATEMENT OF GEORGE F. GROB, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. GROB. Madam Chairman, thank you so much for the invitation to come before this Committee and to present our views on a daunting challenge that you placed before us, which was to make specific recommendations on how to make the Medicare program better, without increasing, and possibly simultaneously decreasing the burden on our medical care providers. We have taken your charge seriously, and my testimony contains many such specific recommendations. Let me highlight just a few for you right now.

The first recommendation that we have concerns the payment error rate, a subject which you yourself raised in introducing the subject of this hearing. Our office has just reported that the Medicare payment error rate for the year 2000 was approximately $11.9 billion, with a 6.8-percent error rate, a quite significant reduction from the first year in which we prepared the study, where we had a $23.2 billion problem and a 14-percent rate. And I would like to emphasize—I think I said it in my testimony, but you said it, too—that the best way to solve that problem is to reduce the error. And where we have made this kind of accomplishment, the hassle has gone down along with the reduction, and let me give you one example from that.

Out of the 5 years in which we conducted that study, in the last two we did not detect in the hospital industry any payment error that was due to improper documentation. It did not happen that we detected in the last 2 years that the hospital industry was deprived of one dime because their documentation wasn't correct. They got all the money that was due to them, and Medicare did not have to hassle anybody about that. It was a savings to Medicare, and the hassle factor was reduced. And I am absolutely convinced that if we could reduce that hospital error rate by half, and if we can solve the documentation problem through education and discussion with the hospital industry, then we can solve each and every one of the

problems that we have identified for that payment error rate, and that will reduce a lot of hassle for everyone and save us all a lot of money.

We also raised in our report some severe problems with the accounting systems that are used by the contractors. Elementary accounting systems, such as double-entry accounting and use of integrated supporting documents, are missing for this very expensive program. That should be fixed. This controls perhaps $8 billion a year of expenditures, which are not under the control that they should be placed under.

If these accounting systems were fixed, there would be much better control, and that kind of control and that kind of professionalism would not create a single more moment of hassle for any Medicare provider, but it would greatly improve the Medicare Program.

Another thing which I would like to call attention to that has come up in the testimony of several of our speakers has been problems with the appeals process, and in legislation now before the Committee, there are different provisions, and in recent legislation to put tighter time periods on the time that it would take to consider appeals at various levels of appeal, different processes for perhaps skipping a step in order to get things looked at.

We really believe that a major problem in the Medicare program right now is the appeals process, and in my testimony you will see that we lay forth some rather major reforms to that appeals process that go far beyond the changes that are advocated in the legislation that you have before you. And, in fact, they go in a somewhat different direction.

We believe that the major problem with the appeals process right now is that there are not adequate resources to consider the appeals, that the administrative law judges who are responsible for that do not even work for the Medicare program; they work for the Social Security Administration. The guidance that they follow is not as uniform as it should be. The way patients are treated in their appeals and the way providers are treated should not be the same, and currently it is. And there are other such reforms that need to be made.

We believe that what the appeal system needs right now is not more deadlines. The problem isn't lack of deadlines. The problem is its inability to meet the deadlines. And if we can meet the deadlines with understandable and more uniform provisions, then the hassle will go away, and then the payments will be made right, and everyone will be in much better shape.

We also believe that HCFA ought to have much more flexibility in how it chooses its contractors and how it manages them.

I would like to raise now a more fundamental issue which has to do with the infrastructure. I do believe that we should not skimp on the infrastructure as we look at reforms to be made, and I believe that there has been some skimping on that, particularly in the field of survey and certification. I believe that there has never been enough resources for the reviews of the nursing homes to be carried out as well as it should, or home health or other providers. In fact, nursing homes are reviewed every year, as they should be. But in order to make that happen, we had to reduce the reviews

of home health agencies from every year to every 3 years, for example. And in the nursing home field, there are often delays in conducting follow-up visits to nursing homes after deficiencies have been found.

I believe that the best thing to do to reduce the hassle in the nursing home arena is not to provide more venues for appeals and more litigation but, rather, to establish better standards and training for the people who conduct the reviews so that there is not as much dispute about them to begin with, to find those deficiencies, to raise them quickly, to resolve them rapidly, and then to have the survey teams get back in there and find out if they have been corrected. It is like the payment error rate. The best way to reduce the hassle is to eliminate the deficiencies, to correct the ones that are there, and to resolve problems as they arise quickly.

There are other problems with the infrastructure as well which I will not have time to discuss in the 5 minutes that I have.

I would like to make one matter of clarification now with regard to the pending legislation. I had planned to spend more time in the time that I have right now to go over the pending bill, because we were asked to please give our comments on that bill, and our comments are there. But perhaps it would be better if I were to use this opportunity to introduce to you the notion of what we were trying to do in our comments.

With the Inspector General's Office, we do, in fact, have an obligation to look at fraud, waste, and abuse. But we have broader responsibilities in there, too. Our responsibilities include—and they are in the Inspector General Act—to evaluate the various processes which the Medicare Program and other programs use to be managed and integrity processes that we ourselves don't run but that others do run. We are obligated to review them and evaluate them and make sure that they work very well.

A lot of the studies that we do then, and a lot of the comments that we have, don't go so much to our own authority as they do to our evaluation of what is happening in the Department. And some of the comments that you will see in there about our concerns about granting people immunity and not being able to get the return of money we have is not simply because of the investigations that we conduct, but we are worried that that immunity may be lost in the appeals process for the contractors as well.

Perhaps with more time or in another circumstance we can provide much more detail and explanation here to solve a problem which I think we all see as a common one.

Thank you so much.

[The prepared statement of Mr. Grob follows:]

Statement of George F. Grob, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Madam Chairman. I want to thank you for your invitation to address this panel on Medicare reform. You asked us to discuss how the government can do its job better, to ensure that beneficiaries are protected and that tax payer dollars are used wisely and responsibly without placing undue burdens on providers. I am very pleased to do so.

Medicare is a national treasure. But it would be even more valuable if it were operating more efficiently and effectively. Despite herculean efforts to modernize it and recent success in doing so, there is a sentiment, especially among health care

providers, that it is not as efficient as it should be. In fact, discussions in policy circles and in the national and professional media emphasize its administrative burdens, inefficiencies, and aggravations. There is some talk of major reforms.

The Medicare program has been evolving since its creation. It has been "reformed" and modernized many times—including the gradual abandonment of cost and charge based reimbursement in favor of prospective payment systems and fee schedules, and the introduction of managed care. The Balanced Budget Act of 1997, with its new payment systems for nursing homes, home health agencies, and hospital outpatient departments and the new beneficiary options and protections in Medicare+Choice, is the most recent and substantial reflection of these movements. The program as it is, including the most recent reforms, which are not yet fully implemented, is our starting point for further reforms.

It is with this history in mind, and with insights drawn from more than twenty years of audits, program evaluations, and investigations conducted by the Office of Inspector General (OIG) that I would like to offer our own suggestions on where to go from here.

First, I will identify facets of Medicare program administration which require immediate and continuing attention; then I would like to address some concerns which have been raised about recent initiatives to address waste, fraud, and abuse.

PROGRAM ADMINISTRATION

Following are the recommendations of the Office of Inspector General (OIG) to promote the efficient and effective operations of the Medicare program. We believe that these proposals will also reduce administrative burdens and frustrations for providers. You asked us to be specific; I hope this is helpful.

Further Reduce and Control Improper Payments. Continue, even intensify, ongoing efforts to help further reduce improper Medicare fee-for-service payments. Billions of dollars are at stake, and years of Medicare solvency will be lost if oversight is reduced. As we announced last week in our most recent annual report on this subject, Medicare made $11.9 billion in improper payments in FY 2000, 6.8 percent of all Medicare fee-for-service payments. This is down substantially from the $23.2 billion, or 14 percent, first reported for 1996. But it is still too high. Then as now, most of the error is due to unsupported services and lack of medical necessity for services rendered.

The reasons for these improper payments could range from inadvertent mistakes to outright fraud and abuse. We cannot quantify what portion of the error rate is attributable to fraud. The vast majority of health care providers are honest, hard working professionals dedicated to the care of their patients. I will repeat this later in my testimony, since it deserves emphasis.

Reducing errors would be one of the best ways to turn down the frustration and sense of hassle felt by health care providers and the Medicare contractors who administer the program. For example, our annual reports show that hospital documentation errors have been completely eliminated for the last two years. This not only shows that such improvements can be made, but it also illustrates how one source of controversy and irritation can be minimized for all parties involved. To further achieve such improvements, we recommend more training for providers, further refinement of Medicare guidelines and regulations where needed, concerted efforts to reduce errors with respect to specific codes most frequently found in error, selected surveillance by peer review organizations (PROs) of high risk areas, and adoption by health care providers of compliance plans that promote adherence to Medicare program requirements.

Overhaul Medicare Contractor Structures and Authorities. Allow the Health Care Financing Administration (HCFA) greater flexibility in the methods it uses to select, organize, and supervise the contractors who handle the day-to-day operations of the Medicare program. This includes authorities to use entities other than insurance companies, select them competitively, pay them on other than a cost basis, organize them according to functions or benefits areas, and hold them accountable for performance.

The Medicare program is administered by the Health Care Financing Administration with the help of 50 contractors (Part A intermediaries and Part B carriers) that handle claims processing and administration.

Over the years we have detected serious problems with contractor operations, including fundamental problems with accounting, electronic data processing, and fraud control. We have even uncovered integrity problems with some of the contractors themselves—altering documents and falsifying statements that specific work was performed. In some cases, contractors prepared bogus documents to demonstrate superior performance, which Medicare then rewarded with bonuses and additional contracts. Our investigations have resulted in 15 civil settlements and

criminal convictions since 1993, with total settlement amounts exceeding $350 million. Two contractors pled guilty to obstruction of Federal audits. A number of investigations are ongoing. HCFA has been working to correct problems with contractors. However, some serious concerns remain.

Under the Health Insurance Portability and Accountability Act of 1996 (HIPPA), HCFA was granted new authority and flexibility in contracting for program integrity functions. It may enter into contracts or work orders for specific program safeguard functions, such as medical review, fraud detection, cost report audits, and reviews to identify primary payers to whom Medicare is the secondary payer. We support this authority and look forward to the changes in Medicare contracting that are taking place under the new Medicare Integrity Program.

In contrast to these new and promising developments for integrity functions, the Medicare statute places substantial limits on how HCFA obtains contractor assistance to administer the Medicare program. For example, it limits HCFA to choosing only insurance companies to process Part B claims. As for intermediaries, most of them are selected by the National Blue Cross/Blue Shield Association from companies nominated by providers (e.g., hospitals). All contracts must be cost based; other reimbursement methods such as firm fixed price cannot be used. Furthermore, beyond the program integrity functions mentioned above, HCFA is not allowed to let contractors specialize according to function.

HCFA has proposed broader, more flexible contracting authority in the past, but these proposals were not approved. Intrinsically, more flexibility makes sense and we support it. So does the General Accounting Office.

Another promising development is the designation of specialty contractors such as the durable medical equipment regional carriers. They review and pay all claims for medical equipment and supplies. There are only four of them, which appropriately concentrates their expertise in this complex area. They are bolstered by a data analysis unit, staffed by one of these carriers but supporting them all. This enables them to analyze payment and usage patterns which may suggest possible improper or questionable conduct. They are also able to effectively collaborate on the formulation of national coverage policies and payment control systems. A recent OIG evaluation found that these entities are effective. This approach, however, has not been used elsewhere, except for home health and hospice care. However, even these specialized intermediaries are not supported by the kind of data analysis unit that the medical equipment carrier utilize. We believe that specialty contractors, with a supporting analytic unit, would make sense for problematic areas and recommend that they be more widely used.

More flexibility and specialization will, we believe, bring greater expertise and efficiency to contractor operations. This will, in turn, improve their relations with providers and facilitate provider education and understanding of Medicare rules and regulations.

Improve Accounting Systems. Speed up current efforts to establish a modern, integrated, dual entry accounting system for accounts receivable to accurately portray and control the billions of dollars in transactions in this category annually.

Medicare accounts receivable primarily represent overpayments owed by health care providers to the Health Care Financing Administration and funds due from other insurers when Medicare is the secondary payer. For FY 2000, HCFA reported a net accounts receivable balance of $3.8 billion, comprised of gross outstanding receivables of $8.1 billion and an aggregate allowance for uncollectible accounts of $4.3 billion.

In FY 1998, we had to qualify our audit opinion on the Department-wide financial statements, primarily because of serious problems in Medicare contractors' ability to report accounts receivable. For example, they could not support beginning accounts receivable balances; they reported incorrect activity and collections; and they could not reconcile reported ending balances with subsidiary records. We reported Medicare accounts receivable as a material internal control weakness because Medicare contractors used rudimentary, single-entry accounting systems that lacked general ledger capabilities for Medicare program activity and reported receivable activity to HCFA based on ad hoc spreadsheets.

In collaboration with the Office of Inspector General, HCFA initiated a major effort in FY 1999 to address these deficiencies. As a result of this effort, the receivables balance was fairly presented as of the end of FY 1999. However, internal controls are still not adequate to ensure that future receivables would be properly reflected in Medicare financial reports. The contractors still use ad hoc, single-entry accounting systems, do not accrue liabilities in accordance with generally accepted accounting principles, and do not use proper cutoff procedures.

A project team, formed under the guidance of HCFA's Chief Financial Officer and Chief Information Officer, expect to complete the development and implementation

of an integrated system by the year 2007. Every effort should be made to advance this expected completion date.

Improving the accounting systems will reduce financial errors, thereby improving the soundness of the trust funds, with no additional burden on providers.

Adequately Support the Infrastructure. Do not skimp on resources needed to ensure efficient and effective claims processing, policy development and regulation, and quality assurance. Make a top-to-bottom review of the adequacy and use of currently available resources, seek realistic budgets for the Medicare infrastructure, and maintain reliable funding in the future. Establish reasonable time frames for implementing new reforms to balance the need for consultation with stakeholders and timely introduction of new systems and benefits. Some areas deserving special attention are:

Policy Development and Regulation. The Medicare program has always been subject to considerable legislative change as it has evolved over the years. But the legislative changes in the last several years, particularly those in the Balanced Budget Act of 1997 and the two subsequent years of amendments, have been especially extensive and complex. The HCFA staff scrambled to implement regulations timely, consulting with industry and beneficiary representatives in the process. Their achievements in meeting this work load is impressive. But their limited resources will always place them in an unenviable dilemma. To issue the regulations timely they may have to curtail consultation; to carefully consider industry and beneficiary concerns they may have to miss deadlines. The third alternative is to fall behind on other administrative responsibilities. No matter which path they choose, frustrations will abound among all parties. Ironically, HCFA's requests for staff increases are sometimes portrayed as wasteful bureaucratic layering. Clearly, adequate resources need to be provided and effectively utilized.

Quality Assurance Reviews. More troubling, perhaps, has been the unreliability of resources for quality assurance. There have never been adequate resources to meet the needs for State run but federally supplemented survey and certification reviews of nursing homes, home health agencies, end stage renal dialysis facilities, and the 20 percent of Medicare certified hospitals not accredited by the Joint Commission. Only nursing homes are generally reviewed yearly. But this has been at the expense of the other institutions whose reviews have been curtailed in order to shift survey and certification resources to address the severe problems that were becoming apparent there. For example, home health agencies which were once reviewed annually are now reviewed every three years. This change occurred at the same time that the payment system was being reformed. We have documented gaps in the reviews of psychiatric hospitals and dialysis facilities. Even for nursing homes, which get the annual reviews, follow-up visits when deficiencies are found are often delayed. And above and beyond periodic reviews, resources to investigate complaints in all types of facilities are inadequate.

Patient Care Data Sets. The introduction of prospective payment as the method that Medicare will use for paying skilled nursing homes adds incentives and complications to the medical care system. For example, the calculation of the prospective payment is derived from a patient assessment tool called the Minimum Data Set. This tool has been under development for many years, primarily as a patient care planning system. Now that it is being used to calculate Medicare payments, a financial incentive to control data entry is now present. We recently studied this system and found a significant number of coding problems which could adversely affect both care planning and reimbursement. Nevertheless, nursing homes seem to be trying to learn to use the system, which if properly implemented will be quite useful. A commitment to the refinement and implementation of this system and other systems like it is needed to improve patient care and ensure accurate billing and payment.

Claims Processing Systems. Additional improvements are needed for HCFA data systems used to process claims. For example, studies by our office have found excessive numbers of unused but un-retired provider identification numbers, which increase Medicare's vulnerabilities to false claims. Routine maintenance of data systems could remove such vulnerabilities, but such "household" chores are naturally accorded low priority and are not tended to.

Providing HCFA with the staff that is needed to operate the program will not result in more hassle for providers. It will enable HCFA to respond better to their needs. Improving the critical data systems will reduce payment errors, improve patient care, and make program operations more efficient.

Fully Implement Recently Enacted Payment Reforms. Do not let the growing interest in new reforms distract Departmental policy makers and program administrators from systematically completing the implementation of Medicare+Choice and other reforms, such as those related to nursing homes and home health care.

Monitor, and take appropriate actions to correct, any deficiencies discovered along the way regarding payment integrity and beneficiary protections, including access to services.

While providers worry about being swamped by Medicare rules, beneficiaries and their advocates worry about barriers to service access and poor quality care. This concern stems partially from the growth of managed care (discussed later) and from the new prospective payment systems for nursing homes, home health agencies, and hospital outpatient departments. They also fear that the fixed rates discourage treatment of individuals with complex, expensive medical problems. Structural shifts in the health care industry, including the withdrawal of thousands of home health agencies from the program and announcement of actual or pending bankruptcies in the nursing home industry, have added to the concerns of all parties.

It is overly simplistic to put all the blame on the Medicare program. Prior to the reform of the home health payment system, OIG studies had found a steep rate of improper payments (40 percent) in Medicare home health payments, and investigations had turned up massive fraud involving millions of dollars among some home health agencies at that time. The industry, through its own actions, coupled with reforms of the Medicare payment method and actions taken by HCFA, has done much to address this problem, although the percent of services for which improper payments are made is still too high at 19 percent.

The nursing home industry's financial problems were due, in part, to imprudent, and excessive purchases of nursing homes by private chains. They were expecting continued high profits under predecessor Medicare payment systems. Thus, many of the industry problems resulted from actions taken prior to the reforms taking place. Furthermore, Medicare pays only about 10 percent of the cost of the nation's nursing home care. The remaining 90 percent is funded through Medicaid and private pay sources.

In response to concerns about availability of care under these circumstances, we undertook systematic studies in the last two years to measure access to care. These studies found that few Medicare patients being discharged from hospitals were unable to get home health care or nursing care when they needed it. There was no evidence of patients backing up in hospitals waiting for a home health or nursing home treatment slot. However, some patients with complex and expensive medical conditions did experience some delays. In the last two sessions of Congress, legislation was enacted to increase payment rates for these programs.

Overall, the nursing home and home health program reforms enacted by the Balanced Budget Act of 1997 seem well suited to the problems they attempted to address. For both programs, payments for patients with expensive, complex problems are higher than those for patients with less severe problems. Home care is paid on a 60 day cycle, so there is no limit to the care of individuals with longer term problems. For nursing homes, the payment is made on a daily rate basis, again providing adaptation for patients with longer term needs. The new payment systems reduce vulnerabilities inherent in the previous systems, which promoted unnecessary care in some cases. But these reforms are not yet fully implemented. The danger to avoid is that with new policy initiatives on the front burner, policy makers and administrators may get distracted from the management of previously legislated reforms.

HCFA needs to monitor these changes carefully, particularly to insure that payments are made timely and correctly. We will continue and even expand our own annual reviews, particularly those intended to ensure that beneficiaries have access to nursing home and home health care and receive quality services while the new payment systems take hold. We will report what we find, one way or the other, so that the Congress, HCFA, and the medical care industries involved can respond accordingly.

The most chaotic phase of program implementation—the initial one—is now nearly over. Methodical completion of implementation can be done smoothly if the health care industry and Medicare program administrators monitor developments and are open to adjustments when needed.

Follow Through on Quality of Care Initiatives. In particular, carefully monitor nursing home reforms to insure a safe environment and high quality of care for residents.

Not all quality of care problems are related to recent changes in payment systems. The Omnibus Budget Reconciliation Act of 1987 contained a major section on nursing home reforms intended to address longstanding patient care issues. Unfortunately, ten years later the Office of Inspector General as well as the General Accounting Office continue to expose serious quality of care problems. We found increases in the incidence of bed sores, nutrition problems, and conditions conducive to accidents. The survey and certification system was found to be fundamentally

flawed, allowing nursing homes with serious deficiencies to continue operations despite repeated violations. The methods used to schedule visits eliminated the element of surprise, making it possible for nursing homes to prevent discovery of deficiencies.

Quality of care problems are not limited to nursing homes. Recent national studies identified troubling levels of medical errors in hospitals. Our own program evaluation studies revealed weaknesses in the review system used by the Joint Commission on Accreditation of HealthCare Organizations (JAHCO), which Medicare relies on for quality oversight of 80 percent of participating hospitals. We found that their surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills. There were few random, unannounced reviews and little opportunity for surveyors on site to probe hospital conditions or practices. The whole review process was more collegial than independent and objective. For the 20 percent of Medicare certified hospitals which are not accredited by JAHCO, we found that half had gone without a State survey for more than 3 years (the industry standard) and some for as long as 8 years. Troubling shortcomings have also been discovered in quality oversight systems for psychiatric hospitals, again highlighted in OIG reports.

The Department and the Joint Commission have prepared responsive initiatives to correct the problems identified. However, the corrective actions are complex and have not yet been fully implemented. Furthermore, these problems are the kind that require constant vigilance.

For nursing homes, this means more unannounced onsite reviews, more frequent and intensive reviews of repeat offenders, more follow-up on serious deficiencies, imposition of fines and penalties for serious offenders, with fewer "second chances" to correct their problems, special initiatives to focus on selected serious problems like bedsores, and general improvements in training of State reviewers. For hospitals this means public accountability for JAHCO and State agencies for their performance and determining the minimum appropriate cycle for conducting surveys of nonaccredited hospitals and special reviews by contracted psychiatric review teams for psychiatric hospitals.

Continuous quality oversight does not burden providers the way inconsistent, sporadic, infrequent, and unfamiliar oversight does. Patient care is enhanced, reducing disputes between providers, advocacy groups, and Medicare administrators on the most fundamental aspects of the program.

Restructure Appeals and Grievance Systems. Overhaul Medicare appeals and grievance systems by establishing a dedicated corps of Medicare Administrative Law Judges (ALJs); providing adequate resources to handle current and projected caseload; making guidelines more uniform; adopting separate procedures for beneficiaries and providers; making Departmental Appeals Boards decisions precedential; and improving timeliness of reviews.

Current Medicare appeals and grievances systems are not sufficiently responsive to the needs of beneficiaries, health care providers, or the Medicare program itself. Originally designed with beneficiaries in mind, most appeals are now generated by providers. The non-adversarial nature of the procedures, which were originally intended to simplify matters for beneficiaries, leaves the Medicare program with no representative once the appeal process starts.

The current system was started when the program first began. At that time, Medicare was in the same Department as the Social Security Administration (SSA) and was relatively small in comparison to the Social Security program. It made perfect sense to use the appeals and grievance system of SSA to handle Medicare's needs. Since then, the SSA became an independent agency, and Medicare has grown in size and complexity. But the ALJs who handle Medicare are still attached to SSA with only a small corps dedicated to Medicare. Many ALJs who handle Medicare cases do so in addition to their duties as SSA judges.

These two features of the original appeals and grievance system—its focus on beneficiary complaints, and its status as an adjunct to SSA—have left it ill prepared to deal with the growth and complexity of Medicare and the prominent role, needs, and expectations of providers. As a result, providers experience delays and inconsistent rulings. Medicare has a very limited role in representing the interests of the program.

Compounding the intrinsic weakness of the system is a recent significant growth in workload. For example, the number of ALJ hearings increased from 28,515 in 1996 to 49,253 in 1998. The Departmental Appeals Board reports that appeals to it rose from 46 in 1994 to 670 in 200. Yet, minimal resources have been allocated to this hearing function.

Overall, the system has few champions and needs a top to bottom overhaul.

The recently enacted Benefits Improvement and Protection Act of 200 (BIPA) modified the appeals process by establishing time limits on earlier stages of the appeals process which, if breached, provided for automatic referral to the next higher level. These new provisions, which will go into effect on October 1, 2002, could lead to inappropriate decisions due to unrealistic time spans to address complex questions, a clogging of the appeals channels, and an inability to prioritize decision making.

The BIPA provisions were intended to address legitimate concerns of providers to get prompt answers to their appeals and coverage questions. However, these new procedures are likely to cause additional rather than fewer burdens and aggravations by overwhelming the appeals and review channels. While well intended, they do not address the weaknesses in the fundamentals of the appeals and grievance systems—resources, guidance and standards, organizational locus of ALJs, rules of precedence, appropriate adaptation of procedures to beneficiaries and providers, and timeliness of reviews. A better approach, we believe, would be to conduct a more comprehensive study of the entire process with input from all the affected parties. New recommendations can be considered and implement before the BIPA provisions take effect. The latter can be modified through legislation based on the results of the study.

Build the Monitoring and Assessment Tools Into Future Reforms. Specify the cost and encounter data that the Department, the Congress, and health care industry and Medicare beneficiary stakeholders will need to annually assess the cost, effectiveness, and efficiency of any new reforms enacted. Establish a new independent body, or use an existing one, to analyze and periodically make public reports and recommendations regarding adjustments needed for new programs.

Managed care options have been available to Medicare beneficiaries in some areas since 1982. The original ideas behind this concept were that a single organization being responsible for a patient's care, with financing in the form of capitation payments, would create incentives for preventive care, elimination of unnecessary services, and more efficient administration. Managed care providers would compete for Medicare business by offering Medicare beneficiaries additional benefits beyond those available under the regular fee-for-service Medicare program. The result would be better health care and improved health status, at lower costs.

At the end of each of the last three years, a significant number of health maintenance organizations (HMOs) have withdrawn from the program or reduced their coverage areas. Many have also restructured their benefit and coinsurance provisions. For example, at the end of the year 2000, 65 HMOs chose not to renew their contracts and 53 reduced service areas, affecting more than 934,000 beneficiaries. Approximately 83 percent of affected beneficiaries were able to enroll in another HMO; the remainder had no choice but to return to Medicare-fee-for-service coverage.

There are other issues connected with managed care options, including shortcomings in the understandability of marketing materials and handbooks of information provided to beneficiaries, and issues surrounding appeals and grievance processes.

The Medicare+Choice legislation improved data and information collection aimed at assessing the costs of managed care. Managed care plans are now reporting actual costs in a way that for the first time makes it possible to assess the reasonableness of their cost rates and benefit packages.

Some of the key lessons learned from the current Medicare managed care program are that: market forces alone cannot be depended upon to ensure reliable benefits at reasonable cost; accurate cost is essential for the analysis of proposed new contracts; and reliable, easy to understand member materials are essential to ensure intelligent choice by beneficiaries. Any future Medicare reforms designed to offer additional flexibility to Medicare beneficiaries will need to provide similar transparency about costs and benefits to both beneficiaries and Medicare administrators.

This will enable Medicare to avoid the kind of turmoil recently experienced in managed care, thereby preventing administrative burdens and aggravations for both providers and beneficiaries.

PAYMENT CONTROLS: PROVIDERS' CONCERNS

As previously noted, the OIG annual Medicare payment error rate audit does not determine whether an inappropriate provider payment request is the result of an innocent error, a misunderstanding of Medicare coverage, pricing, or payment rules, carelessness, mismanagement, or outright fraud. It is not a "fraud error" rate and should not be construed as such.

Despite our best and continued efforts to emphasize the nature of the payment error rate and our respect for the integrity of health care providers, some of them

have become more vocal in their objections to what they regard as overzealous scrutiny. Particularly in the physician community, some providers express fear that they will be prosecuted as criminals for making honest billing errors while trying to interpret regulations of an increasingly complex Medicare program.

Let me repeat what I said earlier. The vast majority of physicians and other health care providers are honest, dedicated individuals who work hard for their patients. Their concerns deserve our attention. I would like to take advantage of this opportunity to respond to them. To do so, I must first explain the nature of the Federal fraud and abuse control program, and I need to put it into the context of broader reforms that have been occurring in the Medicare program.

Fraud and Abuse Control Program. To address fraud and abuse, a Health Care Fraud and Abuse Control Program (HCFAC), jointly administered by the Secretary of the Health and Human Services (HHS) through the Office of Inspector General and the Justice Department, was enacted into law as part of the Health Insurance Portability and Accountability Act of 1996. That same law provided HCFA with increased funding for a Medicare Integrity Program (MIP).

The Act provided both new authorities and critical resources to enable HHS, the Justice Department, and the many Federal, State, and local programs and agencies engaged in health care fraud enforcement to better detect, investigate, prosecute, and prevent fraud and abuse. In Fiscal Year 2000 alone, the Federal Government won or negotiated more than $1.2 billion in judgments, settlements, and administrative impositions in health care fraud cases. Actual collections for the year in health care cases exceeded $715 million, with more than $577 million returned to the Medicare Trust Fund. Since inception of the program in October 1997, over $2.1 billion has been returned to the Trust Fund.

The program has also enabled this Department to step up its efforts to exclude from Medicare, Medicaid, and other Federal health care programs providers and suppliers that engage in certain prohibited conduct. During Fiscal Year 2000, over 3,300 individuals and entities were excluded from program participation. Exclusions were based on criminal convictions for crimes related to Medicare or other health care programs, patient abuse or neglect, license revocation, and other misconduct.

Program Structure and Controls. Perhaps more important than fraudulent billings are large but unnecessary payments stemming from perverse incentives and weak controls. For example, much of the historical double digit growth rates of hospital payments in the late 1970's was the product of government policy to pay on the basis of costs and charges, not the result of provider misconduct. Those excessive growth rates were curbed not so much by audits and payment controls but by changing to a new reimbursement model, the prospective payment system. More recently, the Balanced Budget Act of 1997 mandated prospective payment systems for home health care, nursing home services, and hospital outpatient services. These program reforms, along with tougher scrutiny of providers seeking to enroll in the program, increased audit and medical necessity reviews, and provider education reduced Medicare payments by tens of billions of dollars. For example, home health expenditures dropped from $18 billion in 1996 to $9.5 billion in FY 1999.

Provider Concerns. Continued participation of health care providers of all kinds—physicians and other health care professionals, hospitals, nursing homes, home health agencies, laboratories, equipment manufacturers and suppliers—is crucial to the success of the Medicare program. All of them have been profoundly affected by recent Medicare reforms. They are also affected by current regulations and administrative procedures.

However, provider concerns relating to inappropriate investigations are unfounded and both HCFA and the Office of Inspector General are reaching out to physician groups to reassure them. First, under the law, physicians and other health care providers are *not* subject to civil or criminal penalties for honest mistakes, errors, or even negligence. The government's primary enforcement tool, the civil False Claims Act, covers only offenses which are committed with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of the claim.

The False Claims Act simply does not cover mistakes, errors, or negligence. The other major civil remedy available to the Office of Inspector General, the Civil Monetary Penalties law, has exactly the same standard of proof. For a criminal case, the standard is higher. The Office of Inspector General is very mindful of the difference between negligent errors and mistakes on one hand, and reckless or intentional misconduct on the other. As a result of the relatively high standards of proof needed to establish liability, the number of civil and criminal penalty actions initiated against physicians is fairly small, averaging less than 50 penalty actions per year. Last year, as a result of OIG efforts, only 12 of the more than 600,000 physicians who participate in the Medicare program were convicted of health care related crimes.

Both HCFA and the Office of Inspector General have also been engaging health care providers to join in a national effort to eliminate fraud and abuse and have undertaken numerous outreach efforts to help the medical care industry avoid getting into trouble. The cornerstone of OIG efforts has been the publication of voluntary compliance program guidances (developed with industry input) to assist and encourage the various sectors of the private health care industry to voluntarily fight fraud and abuse. In addition, we issue special fraud alerts and advisory bulletins advising medical care providers on topics that warrant their attention. All this information, as well as the results of our audits, investigations, and evaluations, are routinely made available through public presentations and on our web site.

HCFA too has enhanced its provider education efforts and has expedited its process for issuing new regulations, such as those required by numerous program changes mandated by the Balanced Budget Act and subsequent legislation. Their web site has been upgraded to make program information more widely and quickly available than ever before. And they use numerous technical advisory boards made up of health care professionals to advise on policy. In addition, HCFA has organized a "Physician Regulatory Issues Team" to assess the weight of Medicare regulatory burden on physicians. Its goal is to recommend changes to reduce administrative burden.

Program Complexity. Providers are concerned about the complexity of Medicare, even without reference to their potential liability for fraudulent or abusive behavior. Since the inception of Medicare, numerous legislative changes have been made and amendments added to the Social Security Act which have led to substantial changes to the Medicare program. With each addition, HCFA is required to develop new regulations as well as update its contractor and provider rules and guidelines. For example, the Balanced Budget Act of 1997 contained 335 provisions related to Medicare programs, which required the development of a substantial number of new regulations.

Much of the complexity in the Medicare program is not inherent in the program itself, but rather it parallels the ever increasing complexity of our health care system. For example, the development of various forms of managed care and new kinds of vertical and horizontal integration have led to the need for Medicare rules and regulations to evolve along with them.

As noted earlier, the way Medicare pays for health care has changed, through time, from primarily cost/charge based payment systems to new fee-schedule and prospective based arrangements. For example, hospital inpatient, physician, then lab and durable medical equipment services were the first areas of the program to switch to prospective payment or fee-schedule based payment systems. More recently, skilled nursing facility, home health, and hospital outpatient services have moved or are moving to prospective payment systems as well. This transitioning from one payment system to another inevitably involves an intensive and somewhat uncomfortable learning period. In the long run, it is hoped that these new payment systems will simplify and reduce the administrative burdens of providers.

Is the Medicare payment system too difficult 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 error rate review indicates that providers are doing a very good job of negotiating their way through Medicare payment systems, and we estimated 93 percent of all Medicare payments to health care providers were free of error. In the substantial majority of cases, legitimate providers are billing for legitimate services.

Nevertheless, providers remain concerned. Their legitimate concerns about program complexity, inconsistency, burdens, and hassles need to be considered. Providers need high level reassurances that they will not be assessed penalties for honest errors. At the same time, regulations to implement new programs need to be issued in a timely manner, and program integrity concerns need to be addressed.

PROPOSED LEGISLATION

The Medicare Education and Regulatory Fairness Act of 2001 (HR 868) has just been introduced to address some of the concerns of providers which were discussed in the previous section. I was asked to comment on this bill in my testimony, and appreciate the opportunity to do so.

Given what I just said about our appreciation of providers' concerns, we would support some action by HCFA and possibly the Congress to address valid problem areas. However, the Office of Inspector General cannot support this bill as written. While its objectives are worthy, we are concerned that many of the provisions will subject the Medicare Trust Funds to a high level of risk and possibly result in harm to beneficiaries. I will provide summary comments here, but hope that our staffs can meet to discuss these provisions in greater detail. Hopefully, we can find ways to

address the concerns that this bill was meant to address without endangering the integrity of the Medicare program, as this bill would.

First, I will identify the provisions which we believe are most problematic. Then I will identify some provisions which appear to us to be more promising and which merit additional consideration. Our primary concerns are related to:

Judicial and Regulatory Challenges

The bill would nullify longstanding legal doctrines requiring "exhaustion of administrative remedies" and a "case or controversy" in order to appeal matters to Federal court. It would eliminate these requirements for cases challenging the constitutionality and statutory authority of HCFA regulations. This would clutter the Federal courts with hypothetical, possibly trivial cases and deny the courts the advice, insight, and judgement of Federal agencies and administrative appeals bodies in making decisions.

The bill would establish of unreasonable timeframes for hearings by ALJs and the Departmental Appeals Board. While the goal of this proposal may be to expedite the review process, it is highly unlikely that this result will be achieved. In all likelihood, the result will be the premature elevation of appeals to the Departmental Appeals Board and Federal courts, which are not in a position to conduct "de novo" fact finding hearings on an expedited basis.

The bill also requires an additional layer of review or reconsideration if a provider is dissatisfied with a finding that the provider is out of compliance with a particular standard or condition of participation. This would delay the imposition of sanctions and would increase the risk of jeopardizing the health and safety of Medicare beneficiaries.

Repayment Period

The bill would entitle providers to a three year repayment period for overpayments. While repayment plans make sense in some cases (and are already allowed under current law), they could greatly reduce the ability of Medicare to recover overpayments in others. An exception for cases where the Secretary finds clear and convincing evidence of fraud would be difficult to administer and could allow offenders to flee, declare bankruptcy, or otherwise place funds out of reach until such a determination can be made.

Repayments During Appeal

The bill would prohibit recovering past overpayments if appeal is pending. This has the same risks as the previous provision.

Document Requests

The bill would prohibit the carriers from requesting the production of records or documents prior to payment absent cause. This would prevent review of documents supporting the claim prior to payment, even in programmatic areas where past histories of abuse are present. Without this well established and recognized tool the integrity of the Medicare program would be seriously jeopardized.

Voluntary Repayment

The bill would establish an unprecedented new form of immunity from investigations to a provider who voluntarily returns overpayments. The intent of this provision is understandable. Providers who make unintentional errors or discover overpayments which they had not sought should be encouraged, not penalized, for voluntarily returning them without fear of penalty or prosecution. However, there is no need for new legislation in this regard. As I mentioned earlier, physicians and other health care providers are not subject to civil or criminal penalties for honest mistakes, errors, or even negligence. However, those relatively few providers who would deliberately and fraudulently steal from the Medicare program would not hesitate to use this provision to immunize themselves from investigation and prosecution, and, in essence, obtain interest free loans from Medicare.

Extrapolation

Extrapolation is the scientifically valid method of statistical sampling, and has been fully accepted by the Federal courts as a method of estimating liability for overpayments. The bill would prohibit recoupments or offset payment amounts based on extrapolation for the first time that a provider is alleged to have received overpayments or when a provider submits a claim for advice of suitability (as provided for later in the bill in the section on education components). These provisions would eliminate an important tool in evaluating overpayments and deprive the trust fund of the full amount owed to it. Ironically, the bill would greatly increase the burden on providers if, instead of using scientifically drawn samples of claims to de-

termine the amount of overpayment, carriers and intermediaries would be required to review the entire universe of suspect claims of a provider. This would also increase Medicare's administrative costs. The provisions would also increase the amount the provider would have to repay, since when scientific samples are used instead of universe reviews, the amount of the overpayment to be collected is often based on the lower end of the sample's confidence level rather than the midpoint, the most likely estimate of the overpayment amount. Most importantly, it provides an inappropriate "safe harbor" immunizing a provider from full liability. Finally, the few fraudulent providers that there are would not hesitate to use these provisions to protect their ill gotten gains from recovery and themselves from surveillance or prosecution.

Claims Processing Screens

The bill would require HCFA to reveal claims processing screens to providers. Honest providers do not need to know the screens. Explaining them to dishonest providers is the equivalent of instructing them how to avoid detection and successfully exploit the program. Fraud detection through prepayment review would be nullified.

Advisory Services

The bill would give providers immunization from investigation as a result of seeking advice on billing and cost reporting provisions of the Medicare program. It is reasonable for honest providers to be able to seek advice about their claims without fear of investigation or prosecution. However, this provision would provide a dishonest provider immunization from investigation, a result which is not at all desirable.

Long Term Care

The various provisions relating to appeals in connection with long term quality improvements cause us to have many of the same kinds of concerns raised in the sections above—unnecessary, additional levels of review, unrealistic timeframes for moving to the next higher level of review, and suspension of remedies. All of these could seriously jeopardize patient safety and quality of care.

Promising Proposals

It is obvious that parts of the proposed bill are intended to assure honest providers that they will not be subject to investigation, prosecution, or harassment as a result of good faith efforts to comply with Medicare requirements. Unfortunately, many of these same provisions would play into the hands of the small number of unscrupulous individuals who use sophisticated means to exploit weaknesses in the Medicare program. Honest providers do not need the additional protections provided here. However, they certainly deserve practical assurances that their good efforts will not result in their being punished.

While I believe that most providers concerns can be addressed through administrative rather than legislative means, those sections of the bill relating to educational programs, advisory services, deferral of penalties until exhaustion of appeals, repayment periods, and appeals and grievances are worthy of additional review.

More provider education would be especially valuable. We have already seen the beneficial effects of HCFA educational initiatives. They have a lot to do with the substantial drop in the payment error rate and clarification of documentation standards. Our own efforts in working with the provider community in developing compliance guidelines have convinced us of the usefulness of outreach and education.

Similarly, providers ought to be able to get answers when they have questions about submitting their bills. A program through which HCFA can provide them advisory services would be very useful. Our own experience in administering such a program has convinced us of the benefits. We urge that any such initiative be fully funded. As noted earlier, however, we would not support the granting of immunity in connection with requests for advice.

Other provisions of the bill could be helpful if substantial changes were made to them. For example, extended payback periods would make sense if they were necessary to prevent bankruptcy or severe hardship to a provider who received overpayments innocently. However, an automatic three year privilege would not be appropriate in all cases. Similarly, while deferral of penalties until final determinations are made could be reasonable in many cases, this would not be desirable if patient care were placed at risk. For both of these provisions, consideration should be given to the payment of interest to the Medicare Trust Funds—for example, for overpayment amounts sustained after appeal and during a repayment period.

As noted earlier, the Office of Inspector General fully understands the need to improve the appeals and grievance system. However, we propose a thorough overhaul of this system. Simply specifying time limits for review, especially unrealistic ones, will not correct the underlying problems, as described earlier.

Finally, I would also point to the various recommendations which are included in the first part of my testimony. Their implementation would reduce frustrations and improve Medicare payment systems.

I hope that we can find ways, primarily through education and communication, to provide the honest providers with the understanding and assurance they deserve in their medical practice. We look forward to working with the medical care community in finding ways to do this.

CONCLUSION

Medicare is important to all of us. I hope that the suggestions provided here from the Office of Inspector General will be useful in streamlining the program, reducing frustrations of providers and administrators alike, and making the program better for Medicare beneficiaries. We are ready to help this committee and all parties involved to find a better way to manage this program. Thank you for the opportunity to present these ideas to you.

Chairwoman JOHNSON. Thank you.

Dr. Moffit.

STATEMENT OF ROBERT E. MOFFIT, PH.D., DIRECTOR, DOMESTIC POLICY STUDIES, HERITAGE FOUNDATION

Dr. MOFFIT. Madam Chair, my name is Robert Moffit. I am the director of Domestic Policy Studies at the Heritage Foundation. I want to express my sincere appreciation to you for the honor to testify before the House Ways and Means Subcommittee on Health. I want to stress that the views that I am expressing today are entirely my own and should not be construed as representing any official position of the Heritage Foundation.

My professional interest in Medicare and the delivery of health care services is more than academic, although I spend an awful lot of time studying health care policy. I served as Deputy Assistant Secretary for Legislation at the Department of Health and Human Services during the Reagan administration, and I also served as Congressional Relations Director at the Office of Personnel Management, the agency that runs the Federal Employee Health Benefits Program, which, as you know, is a prominent model for Medicare reform. So I have practical experience in dealing with both programs and responding to congressional inquiries on problems in both health care systems.

I want to make a few observations on this conversation we are having this morning. One of them is obvious. It is that Medicare's regulatory complexity is not the fault of the Health Care Financing Administration, the agency that administers Medicare. On this I agree with Congressman Stark. Parenthetically, it is a Historic occasion when the Heritage Foundation and Congressman Stark find themselves in agreement. Perhaps a solar eclipse will shortly follow. But the criticism of the Medicare regime should not be a criticism of the career staff of HCFA or HCFA as an agency of the Federal government.

The reason why we are having these discussions is because of the structure of the Medicare Program. Medicare is an entitlement program. More importantly, it is a defined benefits program. If you

have a defined benefits program, Congress must determine what benefits Medicare patients will get, and subsequent to congressional authority, HCFA and its contractors determine what is or is not covered for purposes of reimbursement, and what specific medical services, treatments, and procedures Medicare patients will get and how and under what circumstances they will get them.

This is endemic to today's Medicare Program. It means that HCFA must write increasingly detailed rules to the extent to which medical benefits modify or change. If Congress doesn't want to change this structure, there is no simple way around these regulatory problems.

A second observation: HCFA is overwhelmed by the size and scope of its current regulatory responsibilities and is in a state of managerial crisis. HCFA also has responsibilities beyond Medicare: for Medicaid, the State Children's Health Insurance Program, and enforcing provisions of the Health Insurance Portability and Accountability Act. HCFA oversaw a total estimate payment of about $370 billion for health services last year. As GAO and others have noted, it is becoming progressively harder for HCFA to fulfill all of these responsibilities.

This managerial crisis has been developing over time. Our colleague, Lynn Etheredge, at George Washington University, wrote in the October 2000 edition of Health Affairs that the management crisis at HCFA has arrived.

A third observation: Medicare's regulatory complexity is compromising the quality and delivery of medical services and insurance products. In my written testimony, I detail this. But this is becoming evident in at least two areas: the access to medical technology and the use of private plans in the Medicare Plus Choice program.

Fourth: Medicare's regulatory complexity is bound to get worse. With the rising demand for medical services by a rapidly aging population, a Medicare-eligible population that will double over the next three decades, the pressures to accommodate those increased demands and increased costs within the existing framework of administrative pricing and benefit setting will intensify. Congressional debates over physician and hospital payment or reimbursement for home health care or skilled nursing facilities or prescription drugs, or how to cover or whether to cover new medical devices or procedures, is going to require even more congressional time and attention and will require even greater administrative effort and even more detailed rule-making on the part of the Health Care Financing Administration.

Finally, the expansion of Medicare benefits, including the addition of a prescription drug benefit, without addressing the managerial and regulatory problems plaguing the program, I think, would be a profound mistake. We have managerial problems in Medicare part A, B, and C right now. If you had a prescription drug benefit, without dealing with the current regulatory regime, you are asking for much more trouble.

My colleagues at the Heritage Foundation think that the best way to solve this problem is to change the program's structure, and the way to do that is to go to a tested model that has been proposed by the President and by the Bipartisan Commission, and that is the Federal Employee Health Benefits Program (FEHBP).

I just would like to make one observation before I close on the governance of the FEHBP. Students of the Federal employee program have found that among its most attractive features is the brevity and simplicity of its statutory authority. The program is characterized by a notable absence of heavy regulatory control, the relative ease with which the program adopts new health care benefits and absorbs new medical technologies, its relative flexibility in benefit setting. From the standpoint of governance, the Federal employees' system also enjoys a relative freedom from the bitter politics of administrative pricing, the medical income redistribution, and the attendant congressional micromanagement that afflicts the traditional Medicare Program. And the major reason is, in stark contrast to the Medicare Program, the Federal Employees Program is largely a market-driven system, which relies on private sector plans to structure their offerings each year to satisfy consumer demand and compete with each other directly in promoting patient satisfaction. This is in sharp contrast to Medicare. The crucial decisionmaking in the FEHB is not centralized; it is diffuse.

While there are negotiations between OPM staff and major plans, and hundreds of routine transactions between OPM and private plans in the several States, there are literally millions of decision points in the system governed by the diverse wants and needs of Federal employees and their families and the dynamic conditions of supply and demand.

I would close, Madam Chairman, by emphasizing that you are going to have a major political challenge with Medicare reform. But there are going to be technical difficulties no matter what you do. If you decide that you do not want to reform the Medicare system, that is your decision. But all of these regulatory and managerial problems that you heard about this morning are going to intensify and they are going to get worse. If you decide to go to a new system, you are going to have new problems. But you are also going to have a lot of new opportunities as well.

Thank you very much.

[The prepared statement of Dr. Moffit follows:]

Statement of Robert E. Moffit, Ph.D., Director, Domestic Policy Studies, Heritage Foundation

Madame Chair, Members of the Subcommittee:

My name is Robert E. Moffit. I am Director of Domestic Policy Studies at the Heritage Foundation. I wish to express my sincere appreciation to you and Members of the Subcommittee for the opportunity to testify on the subject of Medicare regulations. I must stress, however, that the views I express are entirely my own, and should not be construed as representing any official position of the Heritage Foundation.

My professional interest in Medicare regulation, and how to improve the financing and delivery of medical services to American citizens, is far from academic. During the Reagan Administration, I not only served as Deputy Assistant Secretary for legislation at the Department of Health and Human Services (1986–1989), handling congressional requests and constituent problems related to Medicare, but I also served as the Director of Congressional Relations at the United States Office of Personnel Management (1981–1986), the agency that administers the Federal Employees Health Benefits program (FEHBP), the model for reform embraced by the Bush Administration, the majority of the National Bipartisan Commission on the Future of Medicare and the model embodied in the legislative reform proposals recently introduced by Senators John Breaux (D–LA) and Bill Frist (R–TN). I have thus had a practical experience in monitoring and responding to congressional inquiries on both programs.

Concerning the Medicare's regulatory problems, I have several observations.

First, Medicare's regulatory complexity is not the fault of the Health Care Financing Administration (HCFA), the agency that administers Medicare. Criticism of the Medicare's regulatory regime should not be a criticism either of the career staff or HCFA as an agency of the federal government. This is not to exonerate the agency or its officials from some serious mistakes, or lapses in judgment. But much of the understandable anger directed at HCFA by doctors and medical specialists, and even Members of Congress is too often misplaced.

Growing dissatisfaction among providers over Medicare's regulatory burdens is not merely attributable to HCFA's managerial efficiency, or its lack of managerial efficiency. Rather, it is attributable to the seemingly incessant Congressional delegation of ever greater regulatory responsibilities to the agency, and, more importantly, to the very structure of the Medicare program itself. Medicare is an entitlement program; it is a defined benefits program, where Congress determines what benefits Medicare patients will get; and, subsequent to Congressional authority, HCFA and its contractors, determines what is or is not covered for purposes of reimbursement, and what specific medical services, and treatments and procedures Medicare patients will get and how, and under what circumstances they will get them. HCFA, again subject to Congressional authority, determines what is or is not appropriate or medically necessary. This is formidable regulatory authority. But it is difficult to imagine how Medicare, given its current structure, could function otherwise. Surely, HCFA's most severe critics would not want to surrender to the agency unlimited flexibility to carry out its mandate. If Congress wishes to retain this structure, then Congress must authorize, and HCFA must implement and enforce increasingly detailed regulations that guarantee universal access to a set of legislatively or administratively defined benefits, medical treatments or procedures.

Given this structure and this process, there will be numerous disagreements, powerful and angry dissents, and strong objections from medical providers, seeking exceptions or expansions to these rules. The regulatory exceptions simply complicate the regulatory environment.

So, HCFA's problems are not rooted simply in the absence of a superhuman wisdom, or any inherent deficiencies in HCFA staff to do the necessary regulatory job, or because the agency suffers from an absence of information technology specialists, or aging and outdated information systems unable to cope with the rapidly changing conditions. It is rooted in a work overload that, given the Congressional authorization, is unavoidable. These problems are not going to be solved simply by appropriating funds so that HCFA can acquire the right software or the right hardware, or the right specialists in whatever field of health care policy that is required. Given the current structure of the Medicare program, there is simply no way to avoid these difficulties.

Congress specifies what it will pay for benefits and services, and authorizes HCFA to make any adjustments in accordance with its legislative determinations, or the formulas, that govern Medicare's complex system of administrative pricing plus price caps, including the Prospective Payment System (PPS) for hospital payment and the Resource Based Relative Value Scale (RB–RVS) for physician reimbursement. As my colleague Dr. Len Nichols, a senior economist and health care policy analyst at the Urban Institute has noted, the task imposed on HCFA is to set roughly 10,000 prices in 3000 counties across the United States, a task which it does not, and cannot, do very efficiently or effectively.

On payment issues, as on the benefit issues, as Members of this Subcommittee know, far better than I would even be able to imagine, there are intense pressures to readjust constantly this formula driven Medicare payment system; carve out exceptions; and revise and refine the reimbursements upward. These pressures are invariably intensified after Congress has taken actions to reformulate reimbursements downward, in perennial attempt to control costs in the program. This annual political process also invariably adds to the growing complexity of the system, and makes it progressively less comprehensible for doctors, hospitals and other providers, and, of course, patients.

For the most part, Medicare patients are the passive recipients of this arcane and complicated decision-making process. Medicare's regulatory regime directly impacts only doctors, hospitals and other providers. Compared with the private sector, Medicare's administrative costs, as a percentage of payment for benefits, appears very low, roughly between 1 and 2 percent. But this calculation does not take into account the transactional costs of health providers in complying with this regulatory regime. A major econometric analysis of these costs, and their impact on patients, would be welcome.

Altogether, this process not only frustrates providers—doctors, hospital administrators or home health care officials—but also yields some very odd economic re-

sults. The General Accounting Office has done a number of studies on the subject, which make for interesting reading. Once again, if Congress retains the current structure of Medicare, there is simply no way around these problems or political pressures.

Second, HCFA is overwhelmed by the size and scope of its regulatory responsibilities, and is in a state of managerial crisis. Once again, the regulatory responsibilities of HCFA are not, of course, generated by HCFA; they are imposed by Congress. And, as noted, they are elemental to the very structure of Medicare as a defined benefit entitlement program.

Medicare today covers almost 40 million persons, at an estimated cost of $220 billion. As the General Accounting Office and others have pointed out, HCFA also administers the Medicare Plus Choice program with over 300 managed care plans, and contracts out for the services of others, particularly intermediaries or insurance carriers, in every state in the union. HCFA pays approximately 6000 hospitals, and roughly 700,000 physicians and other providers. Moreover, HCFA must write standards, as a condition for participating in the Medicare program for a variety of institutions and specialties, such as hospitals, home health care agencies, clinical laboratories, nursing homes, skilled nursing facilities, among others. And beyond Medicare, HCFA also has responsibilities for running Medicaid, overseeing the State Children's Health Insurance Program, and enforcing certain provisions of the Health Insurance Portability and Accountability Act. Altogether, HCFA oversaw a total estimated payment of almost $370 billion for health care services last year. As GAO and others have also noted, it is progressively harder for HCFA to fulfill all of these responsibilities.

This managerial crisis has been developing over time. The General Accounting Office (GAO) told Congress in 1998 that ". . . substantial program growth and greater responsibilities appear to be outstripping HCFA's capacity to manage its existing workload." In 1999, 14 prominent health care policy experts, including Dr. Stuart M. Butler, my superior at the Heritage Foundation, and three former directors of HCFA published an open letter to Congress and the White House in the 1999 Winter issue of *Health Affairs* warning of an impending management crisis at HCFA. While these analysts differed on what was the best approach to Medicare reform, they were all agreed on one point: HCFA is, as an institution, in very serious trouble. Following up on this notice, in the October 2000 edition of *Health Affairs*, Dr. Lynn Etheredge of George Washington University, wrote, "The management crisis has arrived. . . It is now widely recognized that HCFA has many problems. Reformers are frustrated, whether their goals are a successful Medicare + Choice Market, modernization of fee for service Medicare, enrollment of eligible children in SCHIP, improved computer systems, new chronic care programs, or better staff morale. Nearly everyone who works with the Medicare or Medicaid programs now understands that something needs to be done about HCFA." While there is an urgent need for action, there is an even more urgent need to do it right.

Third, Medicare's regulatory complexity compromises the quality and delivery of medical services and insurance products. This is becoming evident in at least two areas: access to medical technology and in the use of private plans in the Medicare + Choice program**.**

In the area of medical technology, there is solid evidence that Medicare's processes are painfully slow and compromising patient access to technology that is available to patients in the private sector. Last year, the Lewin Group, a Virginia based econometrics firm modeling health care policy initiatives, conducted a major study on behalf of the Advanced Medical Technology Association that found that Medicare's processes of coverage, coding and payment decisions delay patient access to medical technology. The study found that it takes between 15 months to over 5 years or more to add new medical technologies to Medicare program. Moreover, according to the Lewin study, Medicare's processes for coverage, coding and payment is time consuming and complicated, and impedes patient access and discourages innovation in breakthrough medical technologies.

Likewise**,** the current regulatory regime has damaged the Medicare + Choice program. In their 2000 analysis of the Medicare + Choice program, *The Medicare + Choice Program: Is It Code Blue?* Janice Ziegler and Bruce Fried, a former Director of the Center for Health Plans and Providers at HCFA, wrote, "The regulatory complexity of the M+C program has taken on mammoth proportions and made it difficult for M+Cos to comply with all of the many program requirements. Moreover the breadth and depth of regulatory requirements have imposed a level of micromanagement that significantly hampers—or, in some instances, restricts altogether—the ability of M+COs to make essential business decisions regarding how care should be financed and operations structured. This level of micro-management, when coupled with constantly changing nature of the program requirements and

conflicting directions from HCFA, creates a significant disincentive for M+COs to remain in the program or become new entrants."

As Fried and Ziegler report, beyond the issuance of detailed regulations and "guidance" and Medicare manual changes, HCFA has already issued well over 100 "operational policy letters" (OPLs), the specific directives governing various aspects of plan administration. Moreover, plans have had to meet HCFA's tight deadlines for compliance as well as various state regulatory standards, while wrestling with conflicting federal and state rules. Fried and Ziegler further note that HCFA issues these rules and letters often with little or no thought about how they will impact costs. But, of course, every dollar required to comply with HCFA's increasingly complex administration of the program means one less dollar for drug benefit increases or premium reductions for senior citizens.

Fourth, Medicare's regulatory complexity must get worse. With the rising demand for even more specialized and complex medical procedures within the current framework of the defined benefits system, the regulatory complexity will worsen. With the rising demand for medical services by a rapidly aging population, a Medicare eligible population that will double over the next three decades, the pressures to accommodate those increased costs within the existing framework of administrative pricing will intensify. Congressional debates over physician or hospital payment or reimbursement for home health or skilled nursing facilities, or whether or how to cover new medical devices or procedures, prescription drugs will require more Congressional time and attention and even greater administrative effort on the part of HCFA.

Fifth, the addition or expansion Medicare benefits, including a prescription drug benefit, without addressing the managerial and regulatory problems plaguing the program would be a profound mistake. HCFA already faces serious challenges in running the traditional Medicare program and the beleaguered Medicare + Choice program, which is processing roughly a billion claims each year. The addition of a Medicare prescription drug benefit to the current structure, whatever merits that may have, would also dramatically increase the number of transactions HCFA must oversee and thus add to the program's already formidable managerial burdens.

WHY STRUCTURAL REFORM EQUALS REGULATORY REFORM

If Congress wants to strike at the root of the regulatory problems that affect the current Medicare program, then the remedy of choice is choice itself; a structural reform that preserves a Medicare entitlement to a basic or core set of health benefits, but transfers the lion's share of decision-making in the system over to Medicare patients and the private plans that they personally choose for themselves.

The best working model for such a structural reform, as the majority of the National Bipartisan Commission on The Future of Medicare have advised, is a program that is older than the Medicare program: the Federal Employees Health Benefits Program (FEHBP), which has been serving federal workers and retirees and their families since 1960. Because the government contributes to the cost of the enrollees premium, rather than trying to pay medical providers directly or determine the details of health benefits or the precise level of medical services, the FEHBP is the quintessential "premium support" program.

Having been enrolled in the program personally and having been associated with the program professionally in my capacity as an Assistant Director at the United States Office of Personnel Management, I am acutely aware of the weaknesses of that program, specifically, a lack of variation in premiums or government contributions for younger workers and older workers and retirees or the absence of any risk adjustment mechanism to cope with periodically troublesome problems of adverse selection. Moreover, FEHBP does not yet accommodate flexible spending accounts, widely available to workers in the private sector, and OPM has had an institutional bias against lower cost, high deductible options for employees who might want them. There are also irrational statutory restrictions on market entry of fee for service plans, even though these plans tend to be more popular than HMOs.

Nonetheless the 40 year record of the FEHBP has been exceptionally good. This is particularly so in the area of governance. In 1989, in perhaps the most comprehensive analysis of the FEHBP ever undertaken, the Congressional Research Service noted that historically, the OPM has governed the FEHBP in a fashion that is best described as "passive management". While some might object to such managerial passivity, a positive by-product of OPM's historically light touch has been a progressive evolution of benefits packages, that have become richer and more varied with the passage of time.

Other students of the program—ranging from Professor Alain Enthoven of the University of California to analysts from the Progressive Policy Institute—have found that among its most attractive features is the brevity and relative simplicity

of its statutory authority. The program is also characterized by the notable absence of heavily prescriptive regulation, the relative ease with which the program adopts new health benefits and absorbs new medical technologies, and its relative flexibility in benefit setting. From the vantage point of governance, the FEHBP also enjoys a relative freedom from the bitter politics of administrative pricing, the medical income redistribution and attendant Congressional micro-management that afflicts the traditional Medicare program. The major reason: In stark contrast to the Medicare program, the FEHBP is a largely market driven system, which relies on private sector plans to structure their offering each year to satisfy consumer demand and compete with each other directly in promoting patient satisfaction. Thus, in sharp contrast to Medicare, the crucial decision-making in the FEHBP is diffuse. While there are negotiations between OPM staff and major plans, and hundreds of routine transactions between OPM and private plans in the several states, there are literally millions of decision points in the system, governed by the diverse wants and needs of federal employees and their families and the dynamic conditions of supply and demand. Consider the main features of the program:

• **Broad Choice of Plans.** Over 300 plans are competing for consumers' business. Unlike the rest of working Americans, federal workers and retirees will have a broad choice of private plans from which to choose. These plans may be fee for service plans, preferred provider plans, (PPOs) or health maintenance organizations (HMOs). Unlike many workers in private sector, federal workers are not forced into one type of coverage, such as HMOs, on a "take or leave it" basis, and federal workers and their families can normally choose between a dozen and a dozen and a half plans in most places in America. Unlike Medicare enrollees, their private plans include prescription drug and catastrophic coverage. In fact, virtually all plans cover between 80 and 90 percent of prescription drug costs.

HMOs attract federal employees and retirees, and they are not forced into them. Consider the pattern of choices among federal retirees, many of whom are covered by Medicare as well. In a recent presentation on FEHBP for the National Academy of Social Insurance, Dr. Kenneth Thorpe and Dr. Curtis Florence, found that 83.3 percent of single retirees chose fee for service plans, while only 16.7 percent chose HMOs; for retired couples, 84.2 percent chose fee for service plans, while 15.8 percent chose HMOs.

Paradoxically, the pluralistic system of competing private plans in the FEHBP is operationally simpler for enrollees than the current Medicare program. Unlike the overwhelming majority of Medicare beneficiaries, Federal workers do not have to go outside of the system to buy supplemental coverage for drugs and catastrophic protection, and pay two premiums for two different plans. Medicare beneficiaries, unlike enrollees in the FEHBP, will end up spending roughly half of their health bills in out of pocket costs.

• **Rational Financing.** While the government spends about $220 billion for the Medicare program, covering almost 40 million retirees, the same government spends about $20 billion for the FEHBP, covering 9 million persons. But FEHBP is a program with a more rational payment system, a form of premium support for individuals and families, and a richer, more progressive and more varied health benefits package than Medicare. Under current law, the government pays 75 percent of the cost of any plan up to a maximum amount, set by formula. For 2001, that amount is up to $2250 for single individuals or $5090 for families. If individuals or families want to buy a more expensive plan, they can, but they will pay more for the richer plan. If they want to buy a less expensive plan, they can do that also. It's their choice.

• **Less Bureaucracy, More information, and Higher Satisfaction.** Unlike Medicare, which spells out in detail what benefits, treatments or procedures are to be covered, and what prices is to be paid for each medical service, the FEHBP is far less bureaucratic. Within the framework of annual negotiations, private plans present their combinations of benefits and premiums and co-payments to the federal workforce. Plans only do well when they sell a package of benefits at a price people want. Within statutory requirements and OPM approval, plan benefit packages differ, and so do their premiums, co-payments, co-insurance and deductibles. The government does not make everybody pay the same for the same package of benefits. Persons can enroll in any plan they wish; they have access to solid information, not only from the federal government, but also from a variety of private sector sources beyond the plans themselves.

Not surprisingly, levels of consumer satisfaction in the FEHBP are high. According to a 1997 survey of FEHBP policy holders who rated their plans as good, very good or excellent, 87 percent of fee for service policyholders described

their plans this way, but 84 percent of HMO enrollees also did so. Not surprisingly, also, enrollees tend to stick with their plans. Based on previous experience, it is likely that no more than 5 percent of FEHBP enrollees will change their plans in a typical year. They pick plans they like, and tend to stay with them, as long as their plans perform on the market basis of price, quality and performance.

HOW SYSTEMIC CHANGE CAN LEAD TO REGULATORY RELIEF

At least for new retirees, there is no reason why Congress could not improve upon the record of the FEHBP and create a superior system for America's senior citizens, largely free of the regulatory complexities that trouble the current Medicare program. At the same time, recognizing there are significant differences between the Medicare population and the current federal workforce, the Congress would want to make sure that the transition to such a system should be undertaken carefully. In the creation of such a system, Congress should consider taking the following steps:

1. Make sure that the newly created administrative agency that oversees a reformed Medicare program—whether it is an independent board or an agency of the Executive branch of the federal government—functions in a fashion broadly similar to the Office of Personnel Management, which administers the FEHBP. The agency should negotiate rates and benefits on behalf of retirees; guarantee that plans offer the statutorily required benefits package; make sure that plans meet fiscal solvency requirements; make sure that plans comply with any statutorily prescribed underwriting rules, including guaranteed issue or renewability requirements; make sure that plans meet consumer protection requirements, including protections against fraud and misleading advertising, and ensure that competing plans provide plan information in plain English. For the FEHBP, OPM performs these functions today, and acts as a referee in setting and enforcing the ground rules among plans. Competing plans themselves do not have to wrestle with an overly burdensome regulatory system in complying with this consumer protection regime.

If Congress should decide to adopt a new competitive system, Congress may wish to protect the system itself from regulatory erosion. Regulatory creep can undermine legislative intent. In order to prevent the devolution of a competitive system into a powerful regulatory regime like that administered today by HCFA, Congress should consider enacting statutory prohibitions against any such agency from imposing government fee schedules, price controls, or premium caps on plans or providers participating in the new competitive system. Moreover, the Congress should make it statutorily clear that practice guidelines on doctors and hospitals, the adoption of quality standards, or the provision of lawful benefits or medical procedures that private plans may offer, over and above any statutorily required benefits package, are issues to be resolved in the competitive private market.

2. Promote Plan Flexibility in Benefit Setting. There are a variety of ways to do this. First, Congress could adopt the model that currently exists in the FEHBP. The Office of Personnel Management (OPM) sends out a call letter in the Spring of each year, outlining what it wants to see included in the plan benefit submission for the coming Fall "Open Season", when federal workers and retirees make their plan choices. OPM often specifies what benefit additions it would like to see in the plan submissions. And these plan submissions are the subject of sensitive and confidential negotiations between the representatives of the private plans and OPM officials during the summer of each year.

While OPM has broad authority to negotiate rates and benefits for each year, OPM is governed by specific statutory requirement in Title V of the United States Code that spells out the *categories* of benefits-such as physician and hospital services—that must be included by law in private plan offering. The law does not specify, however, the precise level of benefit, the duration of medical treatments or procedures, or the mix of premiums, co-payments, coinsurance and deductibles. All of these items are subject to negotiation, and OPM historically, has been flexible on these matters. In creating a new competitive system, instead of setting forth detailed benefits in legislation, Congress could replicate the FEHBP model, and confine itself to setting forth the broad categories of benefits, including catastrophic and prescription drug coverage that private plans competing in the new system must offer.

There are other possible options. Congress could set forth a core package of benefits that must be required, say, based on the current Medicare benefits package, with a further requirement for catastrophic and prescription drug coverage. But then, Congress could authorize the new administrative agency to

allow the plans to offer the actuarial equivalent of that benefits package, with a differing mix of medical treatments or a different combination of benefits, co-payments or, deductibles. Congress could also authorize the new administrative agency to accept automatically, (assuming the inclusion of catastrophic or prescription drug coverage), a new retiree's employment based plan as an approved plan in the new competitive system, thus allowing workers to take their state or ERISA certified employer based plans with them into retirement as their primary coverage and get a government contribution to offset its cost, assuming that the employer would also be amenable to such an arrangement.

3. Authorize sophisticated information collection. Before entering into negotiations with private plans, the new administrative agency should conduct regular surveys among enrollees to get a clearer idea of what Medicare patients want in their insurance packages. With the coming eligibility of the 77 million strong baby boom generation for Medicare coverage, there is likely to be a rich diversity of demand for new and increasingly varied medical services. The new administrative agency should take advantage of sophisticated information technology to assess more accurately the precise nature of this demand, discerning what, precisely, individual enrollees want in terms of access to physicians and specialists, different types of coverage, and different types of benefits and different levels of premium payment and co-payment. This would help the officials to negotiate solid benefits on behalf of retirees at an affordable price. These information programs are already coming to fruition in the private sector. Just as they can be of immense value to employers in fashioning their own health insurance offerings, they could also be invaluable to a new government agency administering a pluralistic system of competing private plans for senior citizens. In this new environment, consumer based information would be the touchstone of all administration decision-making; and persuasion and friendly negotiation would replace regulation.

4. Ensure a smooth transition to a new competitive system by phasing it in, allowing plenty of time for mid-course corrections, and enabling private plans to adjust to the enrollment of new retirees. If there is any lesson that could be drawn from the damaged "Medicare+Choice" experiment, it is the crucial need for a well planned transition. There should be a high level of predictability for private plans, who must develop business plans to accommodate the changes in the system, without the fear that what they are attempting to do will be undercut by precipitous changes in federal regulatory policy. Perhaps the best way to accomplish this objective is to make sure that any new competitive system would be open only to new retirees, allowing it to grow on a year by year bases, and enabling the market to respond and mature. If, after a few years, when the system is up and running, the inevitable wrinkles have been ironed out, the Congress could open the new system up to enrollees in the traditional Medicare program.

5. Stop overloading HCFA. If Congress does create a new competitive system, HCFA should not be tasked with administering it. Given the culture of HCFA as a regulatory agency, it is not in any case the best candidate for partnering with private firms and administering a new market driven system. HCFA should be confined to administering the traditional Medicare program, and given the managerial flexibility to compete with private plan options for the allegiance of retirees. Congress should also consider creating alternative managerial structures for the administration of Medicaid, SCHIP and enforcement responsibilities under the Health Insurance Portability and Accountability Act.

A final thought. Reforming the Medicare program will be technically difficult, particularly in developing a transition to a new competitive system, and it will be politically challenging. But the alternative is to continue to manage Medicare through an increasingly complex body of statutory law, expanded judicial decision-making, and increasingly detailed regulation. Meanwhile, Medicare will face an unprecedented demand for medical services within this decade from an increasingly well educated, diverse and rapidly growing retiree population. Insisting on the *status quo*, and nourishing the inevitable regulatory growth of a fundamentally unchanged Medicare program could prove even more difficult and politically challenging.

Thank you.

Members of The Heritage Foundation staff testify as individuals discussing their own independent research. The views expressed are their own, and do not reflect an institutional position for The Heritage Foundation or its board of trustees.

Chairwoman JOHNSON. Thanks very much, Dr. Moffit.
Hon. Ms. Wilensky.

STATEMENT OF THE HON. GAIL R. WILENSKY, PH.D., JOHN M. OLIN SENIOR FELLOW, PROJECT HOPE, BETHESDA, MARYLAND; CHAIR, MEDICARE PAYMENT ADVISORY COMMISSION; AND FORMER ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Ms. WILENSKY. Thank you, Madam Chair and Members of the Subcommittee. I am here as a senior fellow from Project HOPE and a former HCFA Administrator. Listening to today's discussion makes me glad to emphasize the former.

I am not here, however, to bash HCFA. What I would like to do is to share with you ways in which I believe the regulatory environment might be changed so as to reduce some of the burdens that we have been hearing about on providers without abdicating the fiduciary responsibility of HCFA to be prudent stewards of the Medicare trust funds.

We need to recognize that there is a fundamental tension inherent in HCFA's roles. HCFA needs to establish a user-friendly environment, making sure that seniors get access to high-quality health care, but HCFA also needs to be financially prudent with the taxpayers' moneys.

You have been hearing about the increased levels of frustration that have been reported by providers regarding billing complexities and fears of the billing complexities compounded by integrity activities.

Recently, there has been some empirical evidence that, after years of upcoding—that is, billing for more services than was provided—there is now some indication of downcoding—that is, billing for less intense services that were actually provided. This is not a good sign for the program or for the seniors that are served by Medicare.

What I would like to do is share with you a few strategies that I believe could help reduce provider frustration and also some steps that would help HCFA be able to deliver services, by restructuring the agency, and, finally, to discuss how to get from here to there.

In the first place, I think it is clear we need to have better education for providers; we need to have clearer billing procedures and protocols; and we need to have billing procedures and protocols changed less frequently and on a more regularized basis.

The second area that I want to mention relates to the presumption as to how bills are paid. We have heard this morning about some of the variations that are used by the carriers and the fiscal intermediaries. But, in general, there is a presumption or default that bills are not being submitted accurately. That is a presumption that could be changed in much the way that there was a change in the Peer Review Organization. The presumption would become that bills are properly submitted. Then there would be a search for patterns of abuse based on statistical analyses.

Prior to the early nineties, the PROs used to perform a case-by-case, retrospective analysis, looking for bad outcomes. But once

they found one, it was very difficult to figure out what it meant. As a result, and in an effort to focus more on quality improvement, there was a movement to looking to patterns of care and patterns of outcome that differed from what their peers experienced. It is precisely this, that kind of a change that I think would go a long way to reducing the kinds of frustration that we have heard described this morning.

Finally, I believe that HCFA needs to be more mindful of the time and burden imposed on providers from its various assessment and data collection efforts. We heard some mention made of the minimum data set, the MDS. There is a new data set now called the minimum data set post-acute care, MDS–PAC. The MDS has 350 items. The MDS–PAC has more than 400 items, with seven different timeframes for patient assessment. The MedPAC report that was recently delivered to the Congress, indicated MedPAC's concern about the amount of time taken away from patient care that these assessments tools would require and has suggested that for inpatient rehabilitation that the primary assessment tool, the functional independence measure (FIM), continue to be used. The FIM is much shorter and has been used for a number of years.

Second, restructuring HCFA so that it can focus on Medicare. That would mean taking some of the current enforcement functions, the survey and certification, the clinical lab certification, and the conditions of participation and putting them either with the CDC or with the FDA. Second, moving either all of Medicaid, or at least that portion relating to moms and kids, and the Children's Health Insurance Program with the agency that runs welfare. These are all State-based, income-related programs. Whether or not to move the long-term care portion of Medicaid is a little more complicated.

Whether or not the section of HCFA that runs the Medical Plus Choice Program should be moved depends somewhat on the kind of Medicare reform the Congress chooses to do. As you know, I am also a supporter of a Federal Employees Health Care model as a reform for Medicare. This would require a number of administrative changes. If Medicare does not begin to move toward an FEHBP model, the Medicare Plus Choice might remain a direct part of HCFA. If the reform does not occur, the administration of the Medicare+Choice program should be moved to another agency that is within HHS or an expanded part of the Office of Personnel Management although there would clearly need to be some coordination with HCFA.

Third, if you choose to use PBMs, the pharmacy benefit management groups, to run a pharmacy program for seniors, there will have to be much greater clarity about how much independent power PBM's are to have, where their oversight should be lodged, and resolve many other administrative issues.

Fourth, a word about getting from here to there. Phase-ins for Medicare usually occur over some time when they relate to changes in payment and coverage. My advice is that any restructuring of Medicare should also be phased in. It is best to restructure at the beginning of a term or at the end of a term. Moving relatively separable parts of HCFA is less disruptive than reorganizing all the

people within the agency. But even moving separable parts will be disruptive.

And, finally, Congress and the administration need to recognize that there has been a serious mismatch between HCFA responsibilities and HCFA resources. HCFA clearly needs to do better, but with all due respect, Congress needs to do better with HCFA as well.

Thank you.

[The prepared statement of Ms. Wilensky follows:]

Statement of the Hon. Gail R. Wilensky, Ph.D., John M. Olin Senior Fellow, Project HOPE, Bethesda, Maryland; Chair, Medicare Payment Advisory Commission; and former Administrator, Health Care Financing Administration

Madam Chairwoman and members of the subcommittee: Thank you for inviting me to appear before you. My name is Gail Wilensky. I am the John M. Olin Senior Fellow at Project HOPE, an international health education foundation and I chair the Medicare Payment Advisory Commission. I am also a former Administrator of the Health Care Financing Administration. My testimony today primarily reflects my experiences as a HCFA Administrator as well as my views as a health economist. I am not here in any official capacity and should not be regarded as representing the positions of either Project HOPE or MedPAC.

I am here today to discuss ways in which the regulatory environment might be changed so as 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 in order to make the agency function more effectively. I believe such a reallocation would be desirable, irrespective of reforms to the Medicare program but would be particularly important with some of the reforms under consideration. It would also allow HCFA to concentrate its energies on running Medicare more efficiently and effectively.

Fundamental Tensions Faced by HCFA

HCFA faces certain fundamental tensions with its goals of establishing a user-friendly Medicare, 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 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 to a program as large and complicated as the current Medicare program, but if left unchecked, can mean an important diversion of time 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. This finding is consistent with reports by various types of providers regarding their uncertainty about how to bill Medicare appropriately and their concerns about being charged with making false claims against the Medicare program. While government officials should not countenance abusive behavior by providers, it should be equally worrisome to the Government that providers may be deliberately under-billing Medicare in an attempt to stay clear of the HCFA or the IG. Such behavior will not be to the long-term benefit of Medicare or the seniors it serves.

Strategies to Reduce Provider Frustrations

Among the many complaints raised by providers, uncertainty about proper billing and coding and discrepancies in treatment by various contractors 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 and may require additional resources as well.

The tension between the desirability 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 also a part of the original Medicare legislation. This discretion makes Medicare 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.

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 emphasis 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 focus-

ing 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.

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

There are a variety of administrative issues that need to be considered prior to the implementation of Medicare reform. What functions 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?

The first step, at least in principle, should be to move non-Medicare related functions as well as some 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 or potentially, a new authority that houses both of these agencies.

The oversight of the Medicaid program, which has always been somewhat the stepchild of HCFA, should be moved elsewhere and given appropriate resources and leadership. Where coordination with Medicare is needed, such as for the dually eligible population, interagency agreements can provide the needed exchanges of information and coordination. Putting Medicaid and the approval of proposals submitted by the states under CHIP together 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. The question is whether HCFA will be allowed 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 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.

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 function 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. 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.

Chairwoman JOHNSON. Thank you very much, everyone, for your testimony. It has been very helpful, and some of it will require, as some of you have noted, further discussion beyond this morning's endeavors.

I did want to ask you, Ms. Edelman, aren't there some home care services that our home health agencies provide that are clearly, absolutely not covered by Medicare?

Ms. EDELMAN. Yes, that certainly would be true. But there are so many instances where the home health care agencies are making incorrect assumptions or incorrect determinations that coverage is not there. More than 50 percent of the time, they are incorrect. That is very troubling. The only way that beneficiaries can get into the appeals process is through a demand bill. And so people do need an opportunity to do that.

Chairwoman JOHNSON. I appreciate that, but there are whole categories of services that Medicare doesn't cover at all: services to families with psychiatric problems, home health aides.

Now, there is a category, a group of patients, about which there is no possible controversy. I understand the gray-line area. But I don't know that you really understand what it means to an agency to now give out a form and the choices on the form are: you pay, you stop the services, or you ask for a demand bill.

Now, anybody in their right mind, any senior, is going to ask for a demand bill. So it means that agencies have to go through the demand bill process and submit the bill to Medicare—no, submit to Medicare knowing that they are not ever going to get paid by Medicare. And so it involves not only the paperwork going to Medicare, waiting for Medicare's decision. In Connecticut, it involves your agency then challenging that bill, and most all of them get challenged. This is a 2-month, 4-month, 6-month, 8-month, year, year-and-a-half process.

And all that time the agency gets paid partially by Medicare, then Medicare decides that they aren't going to pay, so they get their money back. And then the agency is bare and unable to bill any other payer, especially Medicaid, which is the primary payer

for the dual eligibles, until the thing is resolved, which may be many, many months.

Now, for a small agency, this cash flow problem—never mind the volume of just xeroxing is extraordinary. And I think if you sat down and sat with our agencies—although, actually, in Connecticut, I hate to say that your organization seems more interested in money than patient care. It is just appalling what has gone on. But it is different than other States. I appreciate that.

But we really have to look at the patient getting service. And when our agencies—now, it is true, the intermediary gave us different direction than the rest of the country. But, truthfully, there are services, there are patients in which there is absolutely a clear-cut case that Medicare won't cover it. And yet to have no line at all, no way for the agency to move ahead, is in my estimation an example of Medicare not being able to be rational.

Now, truthfully, when we talked with them about this, we hoped to draw some of those lines, but I think you underestimate both the burdensomeness in terms of sheer cost of time and money and the irrationality of this process for small agencies that serve a lot of dual eligibles.

Unfortunately, I have to let you comment on that later because I need to just mention to Mr. Grob, I like very much what I hear you saying, and I think most of what you said I don't disagree with. I do think in your comments about the appeals process, you are not noticing that there is a whole level of dialog that needs to go on between you and the people you are overseeing so that we don't have appeals for certain reasons.

There should be a way that a physician can say, wait a minute, you are coding it this way and I am coding it this way and this is why. There should be a level of collaborative discussion before you come to your final conclusions. And certainly when you look at the appeals process, it currently takes a year to have an appeal adjudicated under Part A, and 557 days to have it adjudicated under Part B.

Now, that is what we were trying to address in that bill, and I can't believe you would think that tighter time frames than that would be a problem for anyone.

Mr. GROB. First of all, I absolutely agree with what you are saying about the need for the discourse. And as far as the tighter timeframes are concerned, I think that there certainly can be tighter time frames, with two things in mind. One, would there really be adequate resources for dedicated and professional people to meet those time lines? And, second, would the time lines be reasonable?

I think the ones that are in there now might be a little too tight, just given, you know, what the normal process is. But the concept of time lines is not at all bothersome. The question is: Are they reasonable? Are there resources to meet it? And then going back to your point about the discourse so that we don't have so many arguments, I really agree with that.

Chairwoman JOHNSON. Then we would like—probably you wouldn't want to comment right now, but if you would comment on Gail Wilensky's recommendations, it would be very helpful. I think this kind of view of the system could be far more fruitful to us than some of the activities we are involving ourselves in.

Mr. GROB. I would welcome the opportunity, and I really have to tell you that just in listening to all the testimony that I have heard today, I was impressed on how thoughtful it was, covering a wide range of issues. Many subjects that we have been studying in our office have come out on the table, and I am just delighted to see that they are out here on the table.

Chairwoman JOHNSON. Mr. Stark.

Mr. STARK. Thank you, Madam Chair.

Gail, I think we agree and the Committee agrees that there are changes that need to be made, and I am aware of changes that were made when you ran HCFA and changes before that, and I suppose subsequent to that. In many instances, what we do in HCFA leads to changes in the private insurance market. I believe that you were there, I think, when we did physician reimbursement. Right?

Ms. WILENSKY. Correct.

Mr. STARK. And I think most private insurance companies now take that and use it as a physician reimbursement structure—not the rates, obviously—in their fee-for-service payment, for better or for worse. And I don't know whether imitation is a form of flattery or not.

But, on the other hand, it seems to me that HCFA sometimes follows along. Arguably, the way the intermediaries pay is kind of left over from the way Blue Cross used to pay before Medicare came into existence. They tend in the different areas of the country to pay for the procedures in much the way they used to.

In your experience, either with Project HOPE or at MedPAC, could you say that there is any one major program-Medicare, Medicaid, private insurance? And I will mention the names, but I don't know as you have to. But Aetna, one of the—I can't think of the largest one now in California, Physician Care, or whatever the heck their name is, HCFA. Medicaid I think is generally considered to be more frustrating to the hospitals and physicians and doesn't pay enough.

But is there any one that stands out as being outstandingly better or worse than another in terms of reimbursing hospitals and physicians and clinical labs, in your opinion?

Ms. WILENSKY. I think it depends on what level. When it comes to payment, the payment level——

Mr. STARK. I am thinking of the procedure. I think mostly we are talking here about hassle factor——

Ms. WILENSKY. Because I think actually Medicare pays pretty well. I think Medicare is one of the better payers when it comes to the level of payment.

My sense is that in the hassle factor there is at least one clear difference with the private sector, and that is the local discretion that is granted to the carriers and intermediaries, which means how rules are interpreted differs significantly among carriers.

When it is for coverage of some new medical procedure or technology, there are both positives and negatives. When it comes to interpreting amount, duration, and scope, which goes to a lot of program integrity and billing activity, I don't see much value to discretion. This type of variation is quite different for private plans. Private plans may have good rules or bad rules, but they don't vary

the interpretation. This is an example where Medicare causes a lot of uncertainty and frustration.

Another source of frustration is that HCFA makes amendments on a far more frequent basis, sometimes in response to congressional legislation, sometimes just as a way to roll out these changes, far more than private plans. Private plans tend to make changes in line with their benefit year, unless a major employer comes in midyear and negotiates a different package. Frequent billing changes are very disruptive and confusing. It is very hard on small physician's offices in rural areas. These practices don't have a lot of administrative support. And it is also disruptive in very large institutions.

On the other hand, I am not sure that Medicare pays slower.

Mr. STARK. Well, to follow along, you recognize the resources that we have at our disposal, and it would seem to me that we could not fulfill our responsibilities by letting the American Hospital Association or the AMA write the rules. They certainly should be able to help us. But if we follow along, as the chairman I think is doing correctly, to set up a program of reforms—I think you are advising us that maybe we ought to take a piece at a time.

Could you suggest, a format that we might follow? For example, could we give temporarily additional resources to MedPAC or to CRS or to GAO or a consortium who have the technicians. We don't have the capacity here—even the majority doesn't have that much staff, I don't think—to come back to us with suggestions? Can you suggest a procedure we might follow to get at taking the most critical reforms first and going down the line? Where do we turn to learn that?

Ms. WILENSKY. I think you need to have the individuals who are actively involved in actually running practices or institutions involved, which is unlikely to be the chairman/CEO of major institutions. It will be somebody within the organization. It may take a bit of searching to designate the right person to bring them together, working perhaps with a consortium of CRS, MedPAC, or GAO individuals.

Mr. STARK. Could MedPAC take the lead on that with additional resources?

Ms. WILENSKY. I should probably check whether our executive director thinks he has the talent, and the expertise.

There is some operational expertise in MedPAC, but I will certainly be glad to get back to you.

Mr. STARK. OK, yes.

Ms. WILENSKY. I have found it difficult in the past to get specific recommendations from provider groups that complain about the regulatory burden. I will be eager to read the testimony from the previous panel to see if you have been able to get more specific ideas. It was why I tried working with some senior career employees at HCFA to see if they could come up with two or three very specific ideas. That is why you need to have people who are involved in the working operations working to try and attack various pieces of the problem.

I do think there is a lot of complexity inherent to traditional Medicare. The Federal government needs to decide on the definition of the benefit, the appropriate price for the unit or the bundle,

the quality and whether it should have occurred. The amount of change that resulted from BBA, BBRA, and then the Beneficiary Improvement and Protection Act has been extraordinary. I don't know whether it is correct, but I have heard that there were 700 specific directives to HCFA over those pieces of legislation.

Mr. STARK. From us.

Ms. WILENSKY. From you.

Mr. STARK. Yes. I have heard that it is a large amount, too.

May I extend for one question to Mr. Grob, Madam Chair?

Chairwoman JOHNSON. I thought maybe I would let the other two question, and then I am going to come back and you can come back.

Mr. STARK. OK. Thank you.

Chairwoman JOHNSON. Mr. McCrery.

Mr. MCCRERY. Dr. Moffit, you have said that this burden or hassle factor is going to intensify if the basic structure of Medicare is not changed.

Dr. MOFFIT. Correct.

Mr. MCCRERY. I think you were here earlier, and you heard the testimony of the earlier panel, and you have heard Dr. Wilensky kind of give a middle road of, well, some things could be better, but, you know, private sector is not so hot, either.

Where do you get your conclusion that HCFA and Medicare is just really worse than the private sector in terms of the hassle factor?

Dr. MOFFIT. Well, in terms of the testimony this morning, you have heard testimony from private sector providers who have told you that Medicare is, in fact, more burdensome than private insurance. In my capacity as a policy analyst, I hear from doctors almost every week who complain about Medicare. Now, they complain about managed care, too, but they also complain about Medicare. And in having an opportunity to speak and debate about this subject across the country, I have opportunities to talk before forums sponsored by Members of the medical profession or hospital staffs. My concern is, after talking to them, that there is a profound sense of demoralization among Members of the medical profession. That is to say, they feel that they are losing control over major decisions that affect their professional lives. And they are also concerned about the requirements that they have to comply with just the sheer volume of Medicare rules and regulations.

I am not certain, however, that Medicare should be isolated from the general private health insurance system. Our colleague Professor Uwe Reinhardt, at Princeton University, has said it best: that we right now have perhaps the most bureaucratic health care system perhaps in the world. And the reason: you have large employer-based health insurance arrangements as well. But the real difficulty is that individual patients have less and less control in this system.

Of course, you can go to any doctor that you want in Medicare, assuming he takes Medicare. But that doctor is constrained by the rules and regulations of Medicare, and that is what the physicians have been complaining about this morning.

Medicine is undergoing a rapid change. We are seeing a dramatic change. Biomedical research is advancing rapidly. Medical tech-

nology is also advancing rapidly. And this is going to mean that the pressures on Medicare are going to increase to accommodate these changes; and at the same time, Congress is going to have to deal with the addition of new benefits reflecting scientific changes, but at the same time add such new benefits in a cost-effective manner. And the way Congress is going to do this is to establish a new administrative payment systems or adapt old payment systems to these new medical technologies or services. There will be a resulting political response by physicians or providers that these new payment applications are inequitable, and there will be a tendency either for Congress or the Health Care Financing Administration, to be under new pressures to make more exceptions. The more exceptions you make, the more complex the regulatory system becomes.

My view of the Medicare regulatory system is that it resembles the reproductive behavior of rabbits. The rules will continue to multiply.

Mr. MCCRERY. And is it your conclusion that, left unchanged and allowing the hassle factor to intensify, providers, particularly physicians, will find it less and less attractive to practice medicine and that that may discourage bright young people from even going to medical school? I mean, do you see it as precipitating that kind of reaction?

Dr. MOFFIT. Congressman Stark said this morning that there is no solid statistical evidence that doctors are dropping out of Medicare. The real concern that I have is that doctors will not give up Medicare patients, their current Medicare patients, but they are going to be loathe to take on new Medicare patients.

In the past, we have been able to stem that. We have been able to prevent that from happening by readjusting the payment systems. But we are in the midst of a demographic revolution unlike anything we have ever seen. Within the next 10 years, 77 million baby boomers are going to start to retire, and the demand for medical services is going to be unlike anything we have ever seen before.

Now, certainly physicians depend heavily on Medicare simply because of the size of the Medicare population. So I don't expect a mass exodus. What I do see, and what I am really concerned about, is the consequence of this demoralization that I talked about. I submit to you, at least from my personal experience, that it is very real. Frankly, I think it is one of the more serious problems facing the Medicare system, and I think it is one of the more serious problems facing the country. We have to take this very, very seriously.

What happens when, the medical profession is demoralized? I think you can tolerate some demoralization in many professions. Among health care economists or policy wonks, that is fine. Among college professors, it is a shame, but if they are demoralized, that is not catastrophic. I don't think you can afford demoralization on the police force or in the Marine Corps or in surgery. This is something that this Committee is going to have to address.

Mr. MCCRERY. Thank you.

Chairwoman JOHNSON. That was a very, very excellent answer, according to the demoralization, and it is frankly why we are having this hearing. I think the demoralization is profound. I think it

is a very much bigger part of the nursing shortage than we are going to be able to document or that we are willing to acknowledge. You cannot treat people whose job it is to provide love and skilled care the way we are treating medical personnel from bottom to top. Mrs. Thurman.

Mrs. THURMAN. Madam Chairman, let me also say from somebody who is from the State of Florida, where we have a higher population of seniors, that, you know, part of the thing that we are seeing—and maybe it is not going into the practice, maybe it is because of Medicare choice. I mean, I think there are a lot of other issues going on out there besides Medicare. But, you know, we are seeing in many cases where we just don't have the physicians to take on new patients. It doesn't have anything to do with that they are stopping to see them. It is just there is no room in their practices left because of the overburden and the demographic shifts that are happening in this country. And I think that is part of the issue.

Ms. Wilensky, let me ask you a couple of questions, because I think it is important having you here, both in what you have done with health care but also as a former HCFA Administrator.

In your time, did we have hearings like this about overburdened regulations? And do you remember any time when you served that, in fact, we had as much change, the 700 ideas that were talked about, rules and regulations that had to be put in, or that policies were being driven because we were cutting budgets? I am just kind of curious to know. This is a framework that, you know, I don't believe has always not been there, but I do think we have added some burden on it in this last years.

Ms. WILENSKY. I think you have characterized it well. HCFA is and always has been a very difficult job. You are under intense pressure. Providers—the nature of the program is to have pressure to have more payment and less regulation and to make sure that seniors feel like they are getting good care. That tension is inherent in the program.

The amount of complaint, the frustration by hospitals and physicians, the fact that we were able to document some evidence of downcoding and billing by hospitals is really quite extraordinary, and I think it has to do with the pace of change that has occurred since 1997. I think it has to do with very grave concern by physicians and institutions over being charged with civil monetary penalties and with potential criminal penalties, very aggressive moves to try to go after undocumented billing. I think it is partly an attitude, it is partly a level of change, and it is the pace of changing regulations and the inconsistency.

When you put all of those together, what you are hearing now is a level of frustration that is quite extraordinary, and the fact that you have as much interest being expressed by various Committees of the Congress is very different. There was always some level of interest in this issue by this Committee and by the Finance Committee in the Senate, but the level of interest among a wide variety of Subcommittees in the Congress is extraordinary.

Mrs. THURMAN. Why do you think that is true today than it was before?

Ms. WILENSKY. I think it is——

Mrs. THURMAN. I mean, there has got to be a key reason.

Ms. WILENSKY. I think that it is the amount of change that has gone on in the last 3 years, and I believe it is very aggressive efforts by the inspector general, by HCFA itself in terms of program integrity, by the——

Mrs. THURMAN. Directed by——

Ms. WILENSKY. Department of Justice, by the State attorneys general in going after abusive practices, in some cases unclear practices. I think there is the belief on the provider community that they are being charged as being criminals in what is a very complex and unclear program, and it has raised levels of frustration. But the sheer enormity of the change and the regulations and the billing procedures that that has engendered is different from anything that existed.

Mr. Stark mentioned when I was at HCFA we were focusing on changing the way physicians were reimbursed, and we worked very hard to make sure that that occurred on time, January 1, 1992, reasonably accurately. But when BBA came through, HCFA had to worry about having prospective payment for skilled nursing facilities or home care or outpatient and doing all the other changes that went along at a time where what I have been told is the administrative budget increased approximately 5 percent during a period when the demands were just enormous.

Mrs. THURMAN. And if I remember correctly, there was very little time given to HCFA——

Ms. WILENSKY. Very little.

Mrs. THURMAN. To do those regulations before they were going to be brought back up here as to why aren't these things being done. And it is my understanding from past situations we have actually tried to give HCFA the amount of time to actually implement.

The reason I go along this line of questioning is because I don't want us to be misled that HCFA and Medicare are in trouble. I mean, I actually think they have done some pretty good jobs. I think Medicare, whether you all believe it or not, has done a good job, and I think people depend on it, and they like the program. And, in fact, HCFA has gotten great reviews through some surveys saying that beneficiaries have been happy with the explanations that they have been given, and they felt like they were courteous and got answers.

But, you know, I am worried that we are setting a stage here that is doing something for Medicare reform, maybe just in the name of Medicare reform to change the system, that while there may be some problems in it and, yes, we have to look at it, but we also need to be careful that we don't undo a system out there that people are comfortable with in the most part. Problems? Absolutely. I mean, we just got done voting on paperwork reduction on the floor for small businesses. So we know that that is a problem throughout the system. But I just want us to be careful that we are not totally throwing out something to put something else in and building the case here.

Ms. WILENSKY. I think there is a real—one of the things that I worry about is I think there is a major morale problem at HCFA, in part because HCFA bashing has been very popular.

Mrs. THURMAN. Absolutely.

Ms. WILENSKY. And I think as much as I have recommended restructuring, I hope very carefully, the fact that HCFA had just gone through an enormous restructuring before BBA occurred meant that the agency was in a very difficult position to respond to what was the biggest workload it had ever had placed on it.

But having said that, Medicare is a very important program. I believe it can be made better. I believe that it can better suit the 78 million baby boomers that are going to start to retire. We just have to make sure it is done in a way that doesn't put the existing seniors at risk.

Mrs. THURMAN. And the last comment is I know that in both BBA and the last one, we have also asked MedPAC to do some studies. And we probably ought to also give them the opportunity to respond to some of this.

Ms. WILENSKY. MedPAC has been impressed by the number of new assignments from BBRA and BIPA.

Chairwoman JOHNSON. Thank you, and I appreciate the gentlelady from Florida pointing out that this is not about HCFA. We have some very, very good people at HCFA. It is also, to some degree, about Congress responding to the problems the program faced in 1997 with a very, very big bill.

I think the other thing here—and I think it is important for us to acknowledge—we did not anticipate the unintended consequences of putting in place criminal penalties, and especially putting them in place at a time when loads of new regulations were going to come out, where judgments were going to be very difficult to make. So now you have people trying to make very difficult judgments. They are bound to commit errors, and the penalties are their license, their livelihood, and their reputation in the community.

So I think in the 1997 legislation, which we passed and I helped write—and I recognize the problems. I remember when Sam Gibbons proposed the $800 million more for fraud and abuse, and we were able with that money to set up a center in every State. We needed to do that. God knows we needed to do that. But I don't think we had a chance to really think through what was going to be the interaction.

Now, that leads me to a question I do want to ask, and we will do a second round now. In the area of workplace safety, some States have used a method where OSHA comes in and can do an inspection with you, tell you exactly what you need to do, and then they come back in a month or two, and if you have done it, fine, there are no penalties.

Given the enormous complexity of the laws at this time, do you think there is any role for an OSHA-type education process that would do an inspection, go around with a nursing home or work with a home health agency on their billing and so on, and then if they clean it up, then that is fine?

Now, clearly, if you came in successive years and found exactly the same problems, you know, that would be a problem. But this is a variant of what Dr. Wilensky has talked about. And it also picks up on the incredible lack of education that we do out there.

Do you think there is a role for this kind of an oversight process as a program integrity component?

Mr. GROB. I really appreciate your asking that question. I absolutely do think there is room—in fact, I actually think that for nursing homes, for example, the current rules that pertain to the discovery of deficiencies in treatment is very much along those lines. And I think where it has fallen short is that they simply have not had the resources to meet the kind of deadlines that you are talking about and get back out there right away——

Chairwoman JOHNSON. No, no. The spirit of what has gone on in nursing homes is not along the line that I am suggesting at all. That is not a problem.

Mr. GROB. Could I address the question then of spirit, since the question of demoralization and the question of criminalization has frequently arisen? I really do think it is vital, and could I take a minute on that?

Chairwoman JOHNSON. Sure.

Mr. GROB. I do think that there is concern—and I have heard it over and over—that physicians are afraid and other health care providers are very much afraid of criminalization. But I do wish to emphasize that the word can mean many things to many people.

Last year, 12 physicians were found guilty of a crime. One of them performed operations, cataract surgery, on people who didn't need it.

Chairwoman JOHNSON. I am not denying the important role of oversight in criminal prosecution.

Mr. GROB. Agreed. But a lot of what happens is that other things that are done get brushed with that brush of criminalization. And if I could, I would like to give you an example or two.

Mr. McDermott is not here, but he did ask a question, and he was wondering why the inspector general turned down a claim for a preventive health office visit. And it was explained, of course, that this is not covered by Medicare. But throughout that discussion, it never was said that the inspector general did not turn down that claim—this was an audit that we did to determine the error rate—nor did the inspector general's office ever classify any action like that as being criminal. But Mr. McDermott thought we did. People are finding that when we have our error rate study that we are saying that this is all criminal. No. Every time we issue it we say that it is not, that it could be a mistake, or it could be criminal.

The thing that I am afraid of is that we are seeing here a self-fulfilling—not prophecy but assessment.

Chairwoman JOHNSON. But that is true. I agree with you absolutely. There has never been any willingness, from the very first time you put out the $34 billion, to talk about what the $34 billion really—but that tells you, you must change your process so that the message that goes out will be more accurate.

Mr. GROB. Yes. We agree with that, and we have been trying very hard to find the words to do that. What I think we would like to do is ask for help. We would like everybody here to be saying that we are not talking about criminal behavior when we check the payment error rate. We would like others to join us in saying we are not trying to get you from a criminal point of view. We are trying to make the Medicare Program work better.

And I think if everybody begins talking about it like that, that will diminish the feeling that somehow police are looking out to find a doctor making a mistake. I think all of us really need to help just tone that down. That is a plea that I would make in coming before the panel today.

Chairwoman JOHNSON. Just let me ask you briefly, why is it that HCFA has not used the dual-entry accounting system? In one word or less.

Mr. GROB. I am sorry. I could not hear.

Chairwoman JOHNSON. Why is it that HCFA has not adopted a dual-entry accounting system?

Mr. GROB. We are amazed at that. We have been raising this point since, I think, the early 1990s. We know that it is a very complex matter, but it is just one of these anomalies that is very strange. There is not a reputable business in the country that wouldn't have it.

Chairwoman JOHNSON. Thank you. Mr. Stark.

Mr. STARK. Well, I think Mr. Grob touched on the issue that I wanted to ask him to repeat. I am looking at a letter from a county medical society, which probably I should not identify, but they are complaining to me about methods used to go after fraud. Do your guys wear black leather coats when they go in?

Mr. GROB. Today, I wore my best——

Mr. STARK. This letter says they stormed in and arrested some physicians. It uses inflammatory language but, as a practical matter, it goes on to say that they were arrested and they were not aware they were committing a crime, as indicated by their attorneys.

Now, I understand, in checking on this, that there was a group of physicians here, and several of them have already been convicted of a crime. And I don't believe you could convict somebody of a crime if there isn't intent. I am not a lawyer, but I somehow remember that intent is required to these charges.

Mr. GROB. We cannot do that. The law will not allow it. The intent must be proven.

Mr. STARK. And I don't think that happens a lot, but we do have the Prudential Life Insurance Co. who paid hundreds of millions of dollars of felony fines for copping a plea of stealing billions of dollars from their clients, or Columbia HCA who paid, I think, about $300 million in fines for stealing from the Government.

Crime is not something that we should be shocked about when it happens. But it does seem to me that—just like, I suppose, for those of us who have been audited by the IRS, rarely is there a criminal element, but often they want a lot of money out of us. And they may start out a little higher than what they expect to get. That seems to be aggressive but, I gather, successful in most cases.

I guess what I want to know, and you touched on it, are the facts on arrests. There are arrests from time to time. But there has to be a criminal indictment, right?

Mr. GROB. Yes, a warrant.

Mr. STARK. You have got to go to either a Federal grand jury or—you have got to turn it over the Justice Department. Is that not correct?

Mr. GROB. That is right. We do the investigation and coordinate with the Justice Department as far as——

Mr. STARK. So, basically, you don't arrest anybody?

Mr. GROB. We do, with deputation.

Mr. STARK. So this is like the Attorney General.

Mr. GROB. The Attorney General, FBI.

Mr. STARK. Who has decided that based on the evidence——

Mr. GROB. Yes.

Mr. STARK. So if the doctors are upset, or the hospitals, about being, quote, arrested as it were, their beef is with the Attorney General——

Mr. GROB. Well, I think there are many law enforcement agencies involved. It could even include local law enforcement agencies.

Mr. STARK. OK.

Mr. GROB. But I think the point you are trying to make is the very same point that I was making. I think that when our office, the inspector general's office, becomes involved, people think that what we are doing is a criminal kind of thing. We also have auditors, and they do auditing.

Also, if I could comment, a lot of times when the carriers take action, they think that the inspector general has shown up in their office. Compared to the carriers, the inspector general rarely shows up in the physician's office to examine a claim, for example. And they are rarely involved in determining how much the physician owes that should be paid back to the Medicare Program. That is almost always done by the carriers.

But, yet, people will report that these happen, and they will say, well, the inspector general came—I am not trying to distinguish our office from all the others. That is not my intent. My intent is to show that in the telling of the stories, we are adding to the story, that the story-telling itself is part of the process of criminalizing things, and all I am wishing is—I think we can do it all. I think we can do the crime part. I think we can do the accounting mistakes. And I think we can do the education.

I really do think that all of us can do it, and we can all keep the crime issue separate. I am just hoping that we all talk like we all know that we can keep it separate.

Mr. STARK. I think that there is this misunderstanding, and I hope that we can, both from our side of the podium and your side and the providers' side, not decide that each anecdote is an indication that we are becoming heavy-handed. It is complex, and everybody has added to the complexity, in my opinion. The providers have added to the complexity, happily, because they have got all kinds of exciting new treatments, much of which is new to HCFA, and you have to figure out how to pay for it or whether to pay for it. Indeed, how many claims are processed each year?

Ms. WILENSKY. I think it is close to a billion. I think about a billion.

Mr. GROB. Eight hundred million.

Ms. WILENSKY. It is close to a billion.

Mr. STARK. Eight hundred million.

Ms. WILENSKY. More than 800 million.

Mr. STARK. I mean, that is a lot of claims to grind through, and we are probably talking about a million out of—if that, 500,000,

maybe, where they go awry. So I look forward—and thank you, again, Madam Chairman. I think we can do something, and I think that if we just decide we are going to make the system——

Mr. GROB. Mr. Stark, could I quickly clarify a statement I made? We do participate in making the arrests, the IG's Office.

Mr. STARK. Do you carry a gun?

Mr. GROB. I do not carry a gun.

Mr. STARK. OK.

Mr. GROB. But our agents do when the proper procedures have been followed.

Mr. STARK. Is that true? You really do? That is scary. You ought to get hazard pay, it seems to me, but OK. I stand corrected. Thank you.

Chairwoman JOHNSON. Mr. McCrery.

Mr. MCCRERY. Well, the physicians that I have talked with—and there are numerous physicians—don't just zero in on the criminality element. The hassle factor includes a lot more than just the criminal penalties that are in the law.

Much of it is just the paperwork that they have to do. They have to hire people to do the paperwork, or they have to assign nurses to do it, and that takes them away from the patient care. So it is a lot more than just the criminal element.

Mr. GROB. Yes. I completely agree.

Mr. MCCRERY. And I think Mr. Stark hit on part of the problem, and so did Dr. Moffit, which is just the sheer size of Medicare and the tremendous burden that HCFA has in administering that size program. Even though it is dispersed somewhat among a number of intermediaries, still, it is probably not as dispersed as the private sector, as Dr. Moffit pointed out. And that is why I want to get back to Dr. Moffit's idea that we can't solve this problem within the current structure, we need to change the structure.

I am sure, Dr. Moffit, you have given some thought as to how we transition from the current system to the new system that would be more private sector oriented and all these decisions would be much more greatly dispersed around the country.

Can you share with us some of your thoughts on how we transition to that?

Dr. MOFFIT. Yes, I can, Congressman. In my testimony, I have outlined certain steps that we ought to take if we pursue Medicare reform. The most important is to create a structure, as I said, that broadly resembles that of the Federal Employee Health Benefits Program, with which I am intimately familiar. That system works extremely well.

However, having said that, I think that because of the enormous technical and political challenges that are involved in moving toward a reform of the Medicare system, as envisioned by Senator Breaux and President Bush and many Members of Congress, this ought to be done in a phased-in fashion. If there is any lesson we have learned from the Medicare Choice experiment, it is that this cannot be rushed; it cannot be turned over to an agency whose whole institutional culture is to regulate; but, rather, we have to create a relationship where there is a culture of friendliness toward private firms as competing interests.

But to answer your specific question, there are two ways, to do this. One, is basically insulate the entire current Medicare population from Medicare reform; in other words, just basically confine Medicare reform to the next generation of retirees. Those people who are currently in the Medicare system should be treated entirely different than the future generation. We should then phase the new system in on a year-by-year basis, enabling people when they retire to make a decision about whether or not they want to go into a new competitive system that looks like the Federal Employee Health Benefits Program.

In that transition, they could make a decision about whether they want to pick and choose one of the competing plans in the new competitive system or whether, they would want to keep their current employment-based retirement coverage and bring it with them into retirement as their primary coverage and get a Government contribution to help offset the cost.

This approach is very non-threatening. It is the least disruptive. But by moving toward a phase-in like that, it would enable the new administrative agency— I don't think that HCFA should run a new competitive system—to make the mid-course corrections over time that are going to be necessary. There is going to be a lot of wrinkles in moving to a new competitive system. But at the same time, with a smaller and growing number of people in the system, it would give a new agency an opportunity to properly manage without a great deal of disruption. This way we can avoid the kinds of problems we have had in the past with the "Medicare+Choice" program.

You talked earlier about fraud and abuse. There is nothing in the Federal Employee Health Benefits Program in terms of those problems—the size of the problems in fraud and abuse— that you have had in Medicare. You do not have the same kinds of problems with claims disputes that you have in Medicare. You don't have the same kinds of grievance difficulties. And, as a former Congressional Relations Director for the Office of Personnel Management, I dealt with probably the most highly educated and sensitive constituency in the world, Federal retirees and Federal employees, who know how the system works and who write their Members of Congress. And I can tell you from my experience, I very rarely was summoned to a congressional office where a Congressman sat me down and said, "Moffit, you better do something about the Federal Employee Health Benefits Program because it is not delivering the kinds of services that my constituents want." Rarely did that conversation happen.

We had a lot of debates about retirement. We had a lot of debates about labor-management relations. We had a lot of questions in those areas. But the point is, if you want consumer satisfaction and you want good administration, move into the new system slowly; phase it in year by year, and give the new administrative agency the flexibility to make the mid-course corrections that will be necessary.

Mr. MCCRERY. Well, the fact is that under FEHBP, each individual insurance company providing those benefits is going to provide the fraud and abuse protection.

Dr. MOFFIT. That is right.

Mr. MCCRERY. It is in their own selfish interest to do that, and they do it.

Dr. MOFFIT. That is right.

Mr. MCCRERY. I can assure you they do.

Dr. MOFFIT. They police it very closely, Congressman.

Mr. MCCRERY. And whether they do a better job than HHS or HCFA, I don't know. We could have a hearing on that.

Dr. MOFFIT. I think that is an excellent idea. Let me just make the point, though, that one of the problems you have here is that the very structure of the Medicare system does not have the same incentives on the part of the carriers to root out fraud and abuse in the same way that private sector companies competing for consumers' dollars have.

Mr. MCCRERY. Right.

Dr. MOFFIT. I mean, that is the point. You have Medicare contractors, 55 of them around the country. If there is fraud and abuse, they don't actually lose the money on their bottom line.

Mr. MCCRERY. Right. I agree. And I also want to point out, Dr. Moffit, that there are certainly in the private insurance industry complaints and grievances. As a former practicing attorney, I can tell you that there are people who don't think they are being treated fairly by a private sector insurance company, and there are grievances. Fortunately, they do have procedures to go through, and often we can resolve those. But to say that there is not any of those I think is probably an overstatement. There are a lot——

Dr. MOFFIT. Let me offer a point, a response to that, though, Congressman. In most private insurance, the employer picks your insurance. The employer owns the policy, and if you don't like the employer's policy, you cannot do anything about it.

Mr. MCCRERY. Right.

Dr. MOFFIT. In the Federal employees' system, if you do not like the rates or the benefits or the premiums or the payments or the deductibles or the way in which a plan handles your claims, you can fire that insurance plan.

Mr. MCCRERY. That is right. Absolutely. Your points about the value of consumer choice are well taken, and if we had a better health care system in terms of delivering and paying for health care than we do—and you know my views on that—then I think we would solve a lot of the problem that physicians are concerned about and prompts them to push us to do more regulation on the Patient's Bill of Rights and things like that. Those problems would be solved by the consumer and by physicians working with consumers. But that is another hearing and another day I hope we will eventually have to restructure the entire health care system, but not today. Thanks.

Chairwoman JOHNSON. Thanks, Mr. McCrery.

I did read that recommendation in your testimony, Dr. Moffit, about phasing this in slowly. The question that occurred to me was that insurance plans depend on a certain volume of premium in order to stably offer coverage. If you open this as slowly as you are recommending, only to incoming seniors, will we have the same kinds of problems we had with Medicare Plus Choice? Because that was one of the problems, that the Choice programs had no ramp-

up time, no consideration for the period when they would not have enough enrollees to cover their obligations.

So how do you ramp it up as slowly as you are recommending?

Dr. MOFFIT. Well, I agree that is a technical problem, and we have to address it.

Chairwoman JOHNSON. Well, we can talk about this later, I guess.

Dr. MOFFIT. Let me say this. I have talked to the Blue Cross/Blue Shield people. I have talked to insurance representatives from the American Association of Health Plans. And the one thing that they stressed to me in terms of the Medicare Plus Choice program and Medicare reform is that, if we are going to have a Medicare reform, what they need most is they need predictability. They need to know how many people are going to come on. They want to be able to absorb them. And at the same time, they want a sound business relationship with the government which is stable, where they can make sound business planning decisions.

So the question is how you phase it in. I suggested perhaps on a year-by-year basis. That is also, of course, linked to a suggestion that I had made earlier in my testimony, which is give Americans who have employer-based health insurance that they like the opportunity to take that into a new competitive system with them as their primary coverage in retirement, if they wish to do so.

Chairwoman JOHNSON. Thank you. Well, we do look forward to working with all of you as we move ahead. As should be very clear by now, we are keenly aware that the explosion of changes in the law since 1997 and the remarkable changes in medicine in the last 5 or 6 years are all part of having created some new problems. But we do need to understand these new problems because they are very significant. They are going to put small providers out of business, without question in my mind. I don't think little can survive with this level of regulatory weight. And that would actually have a terrible impact for seniors.

So this is about senior access to care. It is about the quality of care the seniors have access to. And if we don't deal with the structural, bureaucratic problems of Medicare and don't begin to think about what kind of system can serve the retirees as the number doubles, then we will not have done our duty.

So this is not about blame. There is plenty of that to go around in life. This is about the prospects of strengthening Medicare for the future. And I thank you for your very good testimony and look forward to working with you all as we move through these issues.

Thank you.

[Whereupon, at 1:15 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of American Association of Homes and Services For the Aging

The American Association of Homes and Services for the Aging appreciates the opportunity to submit this statement for the record of the Subcommittee's hearing on March 15, 2001 on essential regulatory relief for health care providers who participate in the Medicare program.

AAHSA is a national organization whose more than 5,600 not-for-profit providers serve over 1,000,000 individuals on a daily basis. Approximately seventy-five percent of AAHSA members are affiliated with religious organizations; the other are sponsored by private foundations, fraternal organizations, government agencies, and community groups. Our members include not only nursing facilities, but also inde-

pendent senior housing, assisted living, continuing care retirement communities, and providers of home health care, adult day care, respite care, meals on wheels, and other services. AAHSA members are characterized by long-standing ties to their communities and a firm commitment to quality.

Although AAHSA's membership spans the continuum of long term care, the majority of our members continue to provide nursing care to residents, either alone or in combination with other services. We actively participated in the development of federal quality standards for nursing home care under the Omnibus Budget Reconciliation Act of 1987 (OBRA), and we continue to support these standards. We were one of the initial members of the Campaign for Quality Care, the coalition of organizations coordinated by the National Citizens' Coalition for Nursing Home Reform (NCCNHR), that worked to reach consensus on twelve key areas of nursing home reform. AAHSA has continued to serve on various committees and workgroups convened by the Health Care Financing Administration to work toward a reasonable and equitable implementation of the regulations and interpretive guidance resulting from the OBRA requirements.

AAHSA has several concerns, however, about the ways in which these standards have been implemented under regulations promulgated by the Health Care Financing Administration (HCFA) and have been enforced under the joint state and federal survey and certification system.

Assessments for purposes of Medicare reimbursement

OBRA '87 requires a full assessment of a resident's condition upon entry and at specific intervals thereafter, recorded on the minimum data set (MDS). The prospective payment system instituted under the Balanced Budget Act requires additional assessments for Medicare payment purposes.

HCFA has determined that these additional assessments must be done according to the full MDS, rather than just according to the specific treatments for which reimbursement is claimed. HCFA developed a short form of the MDS specifically for the RUG–III prospective payment system. It is a subset of the full MDS, and it has every item needed to calculate the appropriate RUG class under the Medicare regulations. HCFA should permit facilities to use this shorter MDS, instead of completing the entire MDS, which means filling out items that are not needed for reimbursement and are not collected for reasons of quality assurance.

The full MDS is a detailed and time-consuming process, as it should be, and requiring the full MDS for Medicare payment purposes when it is not required or needed for care planning is an excessive paperwork burden that does not contribute in any way to quality of care. The current requirements are such that facilities with average Medicare volume are forced, as a practical matter, to dedicate the equivalent of a full-time RN to completing assessments rather than providing care if the facilities are to get all of the paperwork completed and submitted on the time schedule required.

Solution: Allow nursing homes to file the short-form MDS for reimbursement purposes under the prospective payment system, while continuing to complete the full MDS for care planning and quality assurance purposes.

Posting of staffing levels

The recent requirement in Section 941 of the Benefits Improvement and Protection Act, that nursing facilities post numbers of nursing staff for each shift, is potentially misleading and administratively burdensome. The new law requires nursing homes to post daily for each shift the current number of licensed and unlicensed nursing staff, in a uniform manner to be designated by HCFA and in a clearly visible place.

AAHSA members are acutely aware of consumers' need for information on indicators of quality care; however, the posting requirement provides information that is of minimal to no actual value to the consumer. Without any reference to the acuity of the residents being served, or an established criterion for appropriate staffing levels based on resident acuity, simple staff numbers are meaningless. The assumption that quality can be determined by numbers of nursing staff rather than by the efficient use of nursing staff and resident outcomes is both simplistic and potentially deceptive. Such a policy runs completely counter to the philosophy of outcome-based measurement of the quality of care.

Solution: AAHSA strongly urges the repeal of the staff posting requirements under BIPA.

Other regulatory agency requirements

In addition to regulations promulgated by OBRA, nursing facilities must comply with worker protection regulations issued by the Occupational Safety and Health Administration, wage and hour laws enforced by the Department of Labor, environ-

mental requirements promulgated by the Environmental Protection Agency, and with regulations imposed by a variety of state agencies. All of these regulations do not necessarily coordinate with one another, and there may even be conflicts among them.

As an example, OBRA restricts the use of physical or chemical restraints on nursing home residents. The Food and Drug Administration defines a restraint as something that is attached to the body, while HCFA defines a restraint as something attached to or adjacent to the body. These differing definitions have created an issue with respect to bed siderails. HCFA views siderails as a restraint, while manufacturers see no need to label siderails as restraints or provide instructions or warnings about their use, since siderails do not fit the FDA's definition of a restraint.

Solution: AAHSA is working with the Medicare Payment Advisory Commission (MEDPAC), which is studying the combined impact of federal regulations on health care providers, including nursing facilities.

Survey and enforcement

Besides paperwork reduction, nursing facilities need a more balanced and thoughtful system for recognizing and encouraging excellence. The current survey system that has developed under OBRA forces oversight authorities to expend the same amount of time and resources on facilities with exemplary records as they do on those demonstrating chronic or serious quality of care problems. Given the limitations on resources available for enforcement, the mandate that all nursing homes receive surveys of equal frequency and intensity effectively means that facilities that consistently fail to provide quality care do not receive the attention they need from state and federal regulators.

In addition, the system is plagued with inconsistencies in survey results and the imposition of remedies, which nursing facilities have only a limited right to appeal. Determinations of the severity and scope of an OBRA violation are subjective and vary from state to state and from region to region. Nursing homes in one area of the country may be severely penalized for infractions that bring far lighter remedies in other regions. This subjectivity and inconsistency prevent the survey process from serving as an accurate measurement of the quality of nursing home care.

Furthermore, the present regulatory system has developed into an adversarial process that pits surveyors against nursing homes, rather than allowing them to work together to improve quality. HCFA and state survey agencies actively discourage surveyors from discussing their findings with nursing facilities or advising facilities how care might be improved. Even a deficiency-free survey is no longer necessarily accepted as a sign that a nursing home is providing good care. Instead, the assumption often is made that the surveyor simply didn't try hard enough to find out what the facility was doing wrong. In the current environment, it has become almost impossible for a good surveyor and a good facility to coexist.

This negative environment damages employee morale and makes it all the harder for nursing facilities to recruit and retain qualified staff at every level. As will be discussed below, nursing facilities in all areas of the country face a crisis in attracting sufficient numbers of certified nursing assistants, who provide the bulk of hands-on care to nursing home residents. Moreover, nursing homes are losing substantial numbers of directors of nursing, and the decline in new administrators is equally alarming. In the last two years the numbers of candidates sitting for the nursing home licensure examination in many states have dropped by as much as 25%. If nursing homes are unable to recruit and keep dedicated professional staff, the quality of care for residents is bound to suffer.

Our present regulatory system recognizes only adequate levels of care, not excellence. A perfect inspection simply means that no mistakes or violations of the law were observed. It says nothing about whatever positive actions the facility is taking for its residents or any innovative programs it may have put in place for residents or staff. Our current inspection and enforcement system for nursing homes cannot give consumers the information they want and need on which are the best facilities, and there is no consideration being given to developing better measures. To the contrary, the answer to every question about quality in nursing homes now is more regulation and greater penalties.

In the short term, a more collaborative approach to surveys needs to be developed, one that allows surveyors and caregiving staff to work not only on promoting and achieving sustained compliance, but on meeting individual care needs and expectations to improve care. In the long term, we must create a new system; one focused on outcomes and continuous quality improvement, rather than process. The focus of the survey and enforcement process should be on fixing problems and offering expert guidance rather than on punishment.

Solutions: AAHSA recommends the following changes in the nursing home survey and certification process:

• Less frequent or less intense surveys for good-performing facilities: Flexibility is needed to allow facilities with good records to be surveyed at intervals beyond the current fifteen-month statutory limit. States should also be given the option of doing shorter, less intense surveys of facilities that have demonstrated good quality care on previous surveys. This would allow over-sight authorities to better target their resources on facilities with chronic or serious quality of care problems.

• Alternative approaches to enforcement of nursing home quality standards: States should be given greater flexibility to develop and explore innovative approaches to measuring quality of care through state waivers for demonstration projects. These efforts should be directed toward increased use of outcome measures, greater incorporation of quality of life, and improving consistency in deficiency determinations and survey results.

• Informal dispute resolution process: Since severity and scope determinations ultimately lead to the imposition of remedies, the inability to challenge these determinations under the informal dispute resolution process unfairly limits a nursing facility's ability to obtain redress for inappropriate penalties. This process must be open to consideration of severity and scope for any deficiency as well as to the existence of a deficiency. Facilities should also have the right to review before an independent, impartial decision-maker and the opportunity to request a face-to-face review for those deficiencies that cannot be adequately addressed by telephone or in writing.

• Civil Monetary Penalties should be used to enhance quality care: States are required to use funds to improve resident care, yet many states have not adopted programs to use the funds. In addition, HCFA maintains that states cannot use CMPs to provide technical assistance or consultation. Funds should be allowed for surveyor training, consultation and technical assistance to facilities in developing and implementing quality improvement or resident care protocols.

Nursing assistant training lockout

Medicare and Medicaid prohibit nurse aide training by or in a nursing facility if the facility within the last two years has: (1) operated under a (staffing) waiver; (2) has been subject to an extended or partial extended survey; (3) has been assessed a civil money penalty of $5000 or more; or (4) has been subject to certain remedies (i.e., denial of payment for new admissions, or temporary management, termination of provider agreement due to a finding of immediate jeopardy, and/or closure of a facility, transfer of residents, or both). These provisions are severely restricting the ability of nursing facilities to train nurse aides and have proved counterproductive to improving quality of care.

There is little argument for approval of a nurse aide training program by a facility that is providing substandard quality of care. However, the prohibition on training once compliance has been achieved and demonstrated is problematic for providers and residents alike. The two-year duration of the nurse aide training "lock-out" severely impedes the facility's ability to recruit and retain adequate and qualified staff, and to assure provision of quality care.

Opportunities to access alternative training programs are frequently limited and many facilities, even after achieving and demonstrating compliance, find it difficult, if not impossible, to secure training for their aides. The end result can be either new compromises to quality of care or a recurrence of the problems that initiated the disqualification from training. The effect of this particular sanction is counterproductive to the improvement of quality, and to the intent of the law that facilities achieve and maintain sustained compliance.

Facilities that correct their deficiencies and demonstrate compliance should be permitted to resume their nurse aide training programs. Elimination of the 2-year prohibition on providing nurse aide training will preserve the ability of the facility to assure the ongoing provision of required training and competency evaluation of its nurse aides.

Solution: AAHSA urges the elimination of the present two-year prohibition on nurse aide training by or in nursing facilities that are found to be out of compliance with certain federal long term care requirements [Section(s) 1819 and 1919(f)(2)(B)(iii)(I)(b) of the Act]. Once facilities have corrected their deficiencies and demonstrated compliance, they should be permitted to resume their nurse-aide training programs.

Single task workers

Nursing facilities across the country are experiencing a staffing crisis. Insufficient numbers of staff—licensed vocational nurses (LVNs), licensed practical nurses

(LPNs) and registered nurses (RNs)—can endanger quality care for residents. However, one of the greatest challenges currently faced by nursing facilities in assuring quality of life and care outcomes to residents is the ongoing shortage of nursing assistants (CNAs). Higher acuity levels among nursing facility residents as well as projected aging demographics point to a demand for paraprofessional staff in nursing facilities that will continue to escalate. Cornell University's Applied Gerontology Research reports that some 600,000 new nursing assistants will be needed within the next 10 years.

Current law defines a nursing assistant as "any individual providing nursing or nursing-related services to residents in a skilled nursing facility or a nursing facility." The statute requires that nurse aides successfully complete a training and competency evaluation program. The law does not define which specific tasks are considered to be "nursing or nursing-related"; HCFA has determined, under its State Operations Manual, which tasks should be so designated. According to the State Operations Manual, assisting residents with eating or drinking is considered to be a nursing-related task.

In the nursing home environment, many employees who are neither nurse aides nor licensed health professionals also have frequent and regular contact with residents. Permitting these individuals to be trained to perform certain tasks determined to present little or no risk to the resident can offer partial relief to the nurse aide shortage and provide more individual attention to residents.

The area where trained non-nursing assistance is most needed is assistance with eating. In addition to providing assistance at regular mealtimes, examples include a dietary aide who might be permitted to help residents eat birthday cake at a party, or office personnel and activity assistants who might assist with eating during a special event or outing. The ability to provide assistance would be based on a comprehensive assessment of the needs and potential risks to the resident. The personnel performing these tasks could be required to complete in-service training in dining skills and assistance with eating, and demonstrate competence in the duties assigned.

Solution: AAHSA supports legislation to permit nursing facilities to provide specialized or "single-task" training to personnel other than certified nursing assistants. These employees should augment, but not replace existing staff and be allowed to perform certain specific resident-centered tasks without having to complete the full nurse aide training and competency evaluation program. The interdisciplinary team responsible for the care of the resident should determine resident appropriateness and employee competence and ability to perform these tasks. The training programs should be reviewed and approved by the state regulatory authority.

Conclusion

AAHSA appreciates the Subcommittee's willingness to explore regulatory relief that would continue to ensure high quality care while allowing nursing homes to maximize the financial and human resources devoted to caring for their residents. We want to continue working with the Subcommittee on regulatory reform that will recognize the high-quality care that already is being provided in many nursing homes and use them as models for what this field can become.

Statement of the American College of Physicians—American Society of Internal Medicine

The American College of Physicians—American Society of Internal Medicine (ACP–ASIM) which, representing 115,000 physicians and medical students, is the largest medical specialty society and the second largest medical organization in the United States, congratulates the Subcommittee for holding this hearing. Internists provide care for more Medicare patients than any other medical specialty. The most frequent complaint received by the organization is that internists are subject to too much paperwork and, as a result, do not have enough time to devote to patients.

Impact of Medicare Paperwork on Clinical Practice

Time is the most valuable resource in diagnosing and caring for older adults, but it's in short supply due to unnecessary paperwork. Research breakthroughs, new pharmaceuticals and improved diagnostic equipment are of limited value if doctors lack the time to spend with patients.

Visits from Medicare patients typically begin with a surprisingly complex and time-consuming paperwork process. Medicare requires that the physicians and their staffs complete a claim form with diagnosis and service codes and authorizations for

items such as wheelchairs and services such as home health care. The Medicare program assumes physicians know what it will and will not cover. There is no single place to find Medicare's rules, however. The regulations are more than 100,000 pages long and different carriers, who process paperwork for Medicare across the country, have their own rules.

Once a claim is filed, Medicare might hold it because it tripped some random criteria. If Medicare finally pays the claim, carriers have four years to change their minds and demand that the physician repay it. Appeals require more paperwork and time to present the case.

Medicare can sample physician's records to determine if certain services, such as office visits, were paid incorrectly. If a certain percentage were paid wrong, the carrier will demand repayment for similar claims—without looking at the records.

To keep their practices running, many internists simply repay these claims. Opening their practices to a post-payment audit can tie them up for days—essentially shutting down patient care activities.

Medicare patients are the ones who suffer when physicians and their office staff are diverted from patient care activities to unnecessary paperwork. The result can be longer waiting time before being seen by the physician, because he or she is busy answering a demand from Medicare for more information at a time that could have been spent with patients. It can result in the physician seeing fewer patients each day—meaning a longer time for a patient to get an appointment. It can mean having less time with elderly patients and less time to answer questions and discuss new treatments with them. And in the worst cases, it can literally shut down a practice for days. Is it any wonder that more physicians are deciding that they will no longer see new Medicare patients?

The Need for Legislative Relief

Fortunately, bipartisan legislation, the Medicare Education and Regulatory Fairness Act of 2001 (MERFA), H.R. 868/S. 452, has been introduced in both houses of Congress that would greatly improve this state of affairs. ACP–ASIM has strongly endorsed the MERFA legislation and urges Congress to give it prompt and favorable consideration. The bill, introduced by Representatives Toomey and Berkley and Senators Murkowski and Kerry would address these problems by better targeting current Medicare education dollars to provide needed outreach and education to physicians and by instituting common-sense reforms:

1. Medicare rules and policies and answers to frequently asked questions would be made more accessible. The bill would require that carriers respond in writing to requests for guidance on how to bill for services. The written advice provided by the carrier would be binding in any subsequent reviews. (This means that if the carrier told a physician how to bill a service correctly, it couldn't later deny payment or audit the physician's practice because he or she did it wrong based on the carrier's original advice). Similarly, the bill would allow physicians to voluntarily send medical records to the carrier to get a ruling from the carrier on whether or not the documentation is adequate to support the billed service, and carriers could not use this to subsequently target the physician for review. Carrier employees would also be required to give their true names (first and last) when answering questions to assure accountability. HHS would be required to post responses to "frequently asked questions" submitted by health associations in a way that is readily accessible to physicians. Carriers would be required to make prepayment review criteria (screens) and other coverage and audit criteria available to physicians. Physicians would be given a minimum of 30 days advance notice about changes in rules.

2. Medicare would be required to pay claims, without demanding more paperwork, unless there is evidence that the bill is incorrect. Random audits and pre-payment screens that trigger further review would be prohibited.

3. For a first time post-payment audit, Medicare would be required to actually look at the records, rather than making an assumption that some claims were billed incorrectly based on a statistical sample. (Carriers would be allowed to use statistical sampling—or extrapolation—for subsequent reviews of the same physician.)

4. Medicare and its carriers would be required to invest substantially more money in physician education and outreach.

5. Medicare's ability to investigate fraudulent claims would be preserved—the bill specifically applies only to audits in which there is no allegation of fraud. Inadvertent overpayments due to errors or misunderstanding of the rules would be reduced by educating physicians on how to prevent mistakes in the first place, rather than auditing them after the fact.

6. Medicare would be prohibited from collecting alleged overpayments until all appeals are exhausted and a final determination is made. Physicians would also have the option of entering into several different type of re-payment plans if a final deter-

mination is made that they billed incorrectly for certain services (rather than automatically having to pay the money all at once within 30 days, or alternatively, having the money taken out as a reduction in payments for future claims).

7. Medicare would be required to conduct at least four pilot tests of the evaluation and management documentation guidelines that would include a variety of settings. The bill specifies that one of the goals of the pilot tests should be to reduce the need to document non-clinically relevant information.

The Need for Administrative Relief

There are other changes that can and should be made by the administration to reduce administrative red tape, changes that can be implemented by HHS—directly or through instructions to its contractors—without the need for new legislation. The following is a list of recommendations that fall outside the scope of MERFA and can be implemented by HHS Secretary Thompson:

1. The Secretary of the Department of Health and Human Services should create a single source document explaining Medicare regulations that combines the Medicare provider manual, Medicare operational policy letters, and other regulatory documents to clearly communicate to physicians and other medical providers the rules of the Medicare program. This document should be made publicly available via the internet and contain links to local Medicare carrier policies as well.

2. The Secretary of the Department of Health and Human Services should develop a clear mechanism to assess complaints about Medicare policies, make the complaints subject to public scrutiny, and address these complaints in a timely manner. The complaints should be cataloged by type and regulatory response to measure frequency of problems and their solutions.

3. The Secretary of the Department of Health and Human Services should change the regulations governing Medicare post-payment review to reflect the following:

• Review procedures should provide the audited physician the right to review the post-payment audit sample with the actual personnel responsible for the review.

• HCFA should encourage Medicare carriers to utilize as Hearing Officers, licensed physicians of the same specialty and in the same geographical area as that of the physician who requests a Fair Hearing, and to make known to the requesting physician prior to the Fair Hearing the educational and medical credentials of the Hearing Officer.

• HCFA should prohibit carriers from seeking recoupments on "overpayments" made more than two years earlier except in cases of fraud.

4. HCFA should establish a single Medicare liaison office in each region for medical societies and consumer organizations to work with in order to facilitate communication within the existing Medicare regions.

5. State medical societies and Medicare Carrier Advisory Committees (CACs) should be invited to place items on the agendas for CAC meetings—sufficiently in advance of the CAC meeting—to allow for sufficient discussion and resolution of valid physician problems with their Medicare carrier's application of medical review criteria and related issues.

6. Carriers should provide a 60-day public comment period for all proposed policy changes. (The comment period provided by carriers is now limited to 45 days.) Once the comment period is over, the carrier should be required to state, in writing, its reasons for accepting or rejecting the comments made in making the final policy. The written rationale should be shared with the CAC and be made publicly available via the internet.

7. Once a policy is made final, the carrier should release it to the medical community before it takes effect and conduct educational forums, when necessary, to ensure proper implementation of the new policy. Adequate notice (a minimum of 90 days) also should be given before the policy is effective.

8. If local medical review policies (LMRPs) continue to be proposed, they should be required to go through Carrier Advisory Committees to allow for proper input of practicing physicians.

9. HCFA should create a mechanism to coordinate information sharing between the regional Medicare Carrier Advisory Committees. All CAC meeting agendas and minutes should be posted to a single HCFA-maintained website within five business days of the publication of the written materials. This website should also give CAC members in different regions the ability to query each other about carrier policies.

10. The Health Care Financing Administration (HCFA) must ensure that its carriers are held accountable to established Medicare criteria and standards, especially in the areas of claims processing and customer satisfaction, after carrier responsibilities for claims processing and payment safeguards (program integrity) are split under the Medicare Integrity Program (MIP).

11. HCFA should increase surveillance and monitoring of the performance of carriers to assure their accountability to questions and concerns raised by patients and physicians about coverage and other issues.
12. HCFA should enforce its power to penalize carriers for failing to meet established criteria and standards
13. HCFA should solicit local physician input on the adequacy of carrier performance—for both claims processing and program integrity.
14. Physicians should be allowed to request and receive an administrative law hearing to challenge carrier performance of administrative and other policy requirements if earlier resolution attempts cannot solve the problem.
15. Carriers should use color-coded communications. (e.g. red envelop for extremely urgent requests that require a response).
16. Carrier staff must be better trained; HCFA should consider mandating that claims processors be required to be certified and pass a course in applying HCFA payment rules.

ACP—ASIM will be seeking an opportunity to discuss our proposals for administratrative relief with Secretary Thompson, and once confirmed, a new HCFA administrator. We are encouraged that Secretary Thompson has expressed agreement on the need for HCFA to reduce unnecessary red tape.

Conclusion

ACP—ASIM is pleased that the subcommittee is addressing the serious problems that the Medicare regulatory burden poses for physicians and others attempting to care for patients. We strongly urge the Subcommittee to report MERFA to the full Ways and Means Committee for action. We also urge the Subcommittee to exercise oversight over HCFA to assure that necessary administrative changes are also made.

Statement of American Occupational Therapy Association, Inc., Bethesda, Maryland

The American Occupational Therapy Association (AOTA) represents nearly 50,000 occupational therapists, occupational therapy assistants, and students of occupational therapy to promote the interests of the profession and patients. AOTA submits this statement for the record of the hearing on March 15, 2001 on Medicare reform and ways to bring regulatory relief to beneficiaries and providers and restructuring the Health Care Financing Administration (HCFA) in the context of efforts to improve the Medicare program.

AOTA focuses these comments on the issue of the inconsistency of **local medical review policies** (LMRPs) and the processes by which they are developed and interpreted by fiscal intermediaries and carriers across the nation. AOTA has experienced considerable difficulties with the variability of these local policies, in the context of Medicare being a national program with national standards and goals. We urge the Committee to consider these concerns and as part of the effort to modernize the Medicare program and improve the efficiency of HCFA and its contractors. We believe this issue has significant impact on both providers and, more importantly, beneficiaries who are unsure of coverage from one area to the next and therefore suffer unequal treatment.

COVERAGE OF OCCUPATIONAL THERAPY IN LAW AND REGULATIONS

Occupational therapy is covered under Medicare Part A and under Medicare Part B as an outpatient service. Under both Part A and Part B, occupational therapy is provided based on coverage criteria which allow for the provision of therapy which is "medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning." (Carriers Manual, Sec 2217, Intermediary Manual (Sec. 3101.9). Further, occupational therapy is considered reasonable and necessary only where an expectation exists that the therapy will result in a significant practical improvement in the individual's level of functioning within a reasonable period of time. Where an individual's improvement potential is insignificant in relation to the extent and duration of occupational therapy services required to achieve improvement, such services would not be considered reasonable and necessary and would thus be excluded from coverage by Sec. 1862(a)(1) of the Social Security Act.

LOCAL AUTHORITY, LIMITED HCFA OVERSIGHT

While this coverage criteria is established by HCFA, the fiscal intermediaries and carriers have authority from HCFA to develop more explicit local medical review policies (LMRPs). Many attribute this approach to a view that there are regional differences in medical care that should not be overruled by national coverage policy.

HCFA is also supposed to review and approve LMRPs for appropriateness and adequacy. HCFA has not, in our view, exercised sufficient oversight and regulation of the activities of its contractors in the medical review area. AOTA believes that, at a minimum, the authority and latitude of the fiscal intermediaries or other contractors should be supervised and monitored to make these LMRPs consistent.

AOTA understands that the fiscal intermediaries and contractors have the authority to develop LMRPs to describe when and under what circumstances an item or service(s) will be covered and to clarify or provide guidance on national coverage guidelines. Conferring this discretion upon contractors does not, we believe, vest them with the authority to supplant pertinent statutory provisions, regulations, and national coverage policies (which include manual issuances) with informal presumptions. Yet HCFA's oversight and willingness to overrule or moderate LMRP's is limited. AOTA has had many discussions and meetings with HCFA and its contractors over LMRPs to try to assure that the process and resulting products adhere to the overarching principles laid out in Medicare law for benefits and coverage criteria.

HCFA's laissez faire attitude has been attributed both to an interest in allowing local variation as well as to an historical limit on HCFA staffing capacity. However, if HCFA would adopt national guidelines, the redundant (and inadequate) work of fiscal intermediaries in developing these LMRPs would be eliminated. Cost savings in administration should accrue from such streamlining.

RESULTS: INCONSISTENT COVERAGE

In addition, beneficiaries would be assured that occupational therapy is the same service under Medicare in Connecticut as it is in Louisiana as it is in California. Today, this is not the case.

An example that is clear is the coverage of rehabilitation services for individuals who have vision impairments. Coverage for these services is not allowed under many LMRPs around the country, despite the fact that as recently as the Balanced Budget Refinement Act Congress has reaffirmed, by extending referral privileges for these services to optometrists, that coverage for rehabilitation for diagnoses of vision impairment are allowed.

As an example of a broad set of problems with LMRPs, we offer the example of a recently issued LMRP from the Noridian Mutual Insurance Company, Fargo, North Dakota. At present AOTA is developing comments on a draft policy put forward by Noridian, a Medicare contractor. In reviewing the proposed policy, many of the problems that have occurred in other policies are evident:

The LMRP does not use current research and state of the art information. Some of the language used in Noridian's OT LMRP is confusing or does not reflect current OT practice. This may be due, in part, to use of out-of-date sources of information, as listed in the document. Using materials that are not state of practice results in inappropriate terminology and focus of the LMRP, not reflecting a clear picture of contemporary OT practice.

Furthermore, this proposed LMRP does not even reference Medicare manual citations that are correct. Reference to obsolete Medicare policies is absurd coming from a Medicare contractor bound to implement the program under current guidelines.

In addition, the Noridian LMRP, like many others is overly prescriptive. It uses diagnosis codes that do not appropriately recognize the difference between the underlying condition (e.g., stroke) and the therapy treatment diagnosis (e.g., limitations in self-care and toileting skills), it leaves out coverage for certain diagnoses (e.g., Alzheimer's disease and dementia) for which Medicare coverage of occupational therapy is allowed, and generally presents a narrow area of interpretation of individual condition for the practitioner, be it a physician prescribing treatment or a therapist providing treatment.

NATIONAL LEADERSHIP NEEDED

The problems presented by Noridian's policy are not isolated. AOTA has seen many cases in which the LMRPs contain significant and unsupported deviations from the national medical review guidelines contained in the Medicare Intermediary Manual. AOTA has worked to correct many policies' inappropriate and arbitrary restrictions on access to therapy and other services but this should be corrected with a national approach for fairness and consistency. AOTA recognizes the importance of defining scope of benefits and appropriate interpretations of Medicare allowances of coverage, but this patchwork system wastes time and money and does

not serve a national program. We believe the LMRP's should be replaced with a broad and open public process to establish more detailed national coverage criteria.

HCFA should be required to set a national standard to assure beneficiaries consistent coverage wherever they live or receive services. A national standard would assist occupational therapists to furnish skilled occupational therapy services based on an evaluation of individual need and rehabilitation potential within the reasonable and necessary guidance of the Social Security Act.

Such national coverage criteria would assure Medicare beneficiaries equal access to services across the nation. National coverage criteria would replace the process now in which contractors "adopt" other contractors policies, even if those policies conflict with overall Medicare requirements. Thus, an erroneous and improper "national" policy can become established merely by the spread of LMRPs from one contractor to another, by entities that are not publicly accountable, with limited public review and without sufficient intervention or oversight by HCFA. While the Medicare Intermediary Manual does provide LMRP development guidelines, AOTA's experience is that these are not always followed. Relief is limited.

Furthermore, while AOTA may be able to intervene in some of these, many beneficiaries and beneficiary advocates find the existence of multiple LMRPs and standards hinder appropriate access to services.

Even if a national policy is not developed, HCFA could oversee and regulate the activities of its contractors in the medical review area far more than is currently the practice. For instance, HCFA should narrow the fiscal intermediaries' latitude to develop broad, wide-ranging LMRPs without oversight by HCFA. This is rarely done at present.

Indeed, HCFA has contracted under its program integrity efforts for a contractor to review local medical review policies to determine variations. This is being done as part of HCFA's efforts to investigate coverage limitations that could be developed to substitute for the annual cap placed on outpatient rehabilitation by the Balanced Budget Act. AOTA supports efforts of any kind to make these policies consistent and appropriate.

APPEALS

Furthermore, HCFA has just issued the following which further constrains provider and beneficiary rights to consistent policy:

HCFA Pub. 60AB, Trans. No. AB–01–44, March 15, 2001— Binding Effect of LMRP's

(Intermediaries/Carriers),

CHANGE REQUEST 1540

SUBJECT: Binding Contractor Hearing Officers to Local and Regional Medical Review Policies (L/RMRP)

This Program Memorandum (PM) serves to bind contractor hearing officers (HOs) to contractor—issued L/RMRP). This PM is being issued to expedite distribution of the instructions and will be incorporated permanently through revisions to the Medicare Carrier Manual (MCM), the Medicare Intermediary Manual (MIM) and the Medicare Program Integrity Manual (PIM).

HOs must comply with L/RMRP. (See Chapter 1 of PIM, 2.3.2.3 for procedures for developing and adopting L/RMRPs.) Binding an HO to L/RMRP means that the HO must apply pertinent L/RMRP to the facts of a given claim and that the HO may not disregard or override an applicable L/RMRP. This PM affects MCM 12016 and MIM 3794.4. Authority for this PM is found at 42CFR 405.836, the regulation delineating the authority of HOs.

The *effective* date for this PM is March 15, 2001.

The *implementation* date for this PM is March 15, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after December 31, 2002.

If you have any questions, contact Rosalind Little at (410) 786–6972, e-mail RLittle@hcfa.gov or Steve Miller at (410) 786–6656, e-mail SMiller1@hcfa.gov.

This policy is in effect a "gag rule" on hearing officers. It further harms both beneficiaries and providers by preventing a full examination of the facts with regard to coverage denials. This memorandum creates unreasonable and unfair practices restricting the purview of an administrative hearing officer. This is demonstrable administrative overreaching, especially when this procedural restraint serves to further compound the problems in the LMRPs content as discussed earlier.

MAKE MEDICARE A NATIONALLY CONSISTENT PROGRAM

In legislation introduced in the 106th Congress, (now) Chairman Bill Thomas, with (now) Subcommittee Chairwoman Nancy Johnson among others, sought to assure that coverage policy determinations were made more consistent, equitable and efficient. We believe the goals of H.R. 2356 of 1999 remain important and ought to be considered by the Subcommittee on Health and the Ways and Means Committee as part of efforts to reform Medicare.

Beneficiaries and providers deserve consistency in the benefits and providers deserve fair guidance in all areas of the country. The reasonableness and necessity of services should be largely determined by national coverage criteria and should not vary significantly from one region to another. We have also found that many LMRPs, especially in the amount, frequency and duration parameters, are so prescriptive as to impinge upon the ability of professionals to provide care that addresses the medical condition, functional level and rehabilitation possibilities of individual beneficiaries.

We thank the Subcommittee for the opportunity to express our concerns and look forward to aiding efforts to correct these problems and improve the effectiveness of the Medicare program.

Statement of American Physical Therapy Association, Alexandria, Virginia

Madam Chairwoman and members of the Subcommittee, the American Physical Therapy Association (APTA) is pleased to provide written comment for your consideration regarding the important task of reforming the Medicare program. APTA sincerely appreciates your efforts this Congress to explore this issue in greater detail and hold necessary hearings to ensure all views are heard on the matter.

Tommy Thompson, the newly appointed Secretary of Health and Human Services, summarized the feelings of the physical therapy community in a speech given to the American Association of Health Plans on February 26, 2001. The former governor of Wisconsin stated, "Patients and providers alike are fed up with excessive and complex paperwork. Rules are constantly changing. Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses and other health care professionals out of the program."

There are a number of regulations that are unnecessary and take away vital time and resources from patient care. These regulations impact physical therapists working in a variety of settings, which include: hospitals, skilled nursing, facilities, home health agencies, comprehensive outpatient rehabilitation facilities, rehabilitation agencies, and physical therapy private practice offices. If necessary deregulation can take place, physical therapists will be able to provide care to Medicare patients in these settings in a more timely manner, which will speed recovery.

The following are problematic regulations and policies under the Medicare program that impact physical therapy. APTA has notified HCFA that these regulations and policies need to be eliminated, revised, or clarified. In most cases, we are still awaiting action.

Certification/Recertification

Section 1861 (p) of the Social Security Act requires that outpatient physical therapy, occupational therapy, or speech-language pathology services be furnished only to an individual who is under the care of a physician. According to Medicare regulations, for outpatient physical therapy services furnished in rehabilitation agencies, physical therapist private practice offices, outpatient hospital departments, and skilled nursing facilities (Part B), there must be evidence in the patient's clinical record that he or she has been seen by the physician every 30 days. In addition, the clinical record must show that the physician reviewed the plan of care and recertified the need for that care every 30 days. For home health agencies and comprehensive outpatient rehabilitation facilities, the physician is required to review the plan of care and recertify the need for care every 62 days.

The need for a physician visit every 30 days is problematic. In many instances, it takes a week or two before the patient goes to receive his or her outpatient physical therapy treatment. After receiving two weeks of treatment, the 30 days expires, and the patient then needs to see the physician again in order to continue treatment. Returning to the physician's office in this time frame is an inconvenience to the patient and the physician. It is particularly problematic in rural areas, where the patient may have to travel a long distance to get to a physician's office.

Physician signature on plan of treatment

Medicare requires that the physician recertify the need for therapy services every 30 days. Because this policy is not written clearly in HCFA's manuals, there is considerable confusion with respect to when the 30-day time frame begins and at what point the physician signature has to be on the plan of care. It is not clear whether the 30-day time frame begins after the physical therapist conducts an evaluation, after the initial physician visit, or when the physical therapy treatment actually begins. It is also not clear whether the physician signature has to be on the plan of treatment before therapy begins, before the claim is submitted to Medicare, or shortly after therapy begins.

APTA has tried unsuccessfully to obtain clarification from HCFA on these issues. Because there has been no clarification, carriers and fiscal intermediaries throughout the country are interpreting this provision differently. APTA's recommends that the 30-day time frame begin when the therapist sees the patient, and that the physician signature be on the plan before the claim is submitted to Medicare. Because it can often be difficult to obtain physician signatures, requiring the signature before treatment begins would result in delays in needed patient care.

Home Health Agency Prospective Payment System and Medicare Part B

On October 1, 2000, HCFA implemented the Medicare home health agency (HHA) prospective payment system (PPS). The HHA PPS includes a consolidated billing requirement, which mandates that home health agencies must bill and receive payment for all home health services, including physical therapy services, during a 60-day episode of care. Once the patient is discharged from the home health plan of care and is no longer eligible for the home health benefit, an outpatient rehabilitation provider may treat and bill for the services under Medicare Part B.

Since the inception of the HHA PPS, physical therapists have had numerous problems receiving payment under Medicare Part B for services provided to patients recently discharged from a home health plan of care. This is due to the fact that HCFA is unable to track patient discharges until final payment claims have been submitted by the HHA. As a result, the carriers and intermediaries are rejecting Part B claims because the computer edits flag the file as being open under the Part A HHA PPS.

At a meeting with APTA, HCFA staff indicated that there is no immediate solution to this problem. Therefore, APTA respectfully requests that the home health consolidated billing provision be suspended until this computer problem can be corrected. It is unfair to penalize providers because HCFA does not have the adequate resources to operationally implement the consolidated billing policy.

"In Room" Supervision Requirement of Physical Therapist Assistants in Physical Therapist Private Practice Offices

HCFA's final rule, published in the November 2, 1998 Federal Register, HCFA required that a licensed physical therapist in private practice (PTPP) must personally supervise the physical therapist assistants and physical therapy aides. HCFA defines personal supervision to mean the physical therapist must be in the room during the performance of the service. Prior to that date, the standard for supervision was "direct supervision." In our view, the "in the room" supervision requirement is too strict and unnecessary. PTAs are state regulated practitioners, who can safely and effectively furnish therapy services under a less stringent supervision standard. The personal supervision requirement imposes a level of supervision higher than that required for PTAs furnishing services in other Medicare settings.

APTA has provided written opposition to the "in-the-room" requirement in its comments on the Medicare physician fee schedule for the last 2 years, and in numerous other correspondences. APTA has also had several meetings with HCFA on this issue. Most recently, HCFA stated in the final physician fee schedule rule that they are carefully examining the issue. We are still awaiting action.

Correct Coding Initiative Edits

On January 1, 1996, the Health Care Financing Administration (HCFA) implemented a national Medicare policy involving more than 80,000 coding edits that restricted certain coding combinations. AdminaStar Federal developed these code edits under a contract with HCFA. These code pair edits are combinations of two CPT codes that cannot be billed together because either the code pair represents services that are considered mutually exclusive or one code in the pair is considered a component of a more comprehensive procedure code. The CCI edits are applied to serv-

ices furnished in physical therapist private practice offices and in outpatient hospitals.

APTA recognizes the need for HCFA to create edits in their systems to detect inappropriate billing. However, HCFA has created a number of edits that do not make clinical sense, and therefore are inappropriate. APTA has requested that HCFA delete the problematic code pair edits, but is still awaiting such deletion.

Clarification of Use and Documentation of Timed Codes

In March of 2000, HCFA issued program memorandum AB–00–14, "Questions and Answers Regarding the Prospective Payment System (PPS) for Outpatient Rehabilitation Services and Physical Medicine Current Procedural Terminology (CPT) Coding Guidance." This program memorandum answers questions related to Medicare outpatient therapy policies and provides guidance regarding coding therapy services. Because most physical medicine and rehabilitation codes are 15 minute timed codes, the memorandum defines how to bill for a 15 minute unit and how to determine what services count as time. Specifically, in AB–00–14, HCFA states that when billing units of therapy, one unit is equal to or greater than 8 minutes but less than 23 minutes of care. Two units are equal to or greater than 3 minutes but less than 38 minutes, and so on. Providers are instructed not to bill for anything less than 8 minutes of care. HCFA also states "pre-and post—delivery services are not to be counted in determining the treatment service time.

The language regarding counting minutes of therapy has caused considerable confusion. APTA, along with other rehabilitation organizations, met with HCFA in June 2000, to discuss the policy and clarify any confusion associated with it. At that meeting, HCFA agreed to develop a question and answer program memorandum that would further clarify how to determine what time counts as a 15-minute unit and how to bill for units of service. In this program memorandum, HCFA would respond to questions developed by the organizations. The questions were submitted to HCFA on July 21, 2000, and APTA is still waiting for HCFA to issue this program memorandum.

Stark II law

HCFA published an interim final rule (66 *Fed. Reg.* 856) on January 4, 2001, which incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act. This law, referred to as the "Stark II" law, prohibits physicians from referring Medicare and Medicaid patients for designated health services" to health care entities in which they have a financial relationship, unless an exception applies. According to the law, physical therapy is a "designated health service."

APTA was pleased to see that HCFA published a final rule and supports the intent of the Stark II regulations. Physical therapists and patients needing physical therapy services are adversely impacted by physicians that obtain financial gain by referring patients to their own clinic for physical therapy services.

Although we are pleased to see that these issues are being addressed in HCFA's regulations, we are seriously concerned that some of the provisions in the interim final rule weaken the Stark II law and open the door for physician abuses in the provision of physical therapy services.

HIPAA: Final Rule on Privacy of Individually Identifiable Health Information

The Department of Health and Human Services released the long awaited final privacy regulations on December 20. The Final rule implements the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) and sets forth complex limitations on the use of individually identifiable health information by most health care providers (including physical therapists), health plans, and clearinghouses.

While APTA supports the protection of individually identifiable health information, the regulation that was issued is extremely cumbersome for our membership. For example, providers have to ensure the compliance of their business associates and have a new duty to mitigate known privacy violations by third party contractors. Many of our members are small business providers and the cost for implementing the requirements of the privacy regulations will be too onerous.

Reimbursement for Physical Therapy Students

There is considerable confusion regarding HCFA's policy on supervision and reimbursement for therapy student services under Medicare in the outpatient therapy setting. The American Physical Therapy Association (APTA), American Speech Language Hearing Association (ASHA), and American Occupational Therapy Association (AOTA) met with HCFA to discuss this problem in March 2001. After this meeting, HCFA began working on a program memorandum regarding reimbursement of services for students under Medicare Part B. The therapy associations are still awaiting issuance of this program memorandum. We are hoping that the issuance can be expedited. It is our hope that HCFA's policies will ensure that students can continue to obtain the clinical training they need to better serve Medicare beneficiaries in the future.

Provider Education

Many physical therapists have difficulty finding the "right" answer to questions regarding Medicare requirements. Carriers and intermediaries often give incorrect information to providers. There appears to be a lack of communication of information between HCFA national and the carriers and fiscal intermediaries.

In addition to receiving incorrect information from carriers and fiscal intermediaries, providers find that carriers and fiscal intermediaries are interpreting HCFA regulations and policies differently throughout the country. As a result, providers in different regions are subject to different standards for Medicare coverage and reimbursement. There is a need for uniformity. Physical therapists are trying to provide good patient care while complying with Medicare regulations, but because of the confusing and conflicting information they are provided, this has become more difficult.

There is a need for HCFA national to provide clear, concise guidance on its Medicare policies to its fiscal intermediaries and carriers, to national associations, and to providers. This guidance would ensure providers receive accurate and timely information to assist them in complying with Medicare requirements.

HCFA recently contracted with DynCorp to examine inconsistencies throughout the country with respect to Medicare coverage and reimbursement of occupational therapy, physical therapy, and speech-language pathology services. It is our hope that DynCorp and HCFA can remedy this problem through their work on this project.

Alternative Payment Methodology

The Balanced Budget Act of 1997 mandated an alternative payment policy be implemented for outpatient therapy services. Originally, a $1500 limit was placed on outpatient therapy services until an alternative payment policy was developed and implemented. This arbitrary limitation on services proved to have an adverse impact on patients, and in 1999, Congress placed a 2-year moratorium on the $1,500 limit. HCFA is still required to develop the alternative payment policy for outpatient therapy services and report to Congress on an alternative by January 1, 2001.

Due to a provision in the BBA of 1997, beginning January 1, 1999 all outpatient therapy providers, are reimbursed according to the physician fee schedule instead of a cost-based system. Therefore, APTA does not believe its necessary to develop an alternative payment methodology because the needed savings are achieved under the physician fee schedule.

Practice Expense Methodology

In determining payment under the physician fee schedule, there are three relative values: 1) relative value (RVU) for clinical work, 2) RVU for practice expense, and 3) RVU for malpractice expense. In January 1999, the practice expense RVU was revised to be resource based rather than charge based. In the November 1998 Medicare Fee Schedule rule, HCFA discussed its methodology for developing these resource based practice expenses. We believe that the methodology used to determine the physical therapy practice expenses is flawed.

APTA believes that the administrative payroll, office, and other practice expenses per hour used by HCFA in computing the practice expense component of RBRVS under the Medicare Physician Fee Schedule is not sufficient to reflect expenses of physical therapists in private practice. APTA urges HCFA to adopt data from a survey conducted by the APTA during 2000. In the alternative, APTA believes that the "all physician" category more accurately reflects practice expense costs for physical therapists in private practice.

Medical Review and Audits

There are many problems with the current medical review and audit process. In many instances, the auditors do not understand the regulations that apply to physical therapy providers, and thus inappropriately seek overpayments. In addition, providers find that they are not given a reason for the overpayment determination, and carriers and intermediaries are unwilling to answer provider questions about the overpayment determination. Therefore, providers are forced to devote considerable time and resources to defend themselves.

In a number of cases, carriers and fiscal intermediaries seek overpayments based on a "technicality". For example, the physical therapy service was provided, was medically necessary, there is documentation in the file to support the medical necessity of the service provided, and a physician signed the order for services. Despite proof of medical necessity in the clinical record, the auditor still seeks the overpayment because the physician did not date the order. Thus, the provider is required to pay the money back to the Medicare program, because of this missing information.

APTA recommends that HCFA educate its auditors about its policies and regulations pertaining to physical therapy services, and ensure that providers are given sufficient rationale for the overpayment determinations.

Appeals

Approximately, 85% of the appeals that come before the Administrative Law Judges are overturned. When Medicare determines that there is an overpayment, the provider often must pay the overpayment before the appeal is heard. Many physical therapy providers who have received overpayment determinations are small business owners. To require the return of the overpayment when the provider believes the determination was made in error is extremely costly and a violation of due process. Therefore, APTA recommends that HCFA prohibit recovery of alleged overpayments until appeals have been exhausted.

Additionally, APTA believes that HCFA should permit physical therapists to appeal an alleged overpayment without waiving their administrative appeal rights. In many instances, a therapist will receive a consent letter informing them of an overpayment determination. The letter provides three choices: pay back the money and forego any appeal rights; provide additional documentation and forego any appeal rights; or appeal the overpayment determination but subject the company to a full blown investigation. APTA believes that these choices are unfair and deny providers due process.

Conclusion

We appreciate your serious consideration of APTA's concerns and recommendations. We recognize that HCFA has numerous regulations that need to be implemented as a result of the Balanced Budget Act of 1997, the Balanced Budget Refinement Act (BBRA), and BIPA. Because of the major impact of these regulations on the provision of critical rehabilitation services to Medicare beneficiaries, it is our hope that HCFA addresses these issues expeditiously.

We frequently hear from physical therapists that they can no longer provide services to Medicare patients because of the onerous regulations and unfair review processes. The purpose of the Medicare program is to provide access to quality health care services for senior citizens. Unfortunately, due to the number and complexity of Medicare regulations, beneficiaries may have difficult getting access to the rehabilitation services that they need.

The APTA looks forward to working with you and the rest of the Committee members to address these concerns on behalf of the physical therapy community and the patients they serve. For more information, please contact Patrick Cooney at (703) 769–0020. Thank you for your consideration of these comments.

APTA represents more than 68,000 physical therapists, physical therapist assistants, and students of physical therapy. The goal of APTA is to foster physical therapy practice, education, and research.

MAYO FOUNDATION
WASHINGTON, DC 20036
March 23, 2001

Representative Nancy L. Johnson
Chair, Subcommittee on Health
House Committee on Ways and Means
1136 Longworth House Office Building
Washington, DC 20515–6349

Dear Representative Johnson:

On behalf of Mayo Foundation, I would like to submit this information for the record of the Health Subcommittee hearing of March 15, 2001: "Medicare Reform: Bringing Regulatory Relief to Beneficiaries and Providers."

At the hearing, Representatives Stark and Kleczka raised questions relating to the number of pages of Medicare rules and regulations. The source of the numbers referenced in the testimony of several witnesses is an estimate made by Mayo in 1998. The original breakdown of the numbers of pages of regulations and supporting documents, as estimated by Mayo, is attached for the record. This estimate was made in 1998, so it does not include most of the thousands of pages of rules implementing the Balanced Budget Act of 1997. Nor does the total include any number for some of the listed categories for which we were unable to make estimates. We therefore believe this estimate significantly underestimates the real number.

Questions were raised at the hearing concerning the accuracy of the Mayo numbers, and it was stated that HCFA estimated a much smaller number of pages—in the range of 35,000. We stand by the accuracy of our estimate, noting as we have in the past that we are including all Medicare rules, manuals, and other guidance documents that are necessary for providers to deal with the Medicare program. We have circulated our list publicly, and in fact it was included in a publication of the House Budget Committee in May 2000 ("Budget Committee Task Force on Health: Medicare's Regulatory Burden on Providers", Hearing Press Kit, May 18, 2000).

We also believe that there is no point in engaging in an argument with HCFA or anyone else over the definitions of "rules" or the exact number of pages of such. The important points we intended to raise with this count are:

(1) There is a major regulatory overload in Medicare.

(2) The rules are spread out over numerous sources, making it even more difficult to know all the rules that may apply.

(3) Many carrier and intermediary rules vary among the different areas of the country.

Rather than debating the numbers, we believe it is time to move forward to finding solutions to these problems. For that reason, we salute your efforts in holding the hearing: "Medicare Reform: Bringing Regulatory Relief to Beneficiaries and Providers." We are ready to assist you and the Health Subcommittee in any way to improve the Medicare program for beneficiaries and providers alike.

Sincerely,

BRUCE M. KELLY
Director of Government Relations

Medicare Regulations and Supporting Documents

Medicare Laws and Related Laws (SSA and 350 Amendments)	706
Fraud and Abuse Regulation	14,500
BBA of 1997 (statute only)	800
Medicare Regulations (42 CFR)	3,574
21 HCFA Manuals	10,500
HCFA Federal Registers	30,000
('94-'98)	
('87-'93)	2,000
('82-'86)	2,000
Carrier Part B Manuals	500
Correct Coding Manual	340
Carrier Newsletters	4,320
Intermediary Communicators	2,880
Intermediary Medicare Bulletins	2,250
Medicare Administrative Bulletins	5,000
BCA Administrative Bulletins	2,500
HCFA Intermediary Letters	

HCFA Carrier Letters	
HCFA Intermediary/Carrier Letters	
DMERC Manuals	418
HCFA Rulings	
PRRB Decisions	24,000
HCFA Administrator Decisions	2,000
Court Decisions	1,000
HCFA Correspondence	
Carrier Correspondence	
OIG Federal Registers ('94-'98)	1,000
OIG Workplan and Compliance Program Guidance	170
RHC Billing Carrier Instruction manual	300
HCFA Advisory Opinions	
TOTAL	**110,758**

Non-HCFA HHS

ICD9–Code Book	1,680
AHA Coding Clinics for ICD	1,920
CPT Coding Book	588
DRG Guidebook	558
CPT Assistant	480
State Department of Health Interpretive Guidelines	30
GAO Reports on Medicare	2,000
UB92	600
HCPCS	276
CLIA	
JCAHO	
TOTAL	**8,132**

Other Government Agencies

Laws, Regulations, Manuals, State Registers, Enrollment Agreements	
CHAMPUS	7,500
VA	
Medicaid	6,000
FDA	
PHS	
TOTAL	**13,500**
GRAND TOTAL	**132,390**

Statement of National Association of Chain Drug Stores, Alexandria, Virginia

Madam Chairman and Members of the Subcommittee. The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement for the record regarding reform of the Health Care Financing Administration (HCFA), and the agency's major programs, policies, and operations.

We hope that this review will result in a more streamlined administration of the Medicare, Medicaid and S-CHIP programs, and improve the quality of health care delivered to these programs' beneficiaries, eliminate the onerous bureaucracy at the agency, and modernize HCFA's infrastructure. We support your goals, and pledge to work with you to see that the agency begins the process of being more responsive to the needs of beneficiaries and providers.

NACDS represents about 170 chain pharmacy companies that operate about 33,000 retail pharmacies all across the United States. Chain pharmacy is the single largest segment of pharmacy practice. We filled about 60 percent of the 3.1 billion prescriptions provided across the nation last year. Chain community pharmacy has extensive interaction with programs that are administered by HCFA, and is significantly affected by the agency's policies and procedures. Thus, we have a vested interest in the outcome of any major HCFA review and restructuring. Here's how community retail pharmacy participates in these programs.

- **Medicaid:** Community retail pharmacies provide prescription services to millions of Medicaid recipients each year. In fact about 15 percent of all retail pharmacy prescriptions are paid for by Medicaid. Even though many specific

Medicaid policies are controlled by states, HCFA has an important role in setting and enforcing broad policies and procedures through Federal law, regulation, and the state plan amendment (SPA) process. For example, HCFA sets maximum Medicaid reimbursement rates for generic drugs through their Federal Upper Limit (FUL) program, which can have a significant impact on the utilization of lower-cost generic drugs throughout the entire market. All providers, including pharmacies, are significantly affected by state-based waivers approved by HCFA, including those that expand health care services to low-income populations that are not traditionally Medicaid recipients. We will elaborate more on this and other Medicaid program issues later in this statement.

- **Medicare:** While Medicare does not yet have a prescription drug benefit, many community pharmacies already serve as suppliers of Medicare-covered items. For example, pharmacies provide select prescription drugs, such as immunosuppressive and oral cancer drugs; provide durable medical equipment, such as canes, walkers, crutches and ostomy supplies; and provide important diabetic care items, such as test strips and glucose meters. Upon enactment of a prescription drug benefit for seniors, HCFA may have some role in the administration of the benefit. Policies and procedures adopted by HCFA in this regard will have a substantial impact on chain community pharmacy.
- **State-Based Children Health Insurance Program:** Community pharmacies also provide prescription drugs to parents and children enrolled in state S-CHIP programs.

We appreciate the responsiveness of many HCFA staff to our ongoing questions and concerns regarding the operations of these programs. However, we wanted to offer our perspectives on how we believe the agency can improve the administration of certain programs under its jurisdiction to make them more valuable for patients, reduce costs for the system, and facilitate participation of pharmacy providers.

Medicaid Prescription Copays

Some states impose prescription copays as a way of reducing their Medicaid prescription drug expenditures. While these copays only range from 50 cents to $3 per prescription (and some eligible groups are exempted from paying these copays), they can create burdens on Medicaid recipients with limited means, especially those taking multiple prescriptions. Sometimes, the recipient cannot afford the copay, but the pharmacist is obligated under law to provide the prescription anyway. In some states, however, recipients are being actively told to just say that they cannot afford the copay, and that the pharmacist will still have to provide the prescription. HCFA has restricted states' ability to compensate pharmacies for these uncollected copays.

This is unfair to pharmacies, and essentially represents a reimbursement reduction, since the state is not allowed by HCFA to compensate the pharmacist for the value of the uncollected copays. In addition, these unpaid copays represent unfunded mandates on pharmacies, and a reduction in reimbursement to provide the prescription. In some states, these uncollected copays could cost the average pharmacy thousands of dollars each year.

These copay losses are obviously higher for pharmacies in areas that serve a significant number of Medicaid recipients. We believe that the Medicaid program should compensate pharmacies for the value of these lost copays.

Medicaid Federal Upper Limits (FULs) for Generic Pharmaceuticals

Community retail pharmacy was significantly frustrated with HCFA this past year as the agency attempted to develop a credible, reliable, valid Federal Upper Limit (FUL) list for generic drugs. This list represents the maximum amount of Federal matching funds that states will receive for a marketbasket of generic drugs that meet certain Federal criteria.

Not all generics have an FUL, but the accuracy and integrity of this list is important because almost all private third party prescription payors use this list to set their maximum reimbursement amounts for generics. Moreover, more than half the states use these Federal FULs to set their own "maximum allowable costs" for generic drugs in their own Medicaid programs. Thus, the impact of the list extends well beyond Medicaid. If the list is not accurate, and does not reflect current market realities, it will discourage utilization of lower-cost generics in favor or higher-priced brand name drugs.

HCFA is supposed to publish an updated and current FUL list every six months. However, the first major substantial overhaul to the list in almost two years was published by the agency in April 2000. The two-year lag between updates was a serious problem. That is because there were substantial price increases on many generic drugs during this time, which were not reflected on the outdated FUL list, and significant changes in the number of manufacturers in the generic marketplace.

Unfortunately, the April list contained hundreds of inaccuracies, and several more iterations were needed over a period of eight months before the agency published a final list in December that appears to be reasonably accurate. Many of the FULs on the original April list were determined with the prices of products that had been discontinued for many years.

We believe that many of these problems could have been avoided had the agency been more diligent in collecting the appropriate data and assessing the realities of the generic drug marketplace.

Nevertheless, we believe that the agency did work in good faith with Medicaid directors, pharmacy providers, and other affected parties, in identifying and correcting errors with the list. We appreciate that the agency delayed implementation of the list until such a time that most of the problems were corrected.

Assuring the accuracy of this list is critical. In addition to providing the pricing "reference source" that HCFA used to set the FUL, we believe that HCFA should also be required to release the corresponding National Drug Code (NDC) numbers used to establish the FUL. In our opinion, this is the only way that the accuracy and the integrity of the list can be validated. Without this information, there is absolutely no way for providers to know if HCFA is using reliable, valid information to set its FULs.

Medicaid State Plan Amendment Approvals

The federal government gives billions of dollars to state Medicaid programs, and federal law requires HCFA to review state Medicaid plans to ensure that state Medicaid programs are spending that money in accordance with federal law. Unfortunately, HCFA has repeatedly refused to conduct thorough reviews of amendments to state Medicaid plans to make sure that they comply with federal law.

HCFA simply accepts assurances from a state Medicaid agency without investigating whether those assurances are accurate. The result is that HCFA approves clearly illegal state plan amendments. For example, last year a federal court ruled a HCFA-approved state plan amendment discriminating against chain pharmacies to be in violation of the US Constitution, federal statutes, and HCFA's own regulations.

Moreover, Federal law requires Medicaid payment rates to be consistent with efficiency, economy, and quality of care. States cannot arbitrarily reduce Medicaid pharmacy reimbursement to balance their Medicaid prescription drug budgets. States have to comply with several Federal standards when setting Medicaid pharmacy reimbursement. For example, Federal Medicaid law establishes standards for payment rates to providers in state Medicaid programs. See 42 U.S.C. § 1396a(a)(30)(A).

Payments have to be "consistent with efficiency, economy, and quality of care . . . and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that . . . they are available to the general public . . .". In addition, a 1994 memo from HCFA to state Medicaid directors requiring states to justify whether payment rates to pharmacies are "reasonable" and in compliance with Federal law, said:

> *States wishing to modify their EAC (Estimated Acquisition Cost) levels may, among other methods of verification, audit an appropriate number of pharmacies to determine current acquisition costs before making modifications to the EAC levels. . . . we still expect that States will continue their present activities to establish a reasonable dispensing fee level and will document them in their State Plan. Such activities could include: (1) audits and surveys of operational costs; (2) compilation of data regarding professional salaries and fees; and (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc. . . . The methods or standards they utilize to establish such fees are at the discretion of the individual State but should be documented in support of the State plan.*

Yet, we have seen case after case where HCFA simply approves pharmacy payment reductions proposed by the states for budgetary reasons, or the agency fails to adequately assess the evidence presented by the state to justify the reimbursement change. Many of the studies that are submitted to HCFA are deeply flawed, yet the agency relies on these studies to approve state plan amendment changes.

Adding insult to injury is the fact that these pharmacy reimbursement reductions do little to control escalating Medicaid prescription drug program expenditures. Expenditures for prescription drugs in the U.S. Medicaid program increased from $8

billion to about $13.5 billion, or about 69 percent in the last five years (1993–1998). Reasons include:

- ***More Prescription Use per Medicaid Recipient:*** The number of prescriptions used by each Medicaid recipient increased by 23 percent from 1993 through 1998.
- ***Medicaid Recipients Using Higher-Priced Prescription Drugs:*** The average Medicaid prescription price increased 70 percent between 1993 and 1998. However, of this amount, there was an 85 percent increase in the pharmacist's cost of purchasing the drug from the manufacturer. In real dollar terms, the amount that the state pays the pharmacist to dispense the prescription increased by only 0.6 percent—which did not even keep pace with the rate of inflation, which was about 13 percent.

None of these factors can be addressed by reducing pharmacy reimbursement. Yet, HCFA continues to approve these SPAs, knowing full well that experience has shown that pharmacy reimbursement reductions have negligible impact on reducing Medicaid prescription drug spending. The process by which HCFA assess and approves SPAs must change.

Inappropriate Use of Medicaid as Leverage for Pharmacy Price Controls

We are also seriously concerned that states are using pharmacy's Medicaid participation as leverage to extend retail prescription pricing discounts to populations that are not Medicaid eligible. For example, some states, such as California, have added a new material requirement to a pharmacy's participation in the state's Medicaid program. That is, pharmacies are required to charge all Medicare beneficiaries no more than the Medicaid prescription rate, regardless of the beneficiary's income, if they want to participate in Medicaid.

We understand the states' interest in reducing the cost of prescription drugs to seniors. However, we strongly object to arbitrary controls on our prices, especially since these programs do nothing to reduce our cost of buying the drug, which is the overwhelming major cost factor in any prescription. Thus, pharmacies must absorb the entire cost of this discount.

Furthermore, NACDS opposes state efforts to tie participation in these price control discount programs to the Medicaid program. No pharmacy that agreed to participate in the Medicaid program did so with the expectation that it would be required to offer a discounted retail price to populations that were not originally covered by Medicaid.

We also question whether a pharmacy's willingness to provide discounts to senior citizens is germane to its overall fitness to participate in the state's Medicaid program. NACDS recognizes that states have an interest to ensure pharmacy providers are legitimate businesses, are unlikely to engage in fraud, and employ pharmacists and other personnel who are qualified to safely dispense medications and counsel Medicaid recipients. However, requiring pharmacies to provide prescription drugs at discounts to senior citizens, which may jeopardize their long-term viability, does not seem to be reasonable criteria for participation in state Medicaid programs.

HCFA apparently is unaware that states are tying pharmacy participation in Medicaid to participation in non-Medicaid programs. We find it difficult to believe that HCFA is not aware of how states are using the Medicaid program in ways that are unconventional or inappropriate. We believe that the agency should unequivocally tell states that participation in the Medicaid program should not be used as leverage to force pharmacies to participate in programs that do not serve Medicaid populations. If states want to increase access to prescription drugs for seniors, they should establish meaningful prescription drug coverage programs, not retail pharmacy price controls.

Medicaid Prescription Drug Waiver Programs

We are concerned about certain Federal Medicaid waivers that have been approved that extend Medicaid prescription pricing—including drug manufacturers' rebates—to certain low-income populations. Once again, we understand the states' interest in providing reduced priced prescription drugs to low income seniors. We continue to support prescription drug coverage programs as the best method to achieve this goal.

However, these programs simply require the pharmacy to discount the retail prescription price by the cumulative Medicaid manufacturer rebate amount and the Medicaid pharmacy reimbursement discount amount. Pharmacies are then compensated for the retail price reduction amount equal to the manufacturers' rebate by the state, who collects these rebates from the manufacturers.

We do not believe that pharmacies should be required to participate in these programs as a condition of Medicaid participation. We are also concerned about requiring pharmacies to pass along the additional manufacturers' discount at the retail pharmacy counter, without some assurance from the state that they will be able to collect all the rebates from the manufacturer, and provide them to the pharmacies in a timely and consistent manner to compensate for this price reduction.

Medicare Diabetes Education and Training Program

The 1997 Balanced Budget Act (BBA) created a new diabetes education and training benefit for ambulatory Medicare beneficiaries. The intent of the new benefit was to allow ambulatory Medicare beneficiaries with adult-onset (Type II) diabetes to receive important education and training from health professionals, on such aspects as diet, exercise, glucose monitoring and drug therapy—to help them better manage their condition.

These preventive health care services have been proven to improve quality of life and reduce health care costs. Many community pharmacies provide diabetes self-management benefits. These pharmacy-based programs work. NACDS members provided HCFA extensive evidence during the regulation's comment period with significant evidence of patient satisfaction with these programs. Private payors are increasingly recognizing pharmacy's role in diabetes management programs, and studies have demonstrated the value of these programs.

The BBA allowed pharmacy providers to participate as providers in this program by virtue of the fact that pharmacies already provide diabetic supplies and products to Medicare beneficiaries. Unfortunately, the final rule that HCFA promulgated in December 2000—over three years after the enactment of BBA—did not recognize the value of pharmacy-based diabetes self-management services. The rule established restrictive, onerous, and unnecessary standards for provider participation. The result is that community pharmacies will most likely be unable to provide diabetes self-management benefits to Medicare beneficiaries. The many senior citizens with diabetes who could have been helped by visiting their conveniently-located community pharmacy will now have to find an outpatient hospital or a clinic that can comply with the HCFA regulations.

Many community pharmacies that currently do not provide such benefits viewed the BBA reforms as an opportunity to expand the services they provide may not initiate diabetes self-management programs. There is no logical reason why the most accessible health care professionals—pharmacists—and the provider from which diabetics purchase most of their supplies should be logistically excluded from participating in this program. It is a disservice to Medicare beneficiaries and community pharmacies.

Medicare Supplier Issues

Community pharmacies are suppliers of Medicare Part B covered durable medical equipment (DME) and select prescription drugs. NACDS members' frustration with HCFA's inability to administer these benefits knows no bounds. The Agency has been unwilling to adopt computerized on-line systems that almost every other health care payor has used for years.

These on-line claims adjudication systems save health care payors money by assuring eligibility and coverage; preventing fraud, abuse, and over-utilization; and improving customer service by allowing the pharmacy to more efficiently process their claims. Yet HCFA refuses to even consider the value of an on-line claims adjudication system.

HCFA currently contracts with four durable medical equipment regional carriers (DMERCs) to process Medicare Part B claims. The customer service that the DMERCs provide leaves much to be desired. "Provider relations" staff members are often difficult to reach, may not return phone calls, and deliver inconsistent directions to community pharmacies. Moreover, the DMERCs do not communicate changes to the program in a prompt and effective manner.

The recent requirement that Medicare Part B suppliers accept assignment for all covered prescription drugs is a case in point. The requirement went into effect on February 1, 2001. Yet, the DMERCs did not directly communicate this change to our members. In fact, when several chain pharmacies called DMERC staff after February 1, many did not know of this change in policy. In addition, because Medicare does not operate an "on line" claims system, it is impossible for the pharmacy provider to know if the beneficiary has reached their $100 annual Part B deductible, or the "Medicare allowable" amount for a particular product being provided. It is extremely difficult for pharmacies to comply with changes in Medicare policy when DMERC staff are so poorly informed, and when the technology is such that simple,

basic information cannot be provided to pharmacies to help them better serve Medicare beneficiaries.

If the DMERCs operated in the private marketplace, these failures would not be tolerated. HCFA would have replaced the insurance companies that perform the DMERC function years ago. Yet, despite the concerns NACDS and other provider groups have expressed to HCFA, the problems with the DMERCs persist. HCFA needs to be reformed to be more responsive to provider-related concerns.

Conclusion

NACDS supports Congressional action to evaluate HCFA policies and programs, and how the agency's administration of these programs impacts beneficiary access to quality health care and the ability of providers to effectively and efficiently participate in the programs.

HCFA often times appears to make decisions contrary to its own rules and regulations. Moreover, it often fails to understand, or simply ignores, the impact of its decisions on the health care marketplace. Or, more critically, it just doesn't understand the marketplace. We recognize that HCFA may be overworked and understaffed. Congress and the Administration will have to decide how best to structure the agency for the 21st century, and the role that HCFA might have in administering any new prescription drug benefit for seniors. We look forward to working with you in addressing these issues in this Congress to make HCFA more responsive to the patients and providers that it serves. Thank you.