

S. HRG. 107-1038

**REGULATORY RELIEF FOR MEDICARE:
THE CASE FOR CUTTING RED TAPE**

HEARING

BEFORE THE

**COMMITTEE ON FINANCE
UNITED STATES SENATE**

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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(BOZEMAN, MT)

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CONTENTS

OPENING STATEMENTS

	Page
Baucus, Hon. Max, a U.S. Senator from Montana, chairman, Committee on Finance	1

PUBLIC WITNESSES

Trujillo, Alexander, regional administrator, Centers for Medicare and Medicaid Services, Denver, Colorado	4
Aronovitz, Leslie G., associate director, health care, U.S. General Accounting Office, Chicago, Illinois	6
Nordwick, John, president and CEO, Bozeman Deaconess Health System, Bozeman, Montana	8
Wolter, Dr. Nicholas J., chief executive officer, Deaconess Billings Clinic, Billings, Montana	10
Jardine, Jule, Livingston Health Care, Livingston, Montana	12
Henderson, Lori, Northern Montana Care Center, Havre, Montana	14

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Aronovitz, Leslie G.:	
Testimony	6
Prepared statement	25
Baucus, Hon. Max:	
Opening statement	1
Henderson, Lori:	
Testimony	14
Prepared statement w/attachment	35
Jardine, Jule:	
Testimony	12
Nordwick, John:	
Testimony	8
Prepared statement	60
Trujillo, Alexander:	
Testimony	4
Prepared statement	48
Wolter, Dr. Nicholas J.:	
Testimony	10
Prepared statement	63

COMMUNICATIONS

American Society for Clinical Pathology	75
Pluto, Luke A., M.D.	79

**REGULATORY RELIEF FOR MEDICARE:
THE CASE FOR CUTTING RED TAPE**

TUESDAY, MAY 28, 2002

U.S. SENATE,
COMMITTEE ON FINANCE,
Bozeman, MT.

The meeting was convened, pursuant to notice, at 10:15 a.m., in the MSU Foundation & Alumni Center Great Room on the Montana State University campus in Bozeman, Montana.

**OPENING STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR
FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE**

The CHAIRMAN. Okay, everybody, we're going to begin now. We have only two hours here so we want to make the best use of our time.

Good morning, everybody. First, I want to thank everybody who is here. Some of you have come great distances, some greater distances than others. I was just talking to one from Washington, D.C., she says she just loves this, this is the highlight of her year, she put it, to be here in Montana. I encouraged her to stay and not go back to Washington, D.C. She said she was going to see what she can do about that.

Today we're going to discuss how we're going to reduce paperwork regulations and red tape in Medicare, and focus more of our work on patient care. I know that's a goal of all of us involved in health care services, is how are we going to reduce some unnecessary red tape, unnecessary paperwork so we can focus much more of our time on patients and people.

Medicare, as we know, is one of the great success stories of America. It provides health care to millions of seniors, as well as disabled Americans. In our state, that's about 135,000 people. It is not Medicare who provides the care. It's Medicare services that are provided by our doctors and nurses and nursing aides, by physician assistants, physical therapists, lab workers to Montana seniors. It's also care by administrators, by billing specialists, insurance companies, all working in private-public partnership to ensure our seniors have access to quality affordable health care.

The role of Congress is to help make this partnership work. We must ensure that providers are fairly reimbursed for their services. And we must ensure that paperwork doesn't get in the way of patient work when providing quality care to the Montanans. Almost every time I meet with Montana health care providers, I hear one resounding message: excessive paperwork and constantly changing rules, which leaves people confused and sometimes angry.

A few years ago I worked a day at a hospital in eastern Montana. My boss was a nurse's aide named Sharla. Sharla showed me how to do everything from changing sheets to taking vitals and even removing stitches. When my shift was over I met with the administrative staff and they showed me an entirely different side of health care. They told me they lacked the staff to comply with all the rules. They said they put in 50 percent of their time on paperwork, up from 25 percent just 10 years ago. And they told me that paperwork was, itself, threatening patient work.

I expect we'll hear many of the same concerns today, both from our distinguished panel and from the audience. We will hear from representatives of physicians and hospitals, home care agencies and nursing homes. Across the spectrum of care, we'll hear how providers are trying to cope with the ever-changing regulatory requirements that is the growing spread of Medicare red tape. We'll also hear from CMS, that is the Center for Medicare and Medicaid Systems, and the general accounting office and they'll tell us how to fix it.

One of these providers is Mr. Nick Wolter from the Deaconess Billings Clinic, he'll describe difficulties Montana providers have had with reimbursement for air ambulance services. Air ambulance care is expensive. It should not be used when ground transport can be reasonably substituted. For the last several months, Deaconess Billings and Montana's other air ambulance providers have faced bureaucratic roadblocks in getting proper reimbursement for needed air ambulance services. I've tried for months to help resolve this problem. Clearly, Montana is a unique concern because of our great distances. I've been working with CMS and they have made some progress, but not enough, not enough to convince me that essential air ambulance services are reimbursed appropriately.

Last week I introduced to legislation to fix the air ambulance problem. My bill would ensure that good-faith efforts to provide critical emergency care will not be denied by bureaucratic hurdles. But the air ambulance problem is just one symptom of a larger, more serious diagnosis, namely, Medicare's regulatory framework has grown beyond the reach of what most providers can manage, especially providers in our state because we have smaller staffs and often no administrative staffs and, therefore, the burden falls upon the health care staff, the nurses and others and their job is the health care of the patients.

Last year, I introduced legislation to change that. I developed a bill to cut Medicare red tape and reform Medicare's interactions with health care providers. For example, the bill prevents Medicare from issuing new rules more than one business day of each month. This idea came straight from Montana, from one of our providers, who told me they don't have the staff to keep up with almost daily changes in Medicare rules, almost daily changes.

It also shifts resources allocated for Medicare fraud enforcement towards provider education. It's clear to me, after talking to a lot of people in the area, that CMS doesn't do a good enough job educating doctors and providers as to what the rules actually need to say and so forth. There's a lot of good faith, honest mistakes made and then the system tends to hurt those who do make honest, good faith mistakes. A lot of that could be prevented with a lot better

education. It's just not fair to hound health care providers for making honest billing mistakes, unless more efforts are made to educate providers on how to follow the rules.

These are just two of the many common-sense solutions of the bill. Today's forum is an opportunity for us to discuss additional ideas for preventing Medicare red tape. I intend to move this legislation out of the Senate Finance Committee later this year. It has broad bipartisan support and I'm confident it will be signed into law this year.

We have a full panel of experts here today. I look forward to the testimony of everyone. We also have a lot to hear from the audience, and I thank you for coming to participate. Your thoughts from the audience are just as important, and in some respects even more important, than the others here. We want to hear what you have to say because you probably have more than a kernel of good ideas in what you say and we want to follow up with it. And the bottom line here is for quality and accessible care for Montana seniors is working together as Montana's—it's good ol' Montana common sense, just get the job done, and I look forward to hearing from you.

Now a couple of administrative issues. We have to get out of this room by noon, so I urge all the witnesses to be brief and stick to 5 minutes. In fact, I'm going to have Andy—or John back here is going—why don't you kind of do something, say like 4 minutes—at 4 minutes—they can't see you though.

Here you are. Amber's going—she's our clock. So what are you going to do, Amber?

Ms. WILLIAMS. It will turn red when the 5 minutes is up. You will hear a beep.

The CHAIRMAN. So when 5 minutes is up, we'll hear a beep. And we're going to have to enforce it. And off the record.

[Whereupon, an off-the-record discussion was held.]

The CHAIRMAN. Our first witness, we're honored to have him here, it's Mr. Alex Trujillo. Alex is the regional administrator for Centers for Medicare and Medicaid Service of Denver. I know I don't have to say this, but for some of you wondering what in the world is that? That's the outfit that used to be HCFA. And now you're really going to wonder. HCFA, Health Care Finance Administration, is the arm of the Department of HHS, Health and Human Services, that delivers reimbursement to doctors and hospitals and so forth to provide Medicare services, that is health care services to our country's elderly. And in our state, about half the time or more than half the hospital reimbursement is through Medicare, it's that important. So Mr. Trujillo, the regional administrator, is the key guy in trying to help us solve these problems.

Mr. Trujillo is very gracious. He also told us he's going to stay in Montana for several days, up to a week, traveling around the state, getting to know people personally, hearing about the personal problems. I want to thank you very much, Alex, for making that gracious offer. You're on.

STATEMENT OF ALEXANDER TRUJILLO, REGIONAL ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DENVER, CO

Mr. TRUJILLO. Great, thank you, Senator Baucus. I really appreciate the opportunity to be here in Bozeman to talk about some very important issues in terms of regulatory burdens and what the requirements of Medicare are. And I know that many physicians, providers, Members of Congress have raised concerns about Medicare, particularly Medicare's regulatory and paperwork burden and the cost of doing business with Medicare. I'm also aware that these issues are extremely important to you, Chairman Baucus. And I know that you have spent a great deal of time working with CMS, in particular, with Administrator Scully, in trying to make Medicare a better business partner for providers.

Medicare's requirements, I think, are largely outlined in the law and they generate, I believe, many of the concerns that your constituents bring to your attention and to mine. Of course, there is a genuine need for rules in a program that is as large and as complex as Medicare. But rules should exist to help, not to hinder, our efforts in rendering services to these vulnerable populations that we deal with; the poor, the disabled and the elderly.

I'd like to very briefly discuss three goals that CMS has to make Medicare a better business partner: Goal number one is improving agency responsiveness. Since Secretary Thompson and Administrator Scully began last summer, one of their major goals has been to reform how Medicare does business. To promote and improve responsiveness in the agency is doing several things: Sponsoring open door policy forums to interact directly with beneficiaries, with providers, physicians and suppliers. Currently we have 11 forums that meet basically on a monthly basis. When Administrator Scully had been out here in August, there were 10 forums, but as he listened to you, he realized that he was missing one very key one and that was one on rural. And so that became the eleventh forum.

We're also enhancing outreach and education to beneficiaries and providers. Last fall we started by educating seniors through a \$30 million advertising campaign. We also have expanded 1-800-MEDICARE where it is now 24-7. We're responding more rapidly and appropriately to Congressional and external inquiries that come into us. The Agency is also developing and improving training for physicians and providers on new program requirements, increasing the number of satellite broadcasts to health care industry groups and making better use and greater use of web-based training. We also have toll-free lines at each one of our Medicare contractors.

Goal number two is easing the regulatory and paperwork burden. Last summer the secretary created an Advisory Committee on Regulatory Reform. This committee is helping to guide the Secretary's efforts to streamline unnecessarily burdensome regulations that interfere with quality health care for Americans. To support this initiative, we at CMS are focusing on listening and learning to get us on the right track. For example, Administrator Scully personally travels around the country meeting with literally thousands of providers, physicians, beneficiaries, to understand what their issues are so that we can make better changes that will reflect a respon-

siveness to that. We're listening, we're learning, but we're also taking action. We're committed to making common-sense changes and ensuring that regulations that govern our program not only make sense, but are plain and understandable.

We're taking concrete steps to streamline Medicare's regulatory processes, as well. We've developed a Quarterly Provider Update of all changes to Medicare that affect physicians and other providers, to make it easier for them to understand. The Quarterly Provider Update contains a list of all of the regulations that we expect to publish in the coming quarter, as well as the actual publications of those that just occurred in the past quarter. Additionally, we're publishing all of our regulations on a monthly basis, usually on the fourth Friday.

Our third goal is to improve physician and provider education. We recognize that our decentralized nature of our educational efforts has really been inconsistent as we go from contractor to contractor. We centralized responsibility for that educational effort in one division in central office.

On a national basis, we're providing free information, educational courses, and other services, to physicians and providers through a variety of advanced technologies. We're expanding our Medicare provider education Web site, which is www.cms.gov/medlearn. We're providing free computer and web-based training to doctors, providers, practice staff, and other interested individuals. We're establishing electronic newsletters on priority initiatives.

In conclusion, we recognize that physicians and providers play a crucial role in caring for Medicare beneficiaries. We share their concerns regarding the program's regulatory and paperwork burden and we're working hard to address them to bring openness and responsiveness to that process. The Secretary and the Administrator are committed to this effort, and so are the rest of us at CMS. We want to be better business partners. We appreciate your help in our improvement process, Senator. We look forward to continuing to work with Congress and we will continue to seek input from the health care community, as well as from our beneficiaries, and partners in reaching our goals. Thank you for the opportunity to come to Bozeman to discuss these issues with you today.

The CHAIRMAN. Thank you very much, Mr. Trujillo.

I'd like to remind all of us here, we have a real opportunity here today to try and make some progress on this problem, and we all know it's a huge problem, this excessive red tape, all the regulatory problems and the reimbursement, the whole process, it's very significant. So I urge all of us today during these two hours to just cut to the quick, get to the solutions here because we do have this time. The providers are here, Mr. Trujillo is here, I'm here, you're here, so let's see what we can do. Thanks.

We're honored now to have with us Leslie Aronovitz, who is the associate director, health, in the General Accounting Office. In fact, it's Leslie who is the one who told me this is the highlight of her year coming to Montana.

**STATEMENT OF LESLIE G. ARONOVITZ, ASSOCIATE DIRECTOR,
HEALTH CARE, U.S. GENERAL ACCOUNTING OFFICE, CHI-
CAGO, IL**

Ms. ARONOVITZ. Thank you so much, Mr. Baucus. Actually, it was quite the experience, we saw probably every animal in Yellowstone over the last 2 days, and most of them, I hate to admit at my age, never having seen most of them. Being a city girl, it's been quite the amazing, amazing place to be.

But I'm also very pleased to be here today from the General Accounting Office, GAO, which is an apolitical, an independent agency within the legislative branch of the Federal Government. GAO evaluates Federal programs for the Congress, and in that role, we've examined Medicare payment and management issues for quite a few years. My remarks today are going to focus on our findings on two reports that we've issued recently that deal with the challenges that physicians in the Medicare program face to ensure that claims for physician services are billed and paid appropriately.

We issued a report this past February that examined the quality of information that Medicare carriers provide to physicians on a routine basis, covering billing rules and Medicare policies. Our overall finding was not good. We found that carrier communications with the physicians were often incomplete, confusing, untimely, and even incorrect. For example, we found that carriers' bulletins, those are the documents periodically sent to physicians explaining Medicare rule changes, were typically over 50 pages with dense language that were not really organized very well, which made it very difficult to identify relevant or new information. And, unfortunately, the things that I'm telling you in this report are things you probably don't need to hear once again, but it is confirming in a more scientific way that some of your concerns are very, very well-based.

Sometimes we found that release of information by carriers gave physicians little or no notice, advanced notice, prior to a program change taking effect. We also found that carriers' Web sites were also out of date and lacked such key features as easy to use search functions. Now, Mr. Trujillo talked about the fact that CMS does have toll free lines, and we very much feel that that's an integral part of the program. And the fact that Administrator Scully is coming around and listening to providers is also an incredibly important aspect of their initiative. But we also feel that it's not just management of the program but the little customer service rep, who's answering the phone from—a provider in Gardiner, Montana has, has to be equally interested and knowledgeable about the program rules. And in that regard, we looked at the performance of Medicare's telephone call centers, these toll free lines for providers, and we tested the three carriers' call centers, not one in Montana or in—but in other parts of the country, by placing about 60 calls to provider inquiry lines. Our questions, which dealt with the appropriate way to bill Medicare in certain situations, were taken from the frequently-asked-question section of providers—of carriers' Web sites. So these are questions that people had asked over and over again and were confusing to people. We found that only 15 percent of the answers provided by the call center reps were complete and accurate enough for the physician to bill appropriately.

We found that about 35 percent of the time the answer was not accurate, and about 50 percent of the time the answer was only partially correct, but it was not enough information for the physician to take with them, or her, and be able to bill and get paid appropriately.

As you know, CMS is responsible for overseeing carrier operations. We have recommended that it publish one national bulletin with expertise in terms of how to arrange and write these bulletins so that physicians could easily identify program rules and changes. We've also stated that CMS should provide technical assistance to carriers to improve the quality and consistency of the information they disseminate. Now, we have very specific recommendations in each of the areas like Web sites and call centers.

The findings on our second report being released today, as a matter of fact, present much more hope in one area of physician payment and billing—physicians billing Medicare, and that is with the pre-payment and post-payment medical reviews, where physicians, hospitals, home health agencies and other providers has to on request provide medical records to support particular claims. We looked at the carriers' operation in six states, they were California, Illinois, Michigan, Minnesota, New York and Wisconsin. And we found very promising news and that is that in last year's data for these carriers show that CMS's reviews required physicians to submit patient medical records affected no more than 10 percent of the practices in those states, and in some states it was a lot less than that. So, the amount of burden or request for these medical records seems to be lessening, and also, of the claims where—of the practices where there were requests for information, it only averaged between one or two claims per request or per practice on prepayment review. Now, on post-payment review, it averaged about 30 to 40 claims, and that's understandable because that's an after-the-fact-look at a bunch of claims, to see if there's a trend or a problem. We also found that only about one-tenth of 1 percent of the practices were subject to a post-payment review, which is very important. And I'm going to talk about extrapolation later, which is a way that sometimes CMS projects the amount that's owed by a physician or other provider.

We found other good news on the medical review side, and that is that the decisions that carriers are making as a result of medical review are very, very accurate. We have heard concerns that providers said that even after they're burdened and submit their paperwork, that often the carriers make the wrong determination as to whether they're going to pay the claim after the fact or in prepayment. What we found is that, through an independent contractor that we hired with clinical expertise, we concluded that CMS and its carriers, its fiscal intermediators, were mostly on the carrier side, that we did the work. We're quite accurate in the decisions that we made—

The CHAIRMAN. I'm going to have to ask you to summarize in one sentence.

Ms. ARONOVITZ. In summary, I think that we're—I'm coming from this at the—the final analysis, we believe that there's an essential—that it's essential that CMS and its partners take the necessary step to strike a balance between safeguarding the program,

but also making sure that it doesn't place an undue burden on providers. Thank you.

The CHAIRMAN. Thank you, very much, Ms. Aronovitz. That was very, very helpful.

The next one to hear from, Mr. John Nordwick is administrator of the hospital here in Bozeman. I want to thank you, too, John. I was out at your hospital not too long ago where you showed me some concerns you have just regarding health care staff. I want to thank you for your hospitality.

So, well, okay. Now, you've heard from Ms. Trujillo, John, you've heard from Ms. Aronovitz, now it's your turn from your hospital point of view.

**STATEMENT OF JOHN NORDWICK, PRESIDENT AND CEO,
BOZEMAN DEACONESS HEALTH SYSTEM, BOZEMAN, MT**

Mr. NORDWICK. Thank you. My name's John Nordwick, I'm the chief executive officer of Bozeman Deaconess Hospital. Like most hospitals in Montana, we provide health services across the whole continuum of care. In addition to 86 acute care beds, we also operate Aspen Pointe, an independent living facility, and Birchwood, an assisted living facility. In addition, 66 physicians practice in the clinic buildings attached to the hospital.

I thank you for the opportunity to testify. The regulatory process has an enormous impact on health care in Montana, and I welcome this opportunity to share a few thoughts about how we can improve the system.

Regulatory requirements: An unfunded mandate. In my hospital, the amount of resources dedicated to implementing and complying with Federal regulations has grown enormously in the past decade, and with good reason. Since 1996, Congress has enacted several major pieces of legislation which has resulted in massive numbers of regulatory requirements.

For example, the Balanced Budget Act in 1996 resulted in more than 300 changes in the Medicare program alone. The Health Insurance Portability and Accountability Act imposed broad and far-reaching new privacy regulations and fundamentally alters the way we handle the billing process.

In addition, it's mandated by the BBA, the Department of Health and Human Services and involved numerous prospective payment systems for out-patient, hospital, home health and nursing home services.

DHHS has also made major changes in the Condition of Participation and set the licensure and certification requirements for hospitals. DHHS also modified a wide variety of current regulations, including those related to billing, coding, coverage and EMTALA. Each of these required hospitals to invest huge amounts of capital in computer hardware and software training, and additional staff. And taken together, they represent a virtual avalanche that threatens to bury a hospital.

In a study published last year, the American Hospital Association found that for every one hour of care delivered in an emergency room, one hour of paperwork was required. For every hour of surgical and inpatient care delivered, 36 minutes of paperwork was required. For every hour of skilled nursing care delivered, 30

minutes of paperwork was required. And for every hour of home health care delivered, 48 minutes of paperwork is required.

Meanwhile, on the revenue side of the equation, Congress has not approved funding to pay for compliance with all of those requirements and all of this staff time is devoted to paperwork. In fact, since 1996, Congress has set provider rate increases at less than the increase in our inflation.

The net effect of this has been to widen the gap between what Medicare pays hospitals and what we're forced to charge for services. In Montana, this gap grew from 230 million in 1997 to 275 in 2000. These losses are passed on to the privately-insured persons who live and work in our community and make up the difference by paying higher insurance premiums.

The bottom line is that the Federal Government has mandated a whole new set of regulatory requirements and given us, the people who have to implement these mandates, no vehicle for funding their implementations.

CMS's ability to Implement Congressional Mandates—we face a second challenge in dealing with this regulatory morass, CMS's inability to implement Congressional mandates in a timely fashion.

For example, Congress in 2000 authorized critical access hospitals to pay physicians an all-inclusive rate. This was to take effect for a facility fiscal years beginning in 2001. However, CMS still has not implemented the mandate and now says it can't implement it retroactively. What Congress intended to be a fix for CAHs has turned into a nightmare.

The scenario for HIPAA is remarkably similar. The HIPAA privacy regulations take effect on April 1, 2003, yet the Department of Health and Human Services still has not clarified a number of key issues that must be resolved before providers can actually proceed with the implementation.

As if this confusion weren't bad enough, if providers don't comply accurately with these requirements, we're considered to be in violation of Federal fraud statutes and subject to very expensive fines and other penalties.

Providers have the right to expect accurate, complete and timely instructions for implementing new rules. We should be able to get our questions, whether to CMS or the fiscal intermediary, answered in a timely fashion and we should be able to resolve our conflicts over these issues quickly and reasonably. Today, all too often, it's not the case.

I applaud the interest you've shown in addressing these concerns. I appreciate the initiative you have shown and developed in your regulatory reform bill. This bill is a good first step. Much more, again, should be done.

I would argue that the Federal Government should not be allowed to impose any new rules unless it also pays for their implementation. I would also argue that CMS and that fiscal intermediaries be held much more accountable for their performance in meeting Congressional mandates. And finally, I would argue that providers would support additional funding for CMS, if it is contingent on improved performance by CMS.

I recognize the important role the government has in setting standards for the health care system. However, there must be the

kind of balance in the system that ensures the interest of providers and consumers are both met. Thank you.

The CHAIRMAN. Thank you, John, very much. I appreciate that. Next is Dr. Nick Wolter, Billings Deaconess.

STATEMENT OF DR. NICHOLAS J. WOLTER, CHIEF EXECUTIVE OFFICER, DEACONESS BILLINGS CLINIC, BILLINGS, MT

Mr. WOLTER. Thank you. I would like to start by thanking you, Senator Baucus, and your staff for the amount of time you've been putting into looking at solutions for what clearly is a very complex set of problems. But a lot of good things have been done in your support of rural health issues and innovative programs of critical access hospitals. It's made a huge difference.

And also, to CMS, I think that the listening that has been going on in the last year has been healthy. Some of the changes in HIPAA that have recently been announced, some of the clarification and then follow-up reported in the release regulations. There's obviously an attitude about trying to do things in a way that works better, and we thank you for that.

Having said that, if I could just underscore a few things. Providers, physicians and nurses are very concerned about the paperwork. We just heard some statistics from John Nordwick. I saw a study recently. Nurses—that one of the major dissatisfiers of the nursing profession is the amount of paperwork. This, at a time where there is a severe nursing shortage. I also recently saw a survey done by the American Academy of Family Practice that indicates 15 to 17 percent of family practitioners will no longer see Medicare patients. Some of this is reimbursement-related, but much of it is related to regulation and botched regulation. At Deaconess Billings Clinic, we spend one-half million dollars per year on coding specialists to support our 180 physicians. We'll also be spending in excess of \$2 million implementing the HIPAA regulations. And I think the cost, in addition to the complexity of complying with this regulation, is driving people away from seeing this very important segment of our society, and this seriously needs to be dealt with.

If I could give just a couple of other examples of the things we deal with in the regulatory arena. One is preventive medical examines and codes. It's my understanding that when a physician sees a Medicare patient for preventive medical services, these cannot be billed at the same time that the physician is seeing a patient for actual medical problems. And this becomes very, very confusing. In the case of women, however, you are allowed to bill certain preventative tests at the time of a problem visit, but this is not true for men. And so it's very difficult for physicians to sort out how they should treat problems that are encountered at the time of a preventative exam. And we have received interpretations from the carrier, the medical director of our carrier, the Medicare regional office on these questions and it's been very, very difficult to sort out.

In speaking with some of the folks at the Montana Medical Association, they're very, very concerned about the extrapolation issue. How accurate is it? How can appeals be made about extrapolation—

The CHAIRMAN. Nick, do you want to explain extrapolation?

Mr. WOLTER. Yes. That's when a probe study is done of a number of claims, and if there is found to be a number of claims in the probe that are inaccurate, an extrapolation on that small number to a larger number of cases is made and can require payments back that may or may not be accurate if the extrapolation process isn't accurate.

And I think there are a number of people very worried about this and there do not seem to be good appeal processes to deal with extrapolation. And in addition, when new ENM codes are released for physicians, often these are not piloted in a way to make sure that they're workable. And so people find themselves dealing with new coding requirements that are difficult to interpret, and all of the sudden there's a probe study and an extrapolation done. And we would like to see these issues dealt with in Senate bill 1738, known as the MARCIA bill, if not somewhere else.

I'll touch quickly on local medical review policy, air ambulance has been mentioned. We have in well excess of a year received a number of downgrades related to air ambulance transport and I can't really go into all the details here except to say that those of us who feel we are experts in this area feel that any patients being transported appropriately are being downgraded to payment for ground ambulance. We've been unable to achieve any significant resolution on this issue.

For well over 1 year, a physician was not involved in the view of any of these cases. As we are now appealing these cases, we are finding that an excess of 40 percent of them are being quickly turned back in our favor indicating that something is wrong with the process up front. In addition, we're find very inconsistent advice is being given. Recently, we were given verbal advice to balance bill patients if they were not transported to the local—nearest local facility. We were the only organization given that verbal advice and in spite of our requests, we have not been given that in writing.

I think the most important point on the air ambulance issue is there is not a good appeals process in the Medicare system when a significant disagreement occurs about how something is being adjudicated. Rather you have to appeal each claim one by one, which is extremely complicated, expensive and frustrating, I think, both to the intermediary and to the provider.

I see that there's a red light up there.

The CHAIRMAN. Yeah, there is.

Mr. WOLTER. And so I'm going to close on my specifics there, except also to say that we have many regulations that tell physicians how to practice medicine, which room they have to be in when giving the services being provided, and we think it's time for some of that medical micromanagement be taken out of the system.

I appreciate the chance to comment on some of these issues and once again, I do appreciate the spirit in which CMS is beginning to try to address these issues.

The CHAIRMAN. Thank you very much, Nick.

Next up, Julie Jardine.

**STATEMENT OF JULIE JARDINE, LIVINGSTON HEALTH CARE,
LIVINGSTON, MT**

Mr. JARDINE. I'm Julie Jardine. You mispronounced my name.

The CHAIRMAN. I'm sorry.

Mr. JARDINE. I've managed a home health agency in Livingston for 13 years and I'm here to represent the Montana Association of Home Health Agencies. Thank you Senator Baucus and thanks to the Senate Finance Committee for inviting me to present testimony on regulatory relief issues for Medicare. I'm pleased to know that the Senate Finance Committee is working for health care providers, thus allowing us to focus our energies and resources on what we are trained and love to do, provide care to people.

The new Prospective Payment System for home health (PPS), OASIS data collection and submission, Open Based Quality Improvement reports and requirements, HIPAA compliance, the Home Health Advance Beneficiary Notices, medical review and denials, complex billing systems and the Culturally and Linguistically Appropriate Services Standard are some of the formidable and daunting burdens facing home health care delivery this year. Resources expanded to implement all of these regulatory burdens include money and staff time for education, policy implementation, development of quality monitoring tools and capital expenditures necessary to handle additional electronic data.

OASIS answers are used to determine our PPS payment rate and to monitor outcomes. The OASIS data collection is very time consuming. One agency in Montana found that the average time taken for staff to complete and document their OASIS assessments ranged from 42 minutes to one hour and 44 minutes.

In my written testimony, I have outlined some recommendations we have to streamline the OASIS requirements, particularly to require this data collection to Medicare clients only.

PPS has created many layers of additional regulatory complexities for agencies to deal with. Home health agencies have had to request literally hundreds of clarifications of CMS since the implementation of PPS. One example of this is the bundling of medical supplies into PPS payment. Our recommendation is that home health agencies only be responsible for providing medical supplies that are directly related to the patients' current treatment plan.

Medical review of claims has increased with PPS. Denials for technical reasons are just as time consuming to appeal as substantive denials. Our recommendation would be that CMS allow for resubmission of a claim when it is technically correct, rather than requiring that the claim go through the appeals process.

I want to thank you, Senator Baucus, for introducing the Medicare Appeals, Regulatory and Contracting Improvement Act, or MARCIA, as it addresses some of the issues I have mentioned with OASIS and technical denials. It is our hope that the MARCIA bill will be marked up by the Senate Finance Committee soon and passed this session.

Formal written notice is required to advise Medicare beneficiaries when the home health services they need will not be covered under Medicare using the HHABN form. This requirement is especially cumbersome for both the patient—when the patient has

both Medicare and Medicaid covering different aspects of their care.

The culturally and Linguistically Appropriate Services standard requires that we assess the needs of non-English speaking people in our community, have translation available at our expense and that we refrain from using family member for translation. We have very few non-English speaking people residing in rural Montana and translators who are not related to the patient are generally not available. Our recommendation would be that this standard be eliminated or at least allow a waiver for populations in which this is not a problem.

I would be remiss in my testimony if I did not at least touch upon one additional issue that weighs heavily on home health providers nationwide—that of the 15 percent cut currently scheduled for October, 2002. This relates to regulatory reform because our regulations continue to increase without adequate reimbursement to cover the costs. The GAO recently released data analyzing the potential impact of the scheduled 15 percent cut affecting Medicare PPS rates. As a result, CMS is in favor of keeping this 15 percent cut as they assert that home health agencies are making a profit of \$700 per episode. I can tell you that this is not the experience of Montana home health providers.

We greatly appreciate the sensitivity that you, Senator Baucus, have always shown the issues affecting rural providers. It is important for you to understand that our agency and others in Montana are at risk of closing if this 15 percent cut is allowed to go forward. This would severely limit access to health services for even more Montana residents.

In my written testimony, I have outlined numerous inaccuracies in the GAO study. We recommend that the 15 percent cut be eliminated.

We believe in being accountable for our actions and to those we serve. However, our industry is slowly suffocating from the weight of the burdens that have been placed on us. Many agencies in Montana lack the necessary funding and staff to ensure that adequate compliance with these requirements is met.

Finally, I would like to put my hospice provider hat on for a moment. For both home health and hospice providers, the limitation that only physicians can sign a plan of care because they give us orders is quite restrictive in rural areas. My recommendation would be that both the home health and hospice regulations be changed to allow nurse practitioners and physician assistants to write orders and sign a plan of care.

I have also included in my written testimony another issue related to skilled nursing facility rules for medication use that can be restrictive in providing quality hospice care.

In closing, I'd like to thank Senator Baucus for this opportunity to address the regulatory burdens of Medicare on home health agencies in Montana, and across the nation. I hope that the recommendations that we have suggested here are useful as Congress and CMS attempt to reform the system to a more user-friendly one.

The CHAIRMAN. Thank you very much, Julie.

Next, Lori Henderson, Northern Montana Hospital. Lori?

**STATEMENT OF LORI HENDERSON, NORTHERN MONTANA
CARE CENTER, HAVRE, MT**

Mr. HENDERSON. My name is Lori Henderson. I'm administrator of a 153 bed, long-term care facility. It's a hospital-based facility. However, I've been in nursing for 30 years and I've worked in a number of fields in the nursing area, acute care and long-term care.

Taking care of people, that's what nursing homes should be about. But more and more I find us focused on regulatory compliance and getting a good government survey. We spend too much time worrying about what the surveyors want instead of what our patients want. Our business becomes regulatory compliance and our customer is the Federal Government when we should have a vision of providing a safe home for our residents.

For every one rule that we mandated in 1970, there are now 25. At a cost of close to \$50,000, our facility pays one RN to do nothing more than complete MDS assessments and provide oversight to various staff for completing that form. The MDS is a form that is done to assess our long-term care residents and this book is one of the books that helps to define how to fill out that form. It's a very complex form and there's lots of regulations and definitions in it.

We're going to spend nearly a million dollars implementing HIPAA in the next couple of years.

Some of the things that have to go on with long-term care and surveys, we receive our survey report, our long-term care surveys, on a generated form, yet we are forced to respond back on the form by typing it because the state and Federal Government system doesn't allow us to—for electronic submission of the plan of collection. State surveyors are given ten days to generate a survey report, but facilities are given ten calendar days. Therefore, we are—end up working overtime and on weekends, and further stressing the staff who have already put in long hours.

The survey process is very complex. The surveyors themselves are frustrated. They contend that they're understaffed, that "I can't do a good quality review," and they even admit that some of the deficiencies they're writing need some help. For them, being understaffed is an acceptable excuse for not doing a good job. Of course, for us, if we're understaffed, it becomes a deficiency even if we don't do our own paperwork. The process is flawed and does need some revision and help and definition.

One of the things that we really contend with has to do with the interpretive guidelines as they relate to these statutes. Think about an 85-year-old woman who worked in a family-owned business until her dementia prevented her from participating. She's always been physically active and walked several miles a day. Because she has dementia, she resists staff attempts to help her with ambulation. The staff gave her a Merry Walker, which is a walker with wheels and a seat and bars surrounding it for stability, which she uses all day to get around our facility. However, the restraint interpretive guidelines state that this is a restraint and staff must complete a RAP, which is one of the things according to MDS, and that they document accordingly. This device is not a restraint for this woman. It is the best and safest assisted device that she could have and it liberates her to be incredibly mobile and very happy.

If we have a bad survey, we risk losing our CNA, our ability to train CNAs. In addition, our reputation is damaged because our results are soon publicized with or without the benefit of adequate review in fairness of due process. Those are on the internet and we also publicly put them out in our facilities, even if we don't agree with them.

While we don't disagree with external reporting, we are concerned with multiple major examples of inaccurate reporting that fuels the long-term care litigation problem. Survey reports have become fodder for litigation and there are record amounts of litigation in long-term care. Malpractice insurance has become unaffordable and unattainable and the dollars for those premiums are coming out of fixed rates that are used—that could be better used for patient care.

The amount of paperwork and documentation that we do in response to the regulatory and enforcement system is frustrating and further exacerbates our critical staffing problems. Our most precious resource, our staff time, is being diverted to do paperwork and documentation and away from patient care.

In January of this year, we had 29 people on our waiting list to get into our facility, yet we had 20 beds that were left open because we didn't have the staff to take care of them and admit more people. That's an injustice to our facility and the people in our community.

There's an interesting headline I must add. This past week, the Whitefish Pilot reported the closing of North Valley Nursing Home by Labor Day of this year. It's a facility managed as part of a community hospital. Why did it close? Was it poor management or poor care, tragedies and abuse? No, the facility has a reputation for good care, sufficient management, citation-free surveys and a good fiscal plan. They're closing because the rest of the organization can no longer subsidize their excellence—subsidize the losses in trying to deliver care in that kind of environment. They cannot afford their own excellence in the light of government regulatory and funding practices. It is government by the people, for the people. It doesn't feel like that sometimes.

The CHAIRMAN. Thank you, Lori, very much.

Okay. This is going to be a little different. I'm going to ask some questions of some of our panelists. Now, I want to encourage the panelists to also abruptly jump in here if any of you have some questions you want to ask of anybody. That is of any of the panelists or me or whatnot.

The goal here is to make best use of this time to try and get some solutions to these problems.

I begin by asking you, Mr. Trujillo, you heard the GAO report and it wasn't really all that thrilling, I'm sure, from your point of view. What about it, how much of that is accurate and what's being done? Let me just start the meeting as—the toll-free telephone calls, as she said, up to 60 percent, if I'm accurate, did not give complete answers for billing and it is the people on the front line, really, that is the tenacity of telephone calls of the CMS or of the fiscal intermediary or whatnot, that's the interaction, that's where it really counts. And so we all know it's a huge problem, as Mr. Aronovitz just documented it. What's the CMS doing about this?

Mr. TRUJILLO. Senator, let me—

The CHAIRMAN. And I heard your opening statement, which was helpful. But if you could directly address the concerns of this issue individually.

Mr. TRUJILLO. You bet. I think in terms of the information, we absolutely agree. It's got to be accurate so that people understand what needs to be billed, how it needs to be billed, et cetera. You know, this is a tremendously complex program. I think several of the individuals that testified said we got to find a balance, a balance between making sure that we're paying for the right services versus going overboard and being burdensome or creating situations, you know, where people are feeling like if they make a bad move then they are going to be investigated. I'm not sure where that balance is, but I think what we have attempted to do in looking at the report from the General Accounting Office, is to acknowledge that, yes, there are some issues there.

The survey that was done, which was the basis of the report, was done in February and April a year ago. And we think that a lot has changed since then. We believe that with Administrator Skully and Secretary Thompson, that we are on the right track in terms of trying to create a culture of responsiveness.

We have seen a number of areas, such as in the regulatory reform committee, that are seriously looking at saying, what are those regulations that are burdensome? I think in terms of making sure we're giving accurate information, we are working very, very closely with those customer service reps and we have established much, much better expectations and requirements that they understand what their job is. And we're conducting national training schools for those national service reps.

The CHAIRMAN. I'm going to ask that of Mr. Wolter, as well as Mr. Nordwick. You're both CEOs. What would you do if you had Mr. Skully's job, what would you do? How would you address this problem? You're in charge, you got carte blanche. By gosh, you're just—Mr. Skully calls you up and says, John, he says, we got a problem here and you're on the front lines, you know what the problems are, I want you to tell us what we should do here to appropriately balance out, you know, the rights of patients and taxpayers so that—fraud—this minimizes fraud. Yet at the same time, the main goal here is quality health care, people want to get quality health care. I know that you do and I know that all the providers want it, doctors and nurses, everyone does. What's the solution here?

I mean, 50 percent of your time filling out paperwork? I've seen some of the forms that the OASIS folks have, and it's almost this thick. I went through one and I said, oh, my gosh, who reads this stuff?

Mr. NORDWICK. I'm sure this is over simplistic, but we have to quit overreacting. And when there are issues or problems, I think we should address those issues or problems and not create more rules and regulations that—

The CHAIRMAN. So what would you do, positives, solutions?

Mr. NORDWICK. Well . . .

The CHAIRMAN. I know that's an unfair question. I'm asking you out of the blue here.

Mr. NORDWICK. There are so many—yeah. There are so many unintended consequences from these rules, and so I think, as much as possible, try and determine what those things are before, and I think it's the difficulty when providers are—part of the problem is the providers are coming up with solutions and saying, listen, there are going to be huge problems with implementing this and that's kind of disregarded because of the vested interests—you know, suspicion about vested interest that providers would have.

I think many times—I think we have a lot of well-intended things that just don't work when implemented. So I think listening to providers and trying to explore these unintended consequences.

The CHAIRMAN. Listening better is one. Nick?

Mr. WOLTER. I'll give you four that I think—

The CHAIRMAN. Four is better than none.

Mr. WOLTER. I know. Obviously, there needs to be a major streamlining of the regulatory situation and process. There should be some provider input into regulations. There should be better overall national guidance so that there's more consistency from one area of the country to another on the regulations that occur. And this is going to involve some better approach to contractor performance, which also should have some provider input. I think that would really help on the regulatory side. I don't think you cannot address payment issues as far as regulation goes because in a very real sense, I think the incredible cost of the program has driven it to use regulation to try to stay within some sort of a balanced budget.

And I think that what's happened over the years is that we've moved to a situation where one piece has been built on another. We still have significant rural inequities, so that rural areas beneficiaries receive less payment, and in many cases, less benefits than other places. As an example of that, it was announced with some pride that CMS would increase the inpatient payment rate by 2.75 percent. Every single district within Montana had its wage price index decreased at the same time so that in our organization we're going to see less than a one-half increase for our inpatient this year, even though 2.75 percent was the announced number. Which obviously means other areas of the country are getting more than 2.75 percent.

So over and over and over again, I think the payment system creates a lot of problems. And I'll come back to a recommendation on that in a minute.

I also think the benefit, obviously, has to be more universal and that's a whole other issue here. We do need a drug benefit, but we should start with low-income seniors and maybe some catastrophic coverages for everyone else. New technology is not covered very well. We do many a plannable defibrillators at Deaconess Billings Clinic. The cost of the device is less than the DRG payment for presentation and doing that procedure. And we could go on and on and on with this list, but we need a much quicker response to technology and medical decisionmaking than we have, which obviously involves payment again.

And then lastly, again, I think the issue here is ultimately financing. How are we going to afford a system which is so costly already? And I think that a real different way of looking at the

payment in Medicare has to occur if we're going to get back to solving some of these regulatory issues. That probably means that we should have some sliding scale premium payments for more well-to-do seniors, make sure that the low-income seniors get the coverage that they need, and maybe some sort of catastrophic coverage on the top. Otherwise, we're not going to be able to afford to deal with some of those issues. So those would be my corporate recommendations.

The CHAIRMAN. I would like to see if there's a way, if you can, to quantify to some degree this problem, assess it. And then set some benchmarks, you know, some dates by which we're going to see if we could reduce the problem by a certain percentage amount, actually over a certain period of time. Not be totally held to it, but at least to kind of drive us to an enforcement, if you will, to make a little progress here so we're not just talking about this all the time. Does that make any sense? This is an extremely complex area. It's difficult to quantify but yet we've got to do something here. The problems with the Whitefish closure, for example—and the trend is in the wrong direction. There's much more time on paperwork and less time on patient care. That trend is wrong. We want the trend to go the other way.

Part of the solution, I suspect, is something that John said, is the lack of technology, lack of reimbursement to the CMS, to the—you know, the software is not up to date and the staffing is not up to date. And I'm just going to say here that neither administration, the Bush administration or the Clinton administration, has asked for more money in this regard. They just—I'm not going to speculate why, but the fact is that they have not. And neither has Congress added on, even though it's necessary, and even though no administration, at least neither of the last two, have asked for any money to encourage. So it's kind—I'm trying to get a handle on this. Does anybody here know how we can start to get a handle on quantifying all of this? I guess you're our guy, Alex.

Mr. TRUJILLO. Thank you, Senator. You know, I think it is kind of like eating an elephant. It's so huge, you just cannot—

The CHAIRMAN. I'm glad you chose that animal.

Mr. TRUJILLO. It's not native to Montana. You wouldn't find it in Yellowstone.

But I think, you know, we somehow have to figure out how to cut it down to bite-sized pieces, and I think what Administrator Scully and Secretary have done is they have said, let's identify those very most burdensome regulations that are problematic. I mean, things like MDS, and we're seeing some movement on that that will be cutting down the requirement by about half because we recognize how much burden it is. But I think that becomes a start and that's what we've been trying to do for the past year, is to say what's the specific regulation that's problematic? What do we need to do to change it? Is it a regulation that's so based on legislation that we have to go to Congress and say, Congress, we need legislation to fix this? Or is it something that's within our own means to make a change? And so we have it identified.

Administrator Scully calls this really hitting singles. That very few of us have the opportunity to hit the home run and win the

game, but we can hit the singles and we can perhaps come out with that same result.

The CHAIRMAN. Well, that's a good idea. Let's start listing some singles here. What are some? I'm asking for remedies for either some base progress—or your point, you can't solve it all at once, let's take a step in time. What are some, Leslie? Do you have some ideas on both where we hit them and next, where we want to hit them?

Ms. ARONOVITZ. I think there might be two areas to start—well, actually not start but continuing. One of them have to do with holding carriers and this bunch of intermediaries more accountable for their performance. Evolving to that is contracting reform, which means letting contractors make a profit. Right now, it's very hard for contractors to have an incentive to give good answers and to make sure that people are trained and make sure providers get the right information and beneficiaries are paid what they need to because they're not allowed to make a profit on these contracts.

One thing is that GAO has said for years is that no insurance company would manage an insurance program the size of Medicare on a shoestring that CMS did. They have a 1 to 2 percent overhead budget, and that's nothing compared to what you need to do a really reputable job. And if there was a way to give carriers and fiscal intermediaries more incentives, that would help. But performance measures and making sure that CMS holds contractors accountable for what they're telling providers as for how they're viewing claims and denying claims is very important.

And the second area, I think, is what, Senator Baucus, you referred to in terms of program modernization. The IT, the information technology, that's being used right now in CMS is unbelievably old. Right now, the financial management system, it's not even a double-entry general ledger system. I mean, right now, the carriers for the fiscal intermediaries could tell a provider you owe this much in overpayments, and that wouldn't necessarily be the amount that CMS in Central Office thinks they owe.

So there's a lot of trouble with the financial management and even program information, knowing how much—how many service beneficiaries had. Right now, when CMS wants to do data analysis, instead of getting on a computer like you can and sit down on-line and get information you need quickly, sometimes it could take up to six weeks to get a CMS programmer to write a software program just to get management information on a certain issue. Those two areas, I think, really have to be address.

The CHAIRMAN. Okay. I've got contractor reform and program modernization. Those are two singles. Does anyone want to add to the list or subtract from the list of those two significant singles, accomplishments, and add priorities that we can start focusing on overall more than others? Here's your chance, speak up.

Mr. WOLTER. Well, those might be triples. How about things like clarifying a preventative exam versus a problem exam, and making that simpler to deal with? How about advance beneficiary notices, which is a morass for providers and really is an administrative issue which should be dealt with between the Medicare program and the recipient, rather than putting that burden on the providers.

I think one of the reasons Medicare boasts a low administration overhead is that much of the administrative burden is put into the provider community. And these are very discrete singles that could occur, and there are many others. A task force has recently been formed to look at regulation and identify, and it would be nice to see some very specific responses to those issues.

The CHAIRMAN. Okay. Those are two singles.

Mr. TRUJILLO. Senator Baucus, and I think one of the things that can be done and we think is in the right direction is a physician regulatory issues team. What they did is they basically met with physicians, identified about 25 very, very specific areas and said, you know, these are the areas we're working. The ADM is one, certificates of mental necessity. So I think there's some of that that's already occurring and we just need to make sure we keep feeding that so that we can continue to identify those areas that need to be focused on.

The CHAIRMAN. We're going to solve the air ambulance reimbursement problem. Frankly, I've been pretty frustrated about this, as a lot of people in this room. I just introduced legislation to try to move it because it wasn't being resolved between, you know, CMS and BFI and the providers. Certainly, the authority could solve it.

Mr. TRUJILLO. Well, we believe we've got some of the authority. It is a—let me just very, very quickly highlight what's happened since August and whenever the issue was brought up at the hearing in Billings.

We did have a team come out from Baltimore.

The CHAIRMAN. That's right. You're working with a doctor—I forgot his name.

Mr. TRUJILLO. Dr. Olson, who's right here.

The CHAIRMAN. Okay. Well, you're the man.

Mr. TRUJILLO. And I've got to say something here that Dr. Olson has done a tremendous job in meeting with the industry and, in fact, saying what do you think ought to be occurring. And, of course, we heard that. And then sitting down and coming up with a local medical review policy that we thought would provide additional information in terms of clarifying what is meant to be necessary in terms of the transport.

The CHAIRMAN. Can we give ourselves a deadline date when we are to have this thing solved?

Mr. TRUJILLO. Well, what we've done is that local medical review policy was put in place in January, and we've been monitoring the impact of it.

The CHAIRMAN. What's the date? We need a date.

Mr. TRUJILLO. Well, I'd say, I don't know, with 6 months worth of data—well, we've got 4 months worth of data right now.

The CHAIRMAN. Let me ask Nick Wolter that question. What's a reasonable time to get this thing solved?

Mr. WOLTER. Well, of course, we are so frustrated by how long this has taken. And quite frankly, we do agree, I think Dr. Olson has been trying very hard to come up with the improvements in the problem, which we appreciate. But we're a long, long ways away and I think if it's going to take legislation to get this taken

care of, that's where we're putting our efforts right now. We don't see solutions coming from CMS in this situation.

The CHAIRMAN. Well, this has been around too long for that, legislation. I'm going to solve it myself, if all of you don't together in the next couple months. You're not going to like my solution, but I'm going to come up with one.

Mr. TRUJILLO. Well, Senator, I know that Dr. Olson has been meeting with the industry periodically. And one of the things that Dr. Wolter and I talked about last week was the possibility of sitting down and looking from his perspective just exactly what are the facts, you know, in terms of—

The CHAIRMAN. That's—we've been at this for, it seems like, an eternity. It just should have been solved by now, in my judgment.

Mr. WOLTER. Just on this point, one thing I think—and I think this is probably a double since we're using baseball language. I think an appeals process that gets an issue identified and on the table where both sides can share their points of view, whether it's air ambulance or other issues that come up. The lack of effective administrative appeals processes in the program right now don't allow the right conversations to occur sometimes to solve problems. If we had that, I think we could solve a lot of problems more efficiently than what we have now. And I know that you and your staff are working on that and there is some language in the bill you've just introduced, which we appreciate.

The CHAIRMAN. Yeah, that's right. While I have you here, how would you design an ideal appeals process?

Mr. WOLTER. Well, I think it would go something like this. If there seems to be a set of issues so that a number of claims seem to pop up as some difference of opinion, so some threshold is reached so you have an issue to deal with, not one individual claim, there needs to be a body in CMS that has some independence that you can take the issue to; both sides can present their point of view, we can look at what's going on nationally, as well as locally, and some decision can be made as to the appropriateness of the appeal. And then ultimately, there needs to be access to the courts if an appropriate appeals process is used and there's still a difference of opinion.

You know, right now, you really cannot get issues of significance addressed either through a basic appeals process or through any access to the court.

The CHAIRMAN. I'd like to go back to contractor reform. I hear a lot about this, and Leslie said that part of it's carrots and part of it's sticks. What do you think the carrots and sticks would be and why isn't it working in health care? What do you mean by reform?

Ms. ARONOVITZ. When the Medicare program was established, the rules or legislation that enacted it required that insurance companies were the entities that would process claims and pay claims for services that were provided by physicians and other health care providers. We think that nowadays—and they do it without making a profit; they break even, basically. Now, it's not that there were a lot of incentives for carriers and fiscal intermediaries to do this. They get enough—well, supposedly they get enough money to contribute to the company's overhead and operations and all that. But

nowadays, contractors, especially really good ones, say there's no incentive anymore to stay in this business.

We think that there should be a lot more flexibility on the part of CMS. Number one, they should be able to contract with anyone, not just insurance companies, that could show that they know how to process claims and make these kinds of decisions. We're also doing a project right now in looking at the way CMS makes coverage decisions at the local level. We're evaluating this whole idea of the equity and consistency of decisions across states or across contractors. Because there's a lot of concerns that if you're a beneficiary in Montana, you might not be able to get services paid for that you can in different states. So we're looking at those issues.

But in terms of contracting reform, you should be able to contract with anyone that can provide services. You should have a contract that specifically states what performance measures you're going to hold the contractor to. Here's the amount of money you're going to give them and this is what we expect and this is how we're going to regularly evaluate your performance. Those concepts, although they appear kind of in a general sense right now, they don't appeal—appear strong enough to really create an environment where carriers and fiscal intermediaries have to be responsible and have the expertise to be responsible. And that's where I think we really need to go.

The CHAIRMAN. Other thoughts on contractor reform, anybody?

Mr. TRUJILLO. Well, Senator, I think that one of the good examples of what Ms. Aronovitz has said is really provider education. If we give just a set amount of money to a medical contractor to do the work, which is cost reimbursement, then there are going to be areas where they are going to need to back off of it. And I think that's what occurred over the years, is that the provider education became one of those areas that contractors backed off of so they could pay claims timely and so they could do the medical review. And I think that becomes problematic because the impact of that is a longer range impact.

The CHAIRMAN. We never have enough time in this subject. One more issue I just want to raise briefly and that is we're a little different in Montana, and that is in space, distance. There are a lot of reasons we're different, but that's certainly one of them. And it gets to the 15 percent cut in home health. I mean, it just—you know, I hear a lot and that, you know, because of our space and distances, traveling out to homes to do the work of home health and so forth, I would like a couple people on the panel to tell Mr. Trujillo how the uniqueness of our State really does not—it makes regulations that apply to us in Montana different than even the national average and whatnot. Give us some ideas and flavor so that Mr. Trujillo can take that back.

Mr. JARDINE. I can give you some examples in terms of cost to provide care for rural Montana. We in Park County have to serve Cooke City, which is a full 8-hour day for us to send a nurse to that locale.

The CHAIRMAN. Describe to us how far it is.

Mr. JARDINE. They have to drive from Livingston up the Yellowstone River and through the Park and back out to get back to that little corner of Park County. Now, granted, we don't go to Cooke City very often, but when we do it's quite costly and I would say that those are challenges that urban areas don't have to face.

The CHAIRMAN. Describe in a little more detail the drive from Livingston, Ms. Jardine.

Mr. JARDINE. We have buffalo to contend with and snow.

The CHAIRMAN. It's quite a drive.

[Whereupon, the testimony of the panelists was concluded and Senator Baucus took commentary from the audience.]

[Whereupon, the reported portion of the hearing concluded at approximately 11:24 a.m.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

For Release on Delivery
Expected at 10:00 a.m.
In Bozeman, Montana
Tuesday, May 28, 2002

MEDICARE

**Using Education and
Claims Scrutiny to
Minimize Physician
Billing Errors**

Statement of Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues



GAO-02-778T

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the challenges physicians and the Medicare program face in ensuring that claims for physician services are billed and paid appropriately. The General Accounting Office, an agency within the legislative branch that monitors the effectiveness and efficiency of federal programs for the Congress, has conducted oversight of the Medicare program for many years. With annual fee-for-service payments now totaling about \$192 billion, the Centers for Medicare and Medicaid Services (CMS), the agency responsible for administering Medicare, has an important responsibility to safeguard payments for health services delivered to elderly and disabled individuals by hundreds of thousands of providers. In its most recent audit, covering fiscal year 2001, the Department of Health and Human Services' (HHS) Office of Inspector General found that \$12.1 billion, or about 6.3 percent of fee-for-service payments, was improperly paid to Medicare providers.¹

However, physicians and other providers have raised concerns that Medicare's efforts to provide information on billing rules fall far short of the need for clear explanations of the program's increasingly complex coverage policies and billing requirements. Physicians have also raised questions about whether the program's enforcement of payment rules has imposed too great an administrative burden on those billing Medicare. In light of these issues, legislation before this committee seeks to address some of these concerns while maintaining effective payment safeguards.

We have recently completed two studies that examine aspects of the interactions between physicians and carriers—the contractors responsible for processing physicians' Medicare claims.² The first study, issued in February 2002, reviewed the information that carriers provide physicians about billing rules. The study we are releasing today addresses how carriers conduct medical reviews of claims to ensure compliance with those rules. Medical reviews involve a detailed examination of a sample of claims by clinically trained staff and require that physicians submit

¹Department of Health and Human Services/Office of Inspector General, *Improper Fiscal Year 2001 Medicare Fee-For-Service Payments*, A-17-00-02000 (Washington, D.C.: Feb. 15, 2002).

²In February 2002, we issued *Medicare: Communications With Physicians Can Be Improved*, GAO-02-249 (Washington, D.C.: Feb. 27, 2002). In conjunction with this hearing, we are releasing our report *Medicare: Recent CMS Reforms Address Carrier Scrutiny of Physicians' Claims for Payment*, GAO-02-693 (Washington, D.C.: May 28, 2002).

medical records to substantiate their claims. My remarks today will focus on (1) carriers' provision of information to physicians regarding Medicare's billing requirements and program changes, (2) carriers' scrutiny of physicians' claims selected for medical review because they are more likely to have billing errors, and (3) implications of Medicare's recent changes to claims review policies for physicians. (The details of how we conducted our studies are included in the two reports.)

In summary, our February report showed that physicians often do not receive complete, accurate, clear, or timely guidance on Medicare billing and payment policies. At the carriers we studied, we found significant shortcomings in printed material, Web sites, and telephone help-lines that carriers used to provide information and respond to physicians' questions. We concluded that CMS needed to initiate a more centralized and coordinated approach, and provide technical assistance to carriers, to substantially improve Medicare carriers' provider communications.

In the report we are releasing today, we examined the operations of three carriers that serve six states and process claims for about one-quarter of Medicare participating physicians. The vast majority of physician practices—at least 90 percent in fiscal year 2001—had no claims selected for medical review by their carrier. For the relatively few practices with any claims reviewed, the carriers typically requested patients' medical records for no more than two claims during the year. In an independent assessment we sponsored, carriers were found to be highly accurate in their decisions to deny, reduce, or pay claims in full. The overall level of accuracy was consistent across the three carriers at about 96 percent. However, improvements could be made in selecting claims for review that are more likely to be inappropriate, thereby making better use of program resources and reducing documentation requests to providers who have not made billing errors.

In fiscal year 2001, CMS revised its policy on conducting medical reviews under an initiative called Progressive Corrective Action (PCA).³ The policy directs carriers to differentiate among levels of billing problems and tailor corrective actions accordingly. It also instructs carriers to focus educational outreach on physicians who have experienced billing problems. Under PCA, carriers are to limit extrapolation—a process by

³HHS, Health Care Financing Administration, *Medical Review Progressive Corrective Action*, Program Memorandum Transmittal AB-00-72 (Baltimore, MD: Aug. 7, 2000).

which overpayment amounts are projected from a sample of claims reviewed—to those cases that involve major billing problems. In fiscal year 2001, the three carriers in our study virtually eliminated the use of extrapolation. As a result of this and other medical review modifications, the highest overpayment amounts assessed a physician practice by a carrier dropped substantially. The carriers in our study increased feedback to individual physicians concerning the results of medical reviews and how to bill appropriately in specific situations.

Background

Within HHS, CMS provides operational direction and policy guidance for the nationwide administration of the Medicare program. It contracts with carriers—23 in fiscal year 2002—to process and pay part B claims from Medicare physicians and certain other providers.⁴ To help providers bill properly, carriers are required to issue bulletins periodically that publicize new national and local Medicare coverage rules, inform providers of billing changes, and address frequently asked questions. In addition, they must use Web sites and maintain toll-free lines to disseminate new information and respond to physician inquiries.

Carriers are also responsible for ensuring that claims are paid properly. Few claims receive more than a computerized review designed to detect missing information, services that do not correspond to a beneficiary's diagnosis, or other obvious errors. However, in some cases, carriers review claims manually to determine, for example, whether the services physicians bill for are covered by Medicare, are reasonable and necessary, and have been billed with the proper codes. In the most thorough type of claims review, called medical review, clinically trained personnel determine a claim's conformance with payment rules by examining medical records submitted by the physician. Medical reviews can occur before a claim has undergone final processing (prepayment) or after the claim has been paid (postpayment).

⁴Part B covers charges from licensed practitioners, as well as clinical laboratory and diagnostic services, surgical supplies and durable medical equipment, and ambulance services. Part A covers hospital inpatient and certain other services.

**Substantial
Improvement Needed
in Carriers' Routine
Communications**

In our February report, we noted that carrier communications with physicians regarding Medicare rules and program changes are often incomplete, confusing, untimely, or even incorrect. We found that Medicare bulletins were often unclear and difficult to use. The bulletins from 10 carriers we reviewed were typically over 50 pages in length, contained long articles written in dense language, and were printed in small type. Many of the bulletins were also poorly organized, making it difficult for a physician to identify relevant or new information. For example, several bulletins lacked tables of contents and the information provided was not delineated by specialty or by states where it applied. Moreover, information concerning program changes was not always communicated in a timely fashion, so that physicians sometimes had little or no advance notice prior to a program change taking effect.

Carriers' other principal means of communicating information with physicians—Web sites and information call centers—also proved to be problematic. Our review of 10 Web sites found that only 2 complied with CMS content requirements and most did not contain features that would allow physicians to readily obtain the information they need. Sites often lacked logical organization, search functions, and timely information. To assess the accuracy of call-center-provided information, we placed approximately 60 calls to three carriers' provider inquiry lines. The customer service representatives rarely provided appropriate answers to our questions. The three test questions, selected from the "frequently asked questions" on various carriers' sites, concerned the appropriate way to bill Medicare under different circumstances. The results, which were verified by CMS, showed that only 15 percent of the answers were complete and accurate.

CMS has few standards to guide carriers' communications with physicians. While the standards require that carriers issue bulletins at least quarterly, they require little in terms of content or readability. This is also the case for Web sites, as CMS has done little, through standards, to promote clarity or timeliness of the information presented. Similarly, with regard to call centers, the agency has not established a clear performance requirement for accurate and complete telephone responses.

CMS is planning several steps to improve and monitor carrier communications with physicians. These include developing training for customer service representatives and maintaining a CMS Web site that contains, among other things, reference materials on billing changes. In our February report, we recommended that CMS adopt a standardized approach to information dissemination that includes the publication of

one national bulletin for physicians (supplemented with information from local carriers), performance standards for carriers' call centers, and requirements for carriers' Web sites to link to CMS's national information sources.

**Medical Reviews
Affect Few Physicians
and Result in
Accurate Payment
Decisions**

In addition to poor communication from the carriers, physicians have expressed concern about whether carriers apply excessive scrutiny to claims billed appropriately. In our study released today, we focused on the medical review of claims submitted by physicians to three carriers: National Heritage Insurance Company (NHIC) in California, Wisconsin Physicians Service Insurance Corporation (WPS), and HealthNow NY.⁵ Data from these carriers show that more than 90 percent of the physician practices—including individual physicians, groups, and clinics—did not have any of their claims selected for medical review in fiscal year 2001. Table 1 shows that about 10 percent of the practices that filed claims with WPS had a prepayment medical review, while this proportion was even lower at HealthNow NY and NHIC California. In addition, only about one-tenth of 1 percent of the practices for any of the carriers had claims selected for postpayment medical review.

⁵NHIC's California component is a large insurer with separate facilities that serve the northern and southern areas of the state. WPS, also a large insurer, has separate facilities in four states (Wisconsin, Illinois, Michigan, and Minnesota). In comparison, HealthNow NY is a small insurer that serves providers in upstate New York.

Table 1: Physician Practices Whose Claims Received Medical Review, Fiscal Year 2001

Medical review	NHIC California ^a		WPS ^b		HealthNow NY	
	Number	Percent of total ^c	Number	Percent of total ^c	Number	Percent of total ^c
Prepayment	5,580	7.4	13,732	10.1	1,270	4.3
Postpayment	113	0.1	80	0.1	33	0.1

Note: Physician practices were identified by the Medicare Provider Identification Number (PIN).

^aThe number of practices shown include data from northern California for November 2000 to September 2001 and from southern California for December 2000 to September 2001.

^bWPS prepayment data include reviews in Illinois, Michigan, and Minnesota only; data were not available for Wisconsin. Postpayment data include Illinois, Michigan, Minnesota, and Wisconsin.

^cBecause a list of active PINs was not available from NHIC California, we estimated the total number of solo and group practices in California based on data from the most recent American Medical Association census of group medical practices, adjusted for increases in the total number of nonfederal medical doctors as of December 31, 2000, and the number of osteopaths in the state.

^dPercentages are based on lists of active PINs obtained from the carrier.

Source: GAO analysis of carrier data, and physician practice data from the American Medical Association and American Osteopathic Association.

Further, for most of the physician practices that had any claims subject to medical review in fiscal year 2001, the carriers examined relatively few claims. For example, at each carrier, over 80 percent of the practices whose claims received a prepayment review had 10 or fewer claims examined and about half had only 1 or 2 claims reviewed. The typical number of claims per practice that received a postpayment review was 30 to 50.

For those claims that carriers selected for medical review, we found that carriers' decisions were highly accurate regarding whether to pay, deny, or reduce payment. To assess the appropriateness of clinical judgments made by carriers' medical review staff, we sponsored an independent review—by a firm that monitors claims payment error rates for the Medicare program—of the three carriers' payment decisions. This review included samples of physician claims from each carrier that were selected randomly from all claims undergoing either prepayment or postpayment medical review in March 2001. The independent reviews validated the carriers' decisions for almost all claims. As shown in table 2, the carriers and reviewers agreed that the original decisions were correct in 280 of 293 cases examined, or about 96 percent of the time. Carrier decisions tended to be least accurate when they partially reduced payment amounts. In 5 of 59 claims where carriers denied payment in part, our reviewers

determined that the claim should have been denied in full, reduced by a smaller amount, or paid in full.

Table 2: Accuracy of Carrier Medical Review Decisions on Physician Claims (percent)

Carrier decision	Accurate decision rate (percent)		Inaccurate decision rate	
	Overpayment (percent)	Underpayment (percent)	Overpayment (percent)	Underpayment (percent)
All decisions on sampled claims* (n=293)	95.6	2.7	1.7	1.7
Deny in full (n=64)	98.4	0.0	1.6	1.6
Deny in part (n=59)	91.5	1.7	6.8	6.8
Pay in full (n=170)	95.9	4.1	0.0	0.0

*Claims randomly selected from all carrier prepayment and postpayment reviews during March 2001. Although 100 claims were selected from each of the three carriers, five claims from WPS and two from HealthNow NY were excluded either because the billing entity did not meet our definition of physician or because documentation from the carrier associated with the claim was unavailable or not interpretable.

Source: GAO analysis of independent review results.

To avoid payment errors, carriers should target for medical reviews those claims most likely to be billed inappropriately. After identifying and validating a suspected billing problem, they develop computerized edits—instructions programmed into the claims processing system that identify a set of claims meeting specified characteristics.⁶ Although carriers' reviews produced highly accurate payment decisions, their selection of potentially erroneous claims left opportunities for improvement. We examined fiscal year 2001 data on carrier edits used for medical reviews conducted before a payment decision is made. Specifically, we looked at denial rates—the percentage of claims selected for review for particular reasons that were denied, in full or in part—and the average value of the amount denied. We found that denial rates for the edits that accounted for the largest number of claims reviewed by the carriers varied considerably. CMS does not provide information to carriers programwide on criteria for selecting claims to review that have proven to be effective, nor does it encourage carriers to share information on their most productive criteria. These actions could lead to more effective claims reviews with potential

⁶Some edits focus on billing codes for certain clinical procedures; others focus on the frequency with which services are delivered. Carriers develop edits based on their analysis of billing data or other factors that suggest a pattern of erroneous billing, followed up by medical reviews of small samples of claims selected by the edit to test the validity of identified problems.

reduction in inappropriate Medicare payments, better investment of administrative resources, and less burden on providers.

**Under PCA,
Physicians Had Lower
Repayment Amounts
Assessed and More
Individualized
Education**

Carriers in our study conducted postpayment reviews for about 0.1 percent of physician practices. However, individuals involved in such reviews have raised concerns regarding carrier procedures. We found that, since implementation of CMS's revised medical review policy—PCA—in fiscal year 2001, the carriers in our study have adopted a more strategic approach to medical reviews, particularly postpayment reviews. As PCA has been applied to these reviews, carrier requests for documentation from physicians and assessments of amounts to be returned to the program have declined, while efforts to educate physicians individually about appropriate billing have increased.

The following components of the PCA initiative are designed to ensure the effective use of carriers' medical review resources and improve physicians' ability to achieve compliance with program billing rules:

- **Differentiating billing errors by levels of concern.** Carriers are instructed to conduct a "probe" medical review—examining a small sample of a practice's claims—to determine whether a suspected billing problem exists. After taking this interim step, carrier staff classify the billing problems identified in the sample as belonging to one of three levels of concern: minor, moderate, or major. For example, minor concerns can include cases where the percentage of dollars billed in error is small and the billing physician does not have a history of filing problem claims. In contrast, major concerns can include cases where the percentage billed in error is high, or moderate if the physician has not responded to carrier education efforts to correct previous billing problems.
- **Tailoring corrective actions to the seriousness of the billing errors identified.** Across all levels of concern, PCA directs carriers to contact physicians individually to discuss their particular billing problems and to recover payments for erroneous claims. For minor concerns, education may be the principal action the carrier takes. For moderate concerns, carriers may also medically review a portion of the physician's claims prior to payment for a set period of time. For major concerns, carriers may go one step further by reviewing another larger postpayment claims sample in order to estimate and recover potential additional overpayments.
- **Educating physicians about appropriate billing practices.** Carriers must inform physicians and their staffs about billing rules to prevent the

fiscally troubled program while not placing an inappropriate burden on physicians.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions that you or other Committee Members may have.

**Contact and
Acknowledgements**

For further information regarding this testimony, please contact Leslie G. Aronovitz at (312) 220-7600. Rosamond Katz, Hannah Fein, Jenny Grover, Joel Hamilton, and Eric Peterson made contributions to this statement.

TESTIMONY OF LORI HENDERSON

For the record, my name is Lori Henderson. I reside in Havre, Montana and have been employed by Northern Montana Hospital for 24 years. I am the Administrator of Northern Montana Care Center, which is a 153 bed hospital based skilled nursing facility and is a department of Northern Montana Hospital. Northern Montana Hospital is a non-profit community hospital, licensed for 49 beds. My 30 year career in the health care field covers everything from being a CNA; to a Registered Nurse in Emergency, Critical Care, Pediatrics, Outpatient Surgery, Office Nurse, Long Term Care and Quality Improvement and Risk Management. I have been the Administrator of this facility for nearly 5 years.

Health care is a world where "more is better" – except in terms of resources. Those needing health care think "more is better" – they want the best possible care. Those regulating health care also think more is better and pile on regulatory requirements to assure we provide excellent care and do not commit fraud. But those who pay for health care continue to challenge us to do more with less.

Increased regulation increases costs to the health care system. The scope of government regulation and the costs associated with it have skyrocketed. State and Federal mandates have increased 25-fold from 1970-1996, an annual growth rate of more than 15%. Worst of all, the vast majority of these mandates are unfunded. Much of the regulation we are subjected to can best be described as excessive, duplicative or unnecessary. Examples include:

1. At a cost of close to \$50,000 annually, we have one full-time RN who is doing nothing more than completing MDS assessments and providing oversight to various staff on the proper procedures of form completion. If the forms are not completed correctly, the facility risks survey deficiencies AND there is an impact on our reimbursement. The MDS process for long term care and the OASIS process for home health care was very costly for facilities to implement. It is a very complex and labor intensive process. There are simpler and easier ways to assess our patients.
2. Our facility has 3 employees who spend a minimum of 4 hours a week each reviewing the HIPAA guidelines and working with all departments to comply with the ever changing rules that the government will soon be enforcing. Our current fiscal estimate to comply with HIPAA will be close to a million dollars. The experts tell us that nationwide, HIPAA alone will add billions of dollars in new compliance costs to the healthcare system.
3. Family members are distraught and overwhelmed by the complex rules of Medicare billing and Medicaid application.
4. We were JCAHO accredited for 19 years, yet surveyors sent by the federal government still visited our facility annually—basically to second guess the work of the most highly respected accrediting body in the

country. CMS gave deemed status to every entity except long term care. It works for hospitals, home health agencies, labs, outpatient clinics and services. Are those patients or services less important? In my experience, the intensity of the survey process and caliber of surveyors in the JCAHO process is superior to those in the CMS process because JCAHO sends physicians and administrators as well as nurses into the field. Despite this excellent process, we dropped this accreditation in 1997 because without deemed status, it is a duplicative process.

5. We receive our survey report (the 2567) on a computer generated form, yet we are forced to respond back on that same form by typing on it because the state and federal government system does not allow for electronic submission of our plan of correction. We are even told that we cannot attach separate sheets (computer generated) to the 2567—we MUST type on the form. This antiquated system is taking time that anyone would agree could be spent better.
6. State surveyors are given 10 WORKING days to generate our survey report, but facilities are given 10 CALENDAR days to develop a plan of correction in response to the survey findings. If we receive our survey report on a Friday (and this is most often the case), we end up paying our key staff overtime on the weekends to be sure our plan of correction is filed on time. Again, not a good use of our already over-taxed staff or of our overtime pay.

Long Term Care facilities are much like the people they serve. Our elderly are on fixed budgets—their social security or retirement checks. Every time the price of medications or the cost of living goes up, something must be sacrificed because there is just so much money. Facilities such as ours whose payor base is 80-85% Medicare & Medicaid, are essentially on fixed incomes as well. The difference is that for the nursing home, the paycheck (reimbursement) has steadily shrunk while our cost of living (supplies, salaries, regulatory compliance) have gone up dramatically. Something has to give. I'd suggest that what should go is excessive, complex and duplicative regulations which drain both staff and financial resources at the expense of patient care. Every dollar we save by identifying and eliminating unnecessary regulation is a dollar that can be spent on our patients and staff.

As an Administrator, I work with a multi disciplinary staff to create an organization that is customer focused, and tries to operate efficiently to ensure ongoing services for our elderly. Even before I put on my Administrator's hat, I am a nurse—first and foremost, I am a nurse who is an ardent patient advocate. I am a patient advocate whose goal is to promote the health and well being of the people I'm entrusted to serve. We have a responsibility to follow standards of care and to appropriately document the care delivered. Taking care of people—that's what nursing homes are about. But more and more, I find us focused on regulatory compliance and getting a good government survey. Sometimes it seems we spend more time worrying about what the surveyors want than what our patients want. Our business becomes regulatory compliance and our customer is the federal government when we should have a vision of providing a safe home for our loved ones. As an Administrator and as a nurse this is alarming.

We find ourselves documenting our documentation to make sure that we are not only complying with the regulations but that we can prove we complied. We have no choice but to focus on the regulatory system. If we have a bad survey, we risk losing reimbursement and the ability to train CNAs. In addition our reputation is damaged. If you can't train CNAs, you can't recruit and hire more staff and if you can't hire more staff, you are understaffed, therefore out of compliance with regulations. It's a vicious cycle.

To add insult to injury, there also seems to be two standards of expectations when it comes to staffing. State surveyors contend that they are understaffed and therefore, can't do a good job with quality review of the Survey deficiencies they're writing. (State surveyors also have bosses and it all starts in Washington, D.C.). They admit that some deficiencies are being written because of new, less experienced surveyors and because of lack of quality review. But we are then forced to spend time and money disputing these inappropriate findings. For them **being understaffed** is an acceptable excuse for not doing a good job. Of course, if we fail to meet any standard – including those involving paperwork and documentation – we are cited for deficient practice.

This doesn't mean I believe that all regulations are bad, but for skilled nursing facilities there are countless Federal regulations and many are vaguely defined. In addition, there are endless interpretive guidelines and memos and issuances that affect us. Subjective interpretations by individual surveyors and second-guessing of the professional judgment of attending physicians and staff are not unusual. Think about the resident who is 85 years-old and worked very hard in a family owned business until her dementia prevented her from participating in that entity. She has always been physically active and walked several miles a day. Now, due to advanced age and frailness, she is walks unsteady without an assistive device. Because, she has dementia, she resists staff attempts to help her with ambulation. The staff gave her a Merry Walker (a walker with wheels, a seat and bars surrounding it for stability), which she uses all day long to motor around the facility. However, the restraint interpretive guidelines state that this is a restraint and staff must complete a RAP (Resident Assessment Protocol) and document accordingly. This interpretation of the restraint regulation has added complexity and work unnecessary to a common sense intervention for resident care. This device is not a restraint for this woman, it is the best and safest assistive device she could have. It allows her to be incredibly mobile and very happy.

The process is flawed. All too often the outcome of a facility survey is dependent on the interpretation of the regulations by a given surveyor to determine whether or not the facility meets conditions of participation. The interpretive guidelines that surveyors use in determining compliance with the statutes, have taken on a life of their own. They are being used as having the force and effect of regulations, without the benefit of the rule making process. If the facility does not agree with the survey findings, then there is no timely or affordable mechanism to resolve the dispute. Our facility has experienced this first-hand and it feels like there is limited or no due process. And, this negative information is still available to the public in a variety of reports via the Internet – despite the fact that the findings are being disputed. In our

case this has gone on for four years and is still ongoing. If it is ultimately determined that the survey was in error, will there be a retraction by the government?

While we don't disagree with external reporting, we are concerned that inaccurate reporting has fueled the long term care litigation problem. Survey reports have become fodder for litigation, and there are record amounts of litigation in the long term care arena. Malpractice insurance has become unaffordable and unobtainable. The dollars for those premiums are coming out of our fixed rates that should be going for better patient care.

It probably comes as no surprise to you that Montana's nursing facilities are in crisis mode when it comes to finding and keeping qualified nurses and CNA's. The amount of paper work and documentation we do in response to the regulatory and enforcement system exacerbates our problem. Our most precious resource – our staff's time – is being diverted to paper work and documentation and away from patient care. We were also kept from training CNA's for 2 years because of survey findings that we disputed. The dispute is still unresolved. The ability to train CNA's is an important part of keeping our facility properly staffed and providing high quality care. A regulatory system that keeps us from recruiting and training staff is simply wrong – it's not good for our facility or for our patients.

In January of this year, while 29 members of our community were on a waiting list for nursing home beds, 20 of our beds stood unoccupied because we could not hire sufficient staff to care for more patients. At times like that it would be nice to be able to set aside some of the paper work and devote all of our staff resources to patient care—but we can't. Regulatory compliance marches on, even when we are turning away those who need care. Given our staff shortages it would also be nice to be able to pay more. We pay our CNAs and other professional staff what I feel are inappropriately low levels for the work they do. We lose our CNAs to fast food jobs or agency nursing "pools" that charge facilities three times the going rate. We have found that when we are forced to hire agency staff, that the ultimate cost is not what we have to pay them but in how they care for our residents. They don't have a vested interest in the facility, the resident, or the community. They are there for the money and sometimes are not prepared to handle the challenges of long term care.

CNAs are not fast food workers. We are expecting people who often have no more than a high school education to exercise various forms of clinical judgement and to be responsible for loving care of our elderly while functioning as an integral part of a team of professionals. We find ourselves in the paradoxical clutches of a society which seems to place a higher value on the skills of professional athletes who earn millions of dollars a year while at the same time entrusting those who form the backbone of our heritage—our elderly—to someone who earns \$7 an hour.

On the other side of the coin—the reimbursement and billing side—there are also many issues. Medicare and the rules for proper billing procedures are a nightmare. In my experience, while trying to help family members understand the maze of Medicare coverage for long term care, I find that resident, spouse or family members' eyes quickly glaze over. It is simply too complex for them to comprehend and most people are under the misconception that Medicare will help them with their long term care bills. They are astounded and dismayed when they learn that Medicare covers only for a very

limited time and only when a multitude of very specific criteria are met. One of the criteria involves the Resource Utilization Groups or RUGS. There are 44 RUGS under Medicare, however only 26 are considered under the skilled criteria--and they will only pay if very detailed documentation exists in the medical record. The government spends countless dollars auditing this process to make sure that all the "i"s are dotted and the "t"s are crossed or they will not pay the facility. The entire system for documenting the RUGs classifications of Medicare patients and for processing Medicare claims, is extremely complex. It is difficult for providers and patients to know what is expected. It is easy to make mistakes. But, if the government believes that the facility is making too many mistakes there can be denial of payment or worse yet, the Administrator or the facility will be accused of fraud and abuse. As an administrator who would never intentionally submit incorrect documentation or billing, I find the process both intimidating and frightening.

Understandably, family members are even more distraught and overwhelmed by the complex rules of Medicare billing and Medicaid application than providers are. I wonder how many Medicare billing services there are in Montana--how many people make their whole livelihood helping an elderly person who has arrived on their business doorstep with a cigar box full of incomprehensible EOBs, bills, and forms that need completion.

One of the most difficult things I do as an administrator is to explain to an elderly person (or spouse) that Medicare does not pay for their long term care stay. Many of our elderly and their families believe they have coverage. The government needs to do a better job of letting our older citizens know that Medicare is not a likely payor source for their long term care needs. Better information and incentives to provide for themselves through long term care insurance are needed.

The current regulatory environment has accomplished the following:

1. Adversarial working relationships between facilities, the fiscal intermediaries, survey agencies, and other entities. The focus is on the wrong customer and we are all guilty of losing sight of the real customer. The goal should be a collaborative approach to optimizing patient outcomes and quality of life. Most nursing homes provide good care despite the financial, staffing and regulatory burdens they face. We need help--not criticism, accusations and confrontation.

2. Tremendous cost and waste of very valuable, limited, and disappearing resources. Scarce resources are wasted when regulations are excessive, duplicative and miss their mark in terms of promoting quality care.

Solutions:

1. States must be allowed and encouraged to obtain waivers for pilot projects designed to improve the nursing facility survey and enforcement process. These projects should aim to change the tenor of the process from its current punitive approach to one of collaboration where "best practices" are developed, encouraged, and shared by surveyors and facilities and customer satisfaction is taken into account. This is a process begging for innovation and common sense. A frontier state like Montana suffers when a "one size fits all" approach is used. One size does NOT fit all.

2. Allow states to determine whether deemed status for nursing homes will work in their states.

3. Improve the appeals process to afford nursing facilities due process through an objective, timely and affordable avenue to dispute survey findings with which they disagree.

4. Change the nurse aide training requirement to allow nurse aide training by and in facilities once the deficiencies that led to the loss of training are corrected.

5. Regulatory requirements should be set out in properly adopted regulations—not in interpretive guidelines, memoranda and issuances which can be changed with the stroke of a pen by CMS staff.

6. Focus public debate about nursing homes on real problems and real issues—such as staffing and financial issues. The tendency of some in congress to sensationalize poor care in a small minority of facilities around the country does a disservice to facilities—but more importantly to our patients and our hard-working staff. We will not be able to hire staff if the level of the discourse does not change to more productive approaches. The enforcement process must focus on how to punish the bad facilities and reward the good ones.

7. Level the playing field by setting standards for nursing pools/agencies. Such standards might include setting an upper limit on their charges, requiring them to provide a reasonable percentage of their staffing for night shifts, weekends and holidays; and, by tightening up their requirements to ensure that the caliber of people who become travelers are well trained and have clean back grounds.

8. Consistent definitions, i.e. the 10-day time frame for writing and responding to deficiencies should be the same for the state surveyors and facilities—work days for both.

9. Allow us to computerize the way we submit our plans of correction instead of forcing us to manually “type” or cut and paste onto an archaic 2567 form.

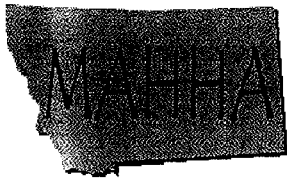
10. Simplify the MDS (minimum data set) form and requirements.

11. Clarify the role of the attending physician in nursing facilities, giving deference to diagnosis and treatment decisions of the attending physician except where substandard practice is alleged—in order to minimize “second-guessing” by non-physician surveyors.

12. Do more to educate seniors about the limitations of Medicare in paying for long term care and about the need to explore other options such as long term care insurance.

13. Provide strong incentives (perhaps tax credits) for the purchase of long term care insurance by seniors or their families.

Health Care providers have no problem with standards that truly improve care. We have no disagreement with prompt punishment of those who abuse patients or the payment system designed to support their care and well being. What we do object to is the frequent and recurrent practice of government agencies making broad sweeping regulatory initiatives, which are poorly funded and are not founded in the practical aspects of our day-to-day work. A single or a few incidents of poor care are assumed to include all nursing homes and ultimately punish an entire industry. Increased regulations often only serve to impede or actually impair the efforts of those of us, like NMCC, who provide good care to patients.



Montana Association of Home Health Agencies

May 28, 2002

Thank you, Senator Baucus and the Senate Finance Committee for inviting me to present testimony on regulatory relief issues for Medicare. On behalf of the Montana Association of Home Health Agencies, I would like to address the issue of the regulatory burdens for Home Health Agencies. I am pleased to know that the Senate Finance Committee is working for health care providers, thus allowing us to focus our energies and resources on what we are trained and love to do...“provide care for people”.

The new Prospective Payment System for home health (PPS), OASIS data collection and submission, OBQI reports and requirements, HIPAA compliance, the Home Health Advance Beneficiary Notices, Medical Review and denials, complex billing systems and the Culturally and Linguistically Appropriate Services Standard are some of the formidable and daunting burdens facing home health care delivery this year. The amount of resources that agencies are required to expend to implement all of these regulatory burdens is very overwhelming to all providers. These resources include money and staff time for education, policy implementation, development of quality assurance tools, and capital expenditures necessary to handle additional electronic data.

OASIS

OASIS requires that all Medicare certified home health agencies obtain assessment information on all home health beneficiaries with the exception of those who are pregnant or less than 18 years of age. To give you an idea of the volume involved, the OASIS regulation manual consists of three parts. Part I of the implementation manual comprises six 3.5 floppy discs. Part II is 168 pages and covers the data submission process for agencies. Part III is an optional section that deals with the free governmental software. OASIS answers are used to determine our PPS payment rate and to monitor outcomes. Thus, accuracy of OASIS assessments is essential. This has required extensive staff training sessions and the implementation of quality improvement auditing processes.

The OASIS data collection is very time consuming. One agency in Montana performed a time study in early 2001 to identify the actual time spent. They found that the average time taken for staff to complete and document their OASIS assessments ranged from 42 minutes for discharge assessments to one hour and 44 minutes for the start of care OASIS assessments. In addition,

they found that the average training time for new staff on proper comprehensive assessments and completion of the form was 10 hours and 45 minutes. The average time for clinical supervisory or Quality Improvement staff to review each assessment to validate the information before it is transmitted to the state was 54 minutes.

Montana Home Health providers would like to recommend the following regulatory reform for OASIS:

1) Limit the collection of OASIS data to Medicare patients only.

- In addition to the fact that Medicare does not pay for the services delivered to other patients, agencies must frequently make nonbillable visits to patients with other payors to collect the OASIS-required data. This is such an intrusive practice that it requires the explanation of the OASIS Privacy Statements, an additional piece of paper and an expense that is not reimbursed to agencies from CMS.
- The primary rationale for OASIS is to use this information for payment for services utilized by Medicare beneficiaries (as noted in the final regulation).

2) Modify the time points at which the OASIS data collection must be done.

- Increase the length of a hospital stay (from 24 to 72 hours) before a Resumption of Care must be done.
- Modify the current requirement for Significant Change in Condition (SCIC), eliminating the need to process a SCIC for "unanticipated improvement." This happens so rarely and only confuses the already overly complex issue. Require a SCIC only if the agency wants to process one to adjust the reimbursement rate when indicated.
- Eliminate OASIS when a known low utilization payment adjustment (LUPA) will occur.
- Eliminate nonbillable visits to collect OASIS data; make it allowable on the next billable visit.
- Eliminate the need to do both a resumption of care and a recertification OASIS if their timepoints overlap in the last 5 days of the episode (when 2 separate HHRGs are necessary). The only reason to do two right now is to answer question #M0825; this is unnecessary and redundant. The information could be consolidated.

3) Allow any qualifying service to conduct the initial OASIS assessment, based on the required patient care.

- If a patient needs Physical Therapy (PT) immediately after getting home, but Skilled Nursing (SN) is ordered only to remove staples in 3 days, PT cannot do the OASIS. The SN must go in and perform a nonbillable visit solely for the purpose of conducting the OASIS. Clearly this is for regulatory reasons only, and does not enhance the clinical care of the patient. It adds to agency expense without necessarily affecting the patient's outcome.

4) Modify the complete and lock dates from the current timelines.

- Many of our agencies have small support staffs. If the OASIS is done on a Friday, it can use up 2-3 days over the weekend, several more days for quality review and/or corrections (depending on availability of the reviewer/clinician), and then if the part-time

staff has the day off, 7 calendar days is unreasonable for a data entry timeline. Extend the completion requirement to 10 calendar days, and the lock timeline to 14 days from day of completion.

5) Allow use of a single form for all OASIS time points.

- This would minimize agency resources necessary to provide multiple forms, staff confusion over which form to use, etc. Items could be consolidated, reduced (see below), or only used initially unless changed.

6) Address Agency expenses to collect, enter, file, and maintain OASIS data.

- The sheer number of OASIS data that must be collected and processed has increased agency expenses far beyond the token, one-time CMS reimbursement to supposedly compensate for OASIS expenses. This payment came once; the OASIS requirements are multitudinous and ongoing.
- Purchase of hardware and software was/is required by many agencies to meet OASIS data requirements.
- Microfilming costs to store data has more than doubled for certain agencies; physical space required for storage of hard copies is outpacing agency capabilities.
- Several agencies have reported staff retention issues related to increasing paperwork burdens (one agency reports a 33% loss of nursing staff due to paperwork/OASIS). Productivity expectations have not changed with the implementation of OASIS and PPS (which has increased the time points that OASIS is required), and nurses are vacating their home health positions for more reasonable environments.
- With an increasing crisis in nursing work force shortages (as well as other providers), the infrastructure of our entire industry is in danger of collapse. Hospitals are already experiencing increased lengths of stay in some states due to inability of agencies to accept patients. We are also competing against increasing compensation in acute care settings, which cannot be matched, by our current reimbursement levels.

PPS Issues

While home health providers recognized the need for home health payment reform and participated in the development of PPS, it has created many layers of additional regulatory complexities for agencies to deal with. Home Health Agencies have had to request literally hundreds of clarifications from CMS since the implementation of PPS. One of the primary examples of this is the “bundling” of medical supplies into the PPS payment. 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. In many instances, the patient was using these supplies prior to the initiation of home health services. Requiring the home health agency to provide these supplies results in a disruption between the patient and the prior medical supplier. Educating patients about this new requirement, ordering, stocking, delivering these supplies and the additional burden of contracting with and paying new vendors has made this new requirement quite cumbersome.

Our recommendation is that home health agencies only be responsible for providing medical supplies that are directly related to the patients’ current treatment plan.

In addition to bundling of medical supplies, PPS bundles outpatient therapy services into the home health payment. This requires us to be aware of when patients receive these services (easier said than done), contract for, bill, and pay providers for all the outpatient procedures that get bundled into the home health episode. For example, if one of our patients requires a video-fluoroscopy swallow study, the home health agency must cover the speech therapist's component of that test. This frequently requires that we have contracts with speech therapists whom are working in a hospital and not even working for a home health agency. This has caused more time to monitor and manage than I am sure CMS realized when these regulations were developed.

Billing problems with PPS have increased staff time. On almost a weekly basis, our clerical staff informs me of some new claims processing problem. These problems hold up claims processing and payment for weeks to months at a time.

Medical Review, Denials, Edits

Medical review of claims has increased with PPS. Agencies can be subject to Automated Edits, Beneficiary Specific Edits, Follow Up edits, New Provider Edits, Random Edits, Referral Edits, Routine Edits, Targeted Review Edits, and Universal Edits. In addition, denials for technical reasons are just as time-consuming to appeal and correct as substantive denials. Prepayment reviews can involve a high percentage of claims each month and a great deal of staff time to copy each page, and can hold up payment for a significant amount of the agency's billed revenue. **Our recommendation is that prepayment review should only apply after a provider has demonstrated non-compliance.**

The vast majority of home health claims that are denied are rejected because they do not meet one or more of the technical requirements set out by the Medicare program. Technical denials include such things as failure to record the verbal order date on a plan of care or not securing physician signatures on all verbal orders prior to billing (including orders for minor treatment changes). While these technical errors can easily be corrected, CMS forces this type of denial into the time consuming and expensive appeals process that is used for all denials. This delays payment by months to in some cases, over a year. **Our recommendation would be that CMS allow for resubmission of a claim when it is technically correct, rather than requiring the claim go through the appeals process.** I want to thank you, Senator Baucus, for introducing the Medicare Appeals, Regulatory and Contracting Improvement Act (MARCLIA), as it addresses some of the issues I have mentioned with OASIS and this issue with technical denials. It is our hope that the Marcia bill (S.1738) will be marked up by the Finance Committee soon and passed this session.

Local Medical Review Policies (LMRP) are often more restrictive than the coverage policy dictates, complicating coverage decisions even further. LMRP's are developed by each intermediary and are often inconsistent from one intermediary to the next. Our agency has appealed several denials related to diabetic patients who need regular foot care. The denials were based on our intermediary's assertion that they did not meet their LMRP for foot care. In all cases, these denials were taken to an Administrative Law Judge, found to meet Medicare's home health regulations, and were paid. This process was very time consuming for our agency. **Our recommendation is that LMRP's be eliminated.**

Home Health Advance Beneficiary Notice (HHABN)

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. The HHABN is CMS's mandatory form for this notification. After several false starts, the HHABN was implemented in March of 2001. Since then, it has been under constant revision. This requirement is especially cumbersome when the patient has both Medicare and Medicaid covering different aspects of care. The process imposes an additional paperwork burden on HHA's, which must complete Medicare paperwork for patients who, in fact, are not eligible for Medicare services or Medicare payment.

Culturally and Linguistically Appropriate Services (CLAS) Standard

This standard was released in December 2000 and now requires that home health agencies have a plan to assess the needs of non-English speaking people in our community, have translation available at our expense, and to not use family members due to confidentiality. We have very few non-English speaking people residing in rural Montana, and translators who are not related to the patient are often not available. This is an unrealistic expectation for rural America. **Our recommendation would be that this standard be eliminated or at least allow a "waiver" for populations in which this is not a problem.**

15% cut in PPS reimbursement to become effective October 1, 2002

I would be remiss in my testimony if I did not at least touch upon one additional issue that weighs heavily on home health providers nationwide--that of the 15 percent cut currently scheduled for October 2002. This related to regulatory reform because our regulations continue to increase without adequate reimbursement to cover the costs of education, implementation, follow-up and the data analysis that comes with cumbersome regulations. The GAO recently released data analyzing the potential impact of the scheduled 15 percent cut affecting Medicare PPS rates. As a result, CMS is in favor of keeping this 15 percent cut; as they assert that home health agencies are making a profit of \$700 per episode. I can tell you that this is not the experience of Montana home health providers. I would like to respond to the problems with this GAO study.

First of all, I find it truly incomprehensible that the GAO thinks it can accurately predict the costs per episode of care under PPS, since the cost reports have been postponed for months now, due to inaccurate data on the PS&R statements supplied by Medicare Intermediaries. They can't and their projections are dangerously flawed.

The GAO analysis is a result of wholesale reliance on data proxies and assumptions, using statistics that do not relate to actual costs or revenue. In the GAO's hasty attempt to analyze the financial status of home health agencies under PPS, the GAO relies on averaging. The diversity of home health patients, the variation of agency costs, and the inconsistency of the home care market place makes averaging extremely dangerous. The GAO data sources have inherent errors and weaknesses. For example, the visit volume data is suspect given that CMS has expressed that accurate data is not available. Over the last five years, CMS, the Congressional Budget Office (CBO) and GAO have consistently based analyses on faulty assumptions regarding home health agency behavioral reactions to reimbursement changes. The GAO relies on an inflation rate applied to 1996-97 data. That approach ignores significant changes in home care including the increased use of information technology, telehealth services, specialist nurses, and alternative profession disciplines. The GAO uses a simplistic approach that fails to account for basic crucial revenue adjustment. These include partial episode payment (PEP) adjustments, significant change in condition (SCIC) adjustments, case mix downcoding, and low utilization payment adjustment (LUPA) losses. Home Health Agencies are experiencing that these adjustments affect approximately 25 percent of all episodes. In summary, the GAO understates expenses, overstates payments and we believe the \$700 profit figure is inaccurate.

We greatly appreciate that you, Senator Baucus, have always been sensitive to issues affecting rural providers. We wish to thank you for your recent introduction of the MARCIA bill, which addresses many of the issues I have mentioned. It is also important for you to understand that our agency and others in Montana are at risk of closing if this 15% cut is allowed to go forward. In rural areas, further agency closures will severely limit patients' access to necessary home medical services. **We recommend that the 15 percent cut be eliminated.**

As you can see from the testimony above, all of this red tape that home health agencies must now comply with drives up costs. For this reason, we greatly appreciate your continued support, Senator Baucus, of the 10% add-on reimbursement for rural agencies. In addition, it is important that Congress restore the 1.1% cut in the market basket.

We believe in being accountable for our actions and to those we serve. However, we as an industry are slowly suffocating from the weight of these burdens that have been placed on us. Many agencies in Montana lack the necessary funding and staff to ensure that adequate compliance with all of these requirements is met. It is a sad commentary that home health nurses spend more time on paperwork and other regulatory requirements than they do on patient care. It is a sad commentary that agencies are expending their sparse educational dollars toward compliance and understanding of the regulations rather than enhancing their clinician's skills to provide quality care for those we serve.

Putting on my hospice provider hat for a minute, I would like to address a few issues related to government regulations for hospice. First, for home health and hospice providers, the limitation that only physicians can sign the plan of care and give us orders is quite restrictive in rural areas. In small, rural communities, there are days at a time when only a nurse practitioner or physician assistant are available to give orders for our patients. **My recommendation would be that both the home health and hospice regulations be changed to allow these advance practitioners to**

write orders and sign a plan of care. Senator Max Cleland is working on a bill that would allow nurse practitioners or physician assistants to sign home health and hospice plans of care. **I would ask that you, Senator Baucus, and other members of the Senate Finance Committee support this bill when it is introduced.**

The second issue for hospice that some hospice providers in Montana are experiencing difficulty with has to do with taking care of hospice patients in a Skilled Nursing Facility (SNF). The SNF rules sometimes are in conflict with providing appropriate palliative care. For example, there is a list of drugs that are considered inappropriate for residents of a SNF. Many of these drugs are utilized for good pain and symptom management for hospice patients. These triggers for poor care in the nursing homes may be indicators of a need for hospice, not necessarily reflective of poor care in the facility. **This regulation should be eased when the patient is terminal and hospice care should be offered to these residents when a change in status reveals that hospice is appropriate.**

In closing, thank you, Senator Baucus, for this opportunity to address the regulatory burdens of Medicare on home health agencies in Montana and across the nation. I hope that the recommendations we have suggested here are useful as Congress and CMS attempt to reform the system to a more “user-friendly” one.

Sincerely,

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48

TESTIMONY OF
ALEXANDER TRUJILLO
REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
ON
REACHING OUT TO HEALTH CARE PROVIDERS
BEFORE THE
SENATE FINANCE COMMITTEE

May 28, 2002

Chairman Baucus, thank you for inviting me to join you here in Bozeman to discuss the Centers for Medicare & Medicaid Services' (CMS) continuing efforts to reach out to the physicians and providers that care for some of the nation's most vulnerable citizens -- the elderly, poor, and disabled. Many physicians, health plans, providers, and Members of Congress have raised concerns about Medicare, particularly Medicare's regulatory and paperwork burden and the cost of doing business with the Medicare program. We share these concerns, and are making every effort to identify and address areas where improvements can be made. *Physicians and other health care providers play a critical role in ensuring that Medicare beneficiaries continue to receive quality health care.* To do that we must streamline Medicare's requirements, bring openness and responsiveness into the regulatory process, and make certain that regulatory and paperwork changes are sensible and predictable.

I also am aware that these issues are extremely important to you, Chairman Baucus. I know that you and the Committee have spent a great deal of time working with CMS, especially Administrator Scully, as well as your colleagues in Congress, to help make Medicare a better business partner for providers. We appreciate all of your work in this important effort, and we look forward to our continued partnership with you, Congress, and the physician and provider community to improve Medicare.

BACKGROUND

This year, Medicare will pay approximately \$240 billion for the health care of nearly 40 million beneficiaries, involving nearly one billion Medicare claims from more than one million physicians, hospitals, and other health care providers. CMS strives to *ensure that Medicare pays only for the services allowed by law, while making it as easy as possible for qualified health care*

providers to treat Medicare beneficiaries. We have to carefully balance the impact of Medicare's laws and regulations on physicians and other providers with our accountability for billions of dollars in Medicare payments.

Medicare's requirements, as outlined in the law, generate many of the concerns that your constituents bring to your attention and to mine. Of course, there is a genuine need for clear rules in a program this large and complex. But rules should exist to help, not hinder, our efforts to assist seniors and the disabled, help control costs, and ensure quality, while remaining consistent with our obligation and commitment to prevent fraud and error. When regulations, mandates, and paperwork unnecessarily hinder the services providers are trying to give, those rules should be changed. And so CMS is working to reform the way Medicare works, making it simpler and easier for everyone involved. We are listening closely to Americans' concerns and learning how we can do a better job of meeting patients' and providers' needs to serve beneficiaries in the best way we can. In many areas, we can be less intrusive to the providers who participate in Medicare and more responsive to the beneficiaries who depend on Medicare.

IMPROVING AGENCY RESPONSIVENESS

Since Secretary Thompson and Administrator Scully began their work last summer, one of their major goals has been to reform the way Medicare does business while ensuring accurate and timely payments to providers and preserving our ability to collect overpayments and pursue fraud. We already have taken aggressive steps to raise the service level of the Medicare program and bring a culture of responsiveness to the Agency. These are not hollow words: creating a "culture of responsiveness" means ensuring high-quality medical care for beneficiaries, improving communication with providers, beneficiaries and Congress, and redoubling our education efforts. To promote improved responsiveness, the Agency is:

- ***Sponsoring Open Door Policy Forums*** to interact directly with beneficiary groups, plans, physicians, providers, and suppliers, to strengthen communication and information sharing between stakeholders and the Agency. Currently, we have 11 forums, and they are open to all providers – rural, urban, small, large, for-profit, and nonprofit – and to the public. They allow outside groups to meet with senior CMS staff on a regular basis, most of them monthly, to bring to our attention those nagging problems that they encounter when dealing

with the Medicare and Medicaid programs. We have had overwhelming success with well over 4,100 attendees participating in person or calling in to more than 50 of these meetings since late last year. In fact, just this month we have had 11 meetings involving more than 700 public participants.

- **Enhancing Outreach and Education** to beneficiaries, providers, plans, and practitioners, by building on the current educational system with a renewed spirit of openness, mutual information sharing, and partnership. Last fall, we started by educating seniors through a \$30 million advertising campaign to engage seniors in the program, combined with a massive enhancement of the 1-800-MEDICARE number. We have expanded the toll-free lines to 24 hours a day, seven days a week, and the information available by phone also has been enhanced so that beneficiaries can obtain specific information about the health plan choices and costs. The Agency also is developing and improving training for physicians and providers on new program requirements and payment system changes, increasing the number of satellite broadcasts available to health care industry groups, and making greater use of web-based information and learning systems across the country. We have also installed toll-free inquiry lines at all Medicare contractors.
- **Establishing Key Contacts for the States** at the regional and central office level. Paralleling the senior staff contacts for industry and beneficiary groups, these staff members are assigned to work directly with the Governors and top State officials to help eliminate Agency obstacles in obtaining answers, feedback, and guidance. Each State now has one Medicaid staff member assigned to their region, and another in Baltimore, both of whom are accountable for each State's specific issues. For Montana, the key contact is in my office, and has been working closely with all of the States in this region, including Montana.
- **Responding More Rapidly and Appropriately to Congress and External Partners** by promptly responding to their inquiries. We have developed an intra-Agency correspondence routing system, and timeliness standards, to respond more efficiently and promptly to congressional inquiries. We also are exploring ways to make data and trend analyses more readily available to our partners and the public in a timely manner. In addition, CMS will make explicit, and widely publicize, the requirements for obtaining data and analyses from us, including protecting the confidentiality of the data.

EASING THE REGULATORY & PAPERWORK BURDEN

A culture of responsiveness alone will not alleviate the regulatory and related paperwork burdens that for too long have been associated with the Medicare program. Last summer the Secretary created an Advisory Committee on Regulatory Reform, which includes patient advocates, providers, and other health care professionals from across the nation. This Committee is helping guide the Secretary's efforts to streamline unnecessarily burdensome regulations and to eliminate inefficient regulations that interfere with the quality of health care for Americans. Providers should focus on patients, not on paperwork. And we recognize that these requirements can have a disproportionate impact on small providers who often do not have the resources that larger providers use to mitigate the effects of such burdens. Earlier this month, the Advisory Committee on Regulatory Reform held a field hearing in Denver, Colorado, where our regional office is located, to gather insights from consumers, doctors, health care providers, and businesses. Similar hearings have been held in Miami, Pittsburgh, and Phoenix. This is one way the Secretary is reaching outside of Washington, D.C. to hear from patients and the providers who care for them. The input gathered at these hearings is helping the Committee develop recommendations both to change specific regulatory requirements and to develop broader reforms. This group is determining what rules need to be better explained, what rules need to be streamlined, and what rules need to be dropped altogether, without increasing costs or compromising the quality of health care services.

To support this initiative, we have developed a program at CMS, focusing on listening and learning, to get us on the right track. For example, Administrator Scully personally travels around the country, meeting with and listening to literally thousands of providers, suppliers, physicians, beneficiaries, and others who live and work with the regulations we create, so he can hear their concerns and better understand the changes we need to make. I know he met with you, Mr. Chairman, last August, and enjoyed talking with providers at the Billings Deaconess Clinic about the needs of Montana rural health care. So far he has had 22 of these town hall meetings with CMS constituents, most of them with their Members of Congress, and he is conducting three more as we speak today. Additionally, health care providers have been working with members of CMS headquarters staff to provide a more thorough awareness of Medicare's impact. The CMS staff spend several days with providers in their offices, learning about their

practices, understanding their daily challenges, and seeing how Medicare's rules and regulations affect their ability to serve patients.

We are listening and we are learning. But we are also taking action. We are committed to making common-sense changes and ensuring that the regulations governing our program not only make sense, but also are plain and understandable. Let me give you a specific example. Recently, a physician assistant here in rural Montana raised a concern with our implementation of the statutory prohibition on paying physician assistants directly. Some of our contractors found our guidance on this issue confusing and were denying payment to any physician practice or practice management group that had a physician assistant as an owner. Because of that confusion, this physician assistant was unable to have an ownership interest in the physician group in which he practiced. We understood and agreed with his concern, and we agreed to look into it. As a result of this review, we issued a program memorandum to our Medicare carriers, effective April 1, 2002, clarifying our policy. Now, if State law permits a physician assistant to have an ownership interest in a medical practice or practice group, our policy is to reimburse the practice notwithstanding the physician assistant's ownership.

In another example, at one of our open door meetings, a group of durable medical equipment (DME) suppliers aired their concerns about paperwork burden. After reviewing their concerns, we put together a high-level group of DME suppliers, CMS policy staff, and the private contractor DME carrier medical directors, to work through their concerns. We are in the process of doing the same thing for small home health agencies and orthotic and prosthetic suppliers. We have a meeting scheduled for June 27 with DME suppliers, suppliers of prosthetics and orthotics, DME Regional Carrier medical directors, and CMS staff to hammer out a solution to their concerns. Our goal is to solve problems quickly. We have taken a number of other positive steps, including:

- Sending a letter to our state surveyors and regional offices clarifying once and for all the requirements that a home health "branch office" has to meet to be designated a branch office under the Medicare program. Specifically, we have clarified that mileage alone will no longer be the sole criterion for determining a branch office's status. This guidance will end misinterpretation of this policy by state survey agencies, and is especially important in large,

rural states such as Montana where it is quite common for a home health agency to have a branch office.

- Writing articles for several clinical journals clarifying the scope of Medicare's hospice benefit. We want to ensure that physicians and hospitals understand that we will not sanction them if they appropriately use their best clinical judgment to determine whether a patient will qualify for hospice care.
- Announcing that critical access hospitals will no longer be required to complete the MDS for "swing bed" patients: since we don't need the data for quality or financial purposes, and it makes no sense to make our critical access providers continue to collect it.
- Reducing the paperwork burden on hospitals by shrinking the size and scope of the Medicare cost report. There is a statutory requirement that, for payment, hospitals report their overhead for old capital costs and new capital costs. These forms are long and burdensome, and we are eliminating some reporting requirements and doing away with unnecessary questions. By 2004, the cost report will be even shorter than it is now.
- Working with our hospital contractors to immediately implement key payment provisions of the BBA for critical access hospitals.
- Changing the rules so that the Medicare Secondary Payer form only has to be completed every 90 days. Hospitals have repeatedly complained about the Medicare Secondary Payer form and the requirement that it be completed for patients with secondary insurance coverage time and time again.
- Reforming EMTALA is one of the things we have heard loud and clear in our open door meetings and in the Secretary's regulatory reform task force. This is an especially important concern for rural hospitals that may have difficulty staffing a traditional emergency department 24 hours per day, 7 days a week. Some of the changes that we've proposed are a clarification of where EMTALA applies; we've proposed to clarify that it generally does not apply at off-campus entities such as a physical therapy clinic on the hospital's license. We also clarified that, in general, EMTALA does not apply to stabilized inpatients. We also proposed to modify the rules dealing with hospital-owned ambulances to permit a hospital-owned ambulance to comply with local or regional EMS protocols.

We believe that our outreach efforts, which led to changes like these, will go a long way in

alleviating providers' fears and reducing the amount of confusion and paperwork that, in the past, has all too often been an unnecessary burden on providers.

In addition to these efforts, we are taking concrete steps to streamline Medicare's regulatory processes. We have developed a Quarterly Provider Update of all changes to Medicare that affect physicians, and other providers, to make it easier for them to understand and comply with Medicare regulations and instructions. The Quarterly Provider Update contains a list of all regulations we expect to publish in the coming quarter, as well as the actual publication dates and page references to all regulations published in the previous quarter. The Quarterly Provider Update also generally includes all program memoranda, manual changes, and any other instructions that could affect providers in any way. Additionally, we are publishing all of our regulations monthly, usually on the fourth Friday of each month, barring any extenuating circumstances, such as meeting statutory deadlines. That way, physicians and providers do not have to sift through pages and pages of the Federal Register – or pay someone to do it for them – for proposed rules, regulations, and other changes that may affect them. Furthermore, in an effort to make updated regulations more readily accessible, we routinely post them on our website, www.cms.gov. These postings coincide with the display of these documents in the Federal Register and have been well received by providers and other interested parties.

These changes provide predictability and ensure that physicians and other providers are fully aware of Medicare's changes so they have time to react before new requirements are placed on them. Secretary Thompson and Administrator Scully have been clear: we need to be more responsive to the people who participate in our programs, and our efforts to reduce paperwork burdens on health care providers are just one way that we are trying to do that. In the months ahead, the Secretary's regulatory reform task force, the Open Door initiative, and our other, similar administrative initiatives that we have ongoing will accomplish much, much more. Through these efforts, we are taking administrative action where we are able, and we want to work closely with this Committee and your constituents in the provider community to better understand their needs and to improve our working relationship with them.

IMPROVING PHYSICIAN AND PROVIDER EDUCATION

As part of our efforts to reinvigorate the Agency and bring a new sense of responsiveness to CMS, we are enhancing our provider education activities and improving our contractors' communications with physicians and providers. The Medicare program primarily relies on private sector contractors, who process and pay Medicare claims, to educate physicians and providers and to communicate policy changes and other helpful information to them. We have taken a number of steps to ensure the educational information our contractors share with physicians and providers is consistent, unambiguous, timely, and accurate.

We recognize that the decentralized nature of our educational efforts has, in the past, led to inconsistency in the contractors' communications with physicians and providers, and we have taken a number of steps to improve the process. We have centralized responsibility for CMS's educational efforts in our Division of Provider Education and Training in Baltimore, whose primary purpose is to oversee and coordinate contractor education efforts with national educational activities regarding Medicare policies. We have also implemented several "train-the-trainer" programs for our Medicare contractors on new Medicare policies such as a revised payment methodology for swing beds, instruction and a standardized training manual for the contractors to use in educating physicians and other providers, and consistency so that our contractors speak with one voice on national issues. We are continuing to refine our efforts on a going basis by monitoring the training sessions conducted by our contractors.

On a national basis, we are providing free information, educational courses, and other services, to physicians and providers through a variety of advanced technologies. We are:

- **Expanding our Medicare provider education website, www.cms.gov/medlearn.** The Medicare Learning Network homepage, MedLearn, provides timely, accurate, and relevant information about Medicare coverage and payment policies, and serves as an efficient, convenient provider education tool. The MedLearn website averages over 125,000 hits per month, with the Reference Guides, Frequently Asked Questions and Computer-Based Training pages having the greatest activity. I encourage you and your physician and provider constituents in the audience today to take a look at the website -- it really is a wonderful tool. We also want to hear feedback from you and from your constituents on its usefulness so we

can continue to strengthen its value. In fact, physicians and providers can email their feedback directly to the MedLearn mailbox on the site.

- **Providing free computer and web-based training courses** to doctors, providers, practice staff, and other interested individuals can access a growing number of web-based training courses designed to improve their understanding of Medicare. We also have them available on CD-ROM for those who may have computers but not Internet access. Some courses focus on important administrative and coding issues, such as how to check-in new Medicare patients or correctly complete Medicare claims forms, while others explain Medicare's coverage for home health care, women's health services, and other benefits.
- **Establishing electronic newsletters** on priority initiatives. These listservs have enabled us to keep thousands of subscribers informed about the latest Medicare changes, we expect to continue this practice for future initiatives. We also are investigating the feasibility of developing a new system to capture, compile, and index frequently asked questions, so we can make these available to more clearly communicate our regulations to physicians and providers.

We also recognize that, often, rural providers face unique challenges in caring for Medicare beneficiaries. That's why we recently began a concerted effort to target the Medicare educational needs of rural providers. We plan to develop a provider survey to identify specific rural educational and informational needs. We also are looking into installing satellite dishes at all Indian Health Service facilities to increase access to distance learning programs. We plan to develop a rural health website on our MedLearn webpage, and we are working to enhance our outreach to rural health provider associations, as well as individual rural facilities, to establish a grassroots education and information network.

We also are working to improve the quality of our contractors' customer service to physicians and providers. Last year, our Medicare contractors received 24 million telephone calls from physicians and providers, and it is imperative that the contractors provide correct and consistent answers. Now that we have toll-free call centers at all Medicare contractors, the need is even

more pressing. In the past, we have had problems with our contractor call centers and we are taking significant steps to correct them. We have performance standards, quality call monitoring procedures, and contractor guidelines in place to ensure that contractors know what is expected and so that we can be satisfied that the contractors are reaching our expectations. Last year, for the first time, Medicare contractors' physician and provider telephone customer service operations were reviewed against these standards and procedures separately from our review of their beneficiary customer service. During these weeklong contractor performance evaluation reviews, we identified areas that needed improvement and best practices that could be shared among our other Medicare physician and provider call centers.

We want to know about the issues and misunderstandings that most affect provider satisfaction with our call centers so that we can provide our customer service representatives with the information and guidance to make a difference. So we have reviewed and made significant changes in the wording of monitoring criteria and in the weighting of segments of our contractor performance scorecard to increase its relevance for monitoring provider calls. The scorecard was tested late last year, and implemented nationally in December 2001. It helps us to measure skills that are common to all customer service operations, as well as accuracy and completeness of information specific to CMS. This allows us to more appropriately direct our coaching sessions so providers get the best customer service we can provide. Additionally, via our Satellite Learning Channel, which we launched in November 2001, we provide Medicare contractors with the latest information on contemporary topics of interest. We have installed a network of satellite dishes at all contractor call centers to improve our training efforts with contractor customer service representatives. In addition, we are holding regular meetings and monthly conference calls with call center managers to ensure customer service practices are uniform in their look, feel, and quality.

In addition to monitoring call centers, we have established requirements for the features and content of contractor websites that give providers and suppliers timely and understandable Medicare program information. We now require all Medicare contractor provider/supplier websites to contain:

- all bulletins/newsletters;

- a schedule of upcoming events (seminars, workshops, fairs, and the like);
- on-line registration for contractor-sponsored events via the website;
- features which permit providers to order and receive copies of bulletins;
- a quarterly listing of provider frequently asked questions;
- search engine functionality;
- e-mail based support/help/customer service;
- a "What's New" or similarly titled section;
- an ability to link to other provider interest sites, and
- an area designated as the Medicare Learning Network, which will contain promotional material, supplied by CMS, as well as link to CMS' MedLearn and Best Practices websites.

In fact, most reports indicate that the provider websites were generally clearly presented, user-friendly, and contained an abundant amount of easily retrievable Medicare provider information.

This year, we have instructed our Medicare contractors to establish and maintain electronic mailing lists, listservs, for providers and suppliers. These listservs notify providers via e-mail of important and time sensitive Medicare program information, upcoming provider education and training events, and other announcements or messages necessitating immediate attention. Contractors also will use their listservs to notify providers about new contractor bulletins on their websites.

Just as we are using new technologies for our national provider education efforts, and are working with our co education efforts, we also are working directly with physicians and other health care providers to improve our that we are responsive to their needs. For example, our Physicians Regulatory Issues Team (PRIT) continues to work closely with physicians to clarify our rules and find ways to reduce Medicare's burden on doctors. The team is led by a practicing physician, Dr. Bill Rogers, who experiences first hand the types of concerns that physicians have, and he is doing a great job of helping to address them and to more effectively educate doctors about Medicare's rules and regulations.

We also are taking other steps to communicate more effectively with providers. For example, we are reaching out to physicians and providers at their professional conferences. We recently established a National Physician and Provider Organization Exhibit Program designed to make CMS information available to physicians and providers all over the country at these conferences. And we are establishing plans for a customer satisfaction survey and focus group program. This

will help us to do an even better job of obtaining physician and provider feedback on how we can be a better business partner for them. We will continue to work collaboratively with you and to improve our communications so that, together, we can ensure that Medicare beneficiaries are able to receive the high quality care they need and deserve.

CONCLUSION

Physicians and other providers play a crucial role in caring for Medicare beneficiaries. We share their concerns regarding the program's regulatory and paperwork burden, and we are working hard to address them and bring openness and responsiveness into the process. We also must ensure that regulatory changes and requirements are sensible and predictable. The Secretary and Administrator are committed to this effort, and so are the rest of us at CMS. We want to be better business partners, and we appreciate your help in our improvement process. We look forward to continuing to work with Congress and we will continue to seek input from the health care community, our beneficiaries, and partners in reaching our goals. Thank you for the opportunity to come to Bozeman to discuss these issues with you today, and I am happy to answer your questions.

Statement of John Nordwick, CEO
Bozeman Deaconess Hospital

before the Senate Finance Committee
May 28, 2002

My name is John Nordwick. I am the Chief Executive Officer of Bozeman Deaconess Hospital. Like most hospitals in Montana, we provide health services across the full continuum of care. In addition to 86 acute care beds, we also operate Aspen Pointe, an independent living facility and Birchwood, an assisted living facility. In addition, ** physicians practice in the clinic buildings attached to the hospital.

I also am the Immediate Past Chair of MHA, formerly the Montana Hospital Association. MHA members provide the full spectrum of health care services, including hospital, nursing home, home health and hospice care. In addition, since a growing number of hospitals employ their physicians, we also advocate on their behalf on some issues.

Thank you for this opportunity to testify. The regulatory process has an enormous impact on health care in Montana. I welcome this opportunity to share a few thoughts about how we can improve this system.

I think I speak for most providers when I say that a certain amount of structure is needed to implement the policy directives developed by Congress. However, health care providers are increasingly alarmed about the growth of this regulatory structure, its cost and its impact on access to medical treatment.

Regulatory Requirements: An Unfunded Mandate

In my hospital, the amount of resources dedicated to implementing and complying with federal regulations has grown enormously just in the last decade – and with good reason. Since 1996, Congress has enacted several major pieces of legislation that have resulted in massive numbers of regulatory requirements.

For example, the Balanced Budget Act of 1996 resulted in more than 300 changes in the Medicare program alone. The Health Insurance Portability and Accountability Act imposed broad and far-reaching new privacy regulations and fundamentally alters the way we handle the billing process.

In addition, as mandated by the BBA, the Department of Health and Human Services developed new prospective payment systems for outpatient hospital, home health and nursing home services.

HHS also made major changes in the Conditions of Participation, which set the licensure and certification requirements for hospitals. HHS also modified a wide variety of current regulations, including those related to billing, coding, coverage and EMTALA.

Each of these required hospitals to invest huge amounts of capital in computer hardware and software, training and additional staff. Taken together they represent a virtual avalanche that threatens to bury hospitals.

In a study published last year, the American Hospital Association found that for every one hour of care delivered in an emergency room, one hour of paperwork is required. For every hour of surgical and inpatient care delivered, 36 minutes of paperwork is required. For every hour of skilled nursing care delivered, 30 minutes of paperwork is required. And, for every hour of home health care delivered, 48 minutes of paperwork is required.

Complete records and documentation are necessary for patient safety and quality. But this kind of administrative burden shifts the focus from patient care to paperwork.

Meanwhile, on the revenue side of the equation, Congress has not approved funding to pay for compliance with all of these requirements and all of this staff time devoted to paperwork. In fact, the BBA reduced Medicare spending by at least \$40 billion – and probably a lot more. In each year since 1997, Congress has set provider rate increases at less than the increase in our inflation.

The net effect of this has been to widen the gap between what Medicare pays hospitals and what we are forced to charge for services. In Montana, this gap grew from \$230 million in 1997 to \$275 in 2000. These losses are passed on to the privately-insured persons who live and work in our community who make up the difference by paying higher insurance premiums.

The bottom line is that the federal government has mandated a whole new set of regulatory requirements, but given us – the people who have to implement these mandates – no vehicle for funding their implementation.

CMS's Ability to Implement Congressional Mandates

We face a second challenge in dealing with this regulatory morass: CMS's ability to implement congressional mandates.

For several reasons – most likely the complex nature of congressional mandates, understaffing, underfunding or just their own incompetence – CMS has had enormous difficulty in recent years implementing congressional mandates.

The outpatient prospective payment system is one example of this difficulty. Mandated by the BBA, CMS had a couple of years to get ready to put this new system in place. But despite this lead time, there were major gaps in the technology and software that appeared. Even more troubling was the inability of CMS to provide adequate training and helpful and timely interpretations of the new rules.

As a result, providers were left to stumble through implementation on their own. CMS continues to refine and implement this system even today.

A second example is CMS's implementation of the all-inclusive payment rate for physicians working at Critical Access Hospitals. As passed by Congress, this was to take effect for facility fiscal years beginning in 2001. However, CMS still has not implemented the mandate – and now says it can't implement it retroactively. What Congress intended to be a fix for CAH's has turned into a nightmare.

The scenario for HIPAA is remarkably similar. The HIPAA privacy regulations take effect on April 1, 2003, yet the Department of Health and Human Services still has not clarified a number of key

issues that must be resolved before providers can actually proceed with implementation.

As if this confusion weren't bad enough, if providers don't comply accurately with these requirements, we are considered to be in violation of federal fraud statutes -- and subjected to very expensive fines and other penalties.

Providers should be given accurate, complete and timely instructions for implementing new rules. We should be able to get our questions -- whether to CMS or the fiscal intermediary -- answered in a timely fashion. And we should be able to resolve our conflicts over these issues quickly and reasonably. Today, all too often, that's not the case.

Working Toward Solutions

I applaud the interest you have shown in addressing these concerns. I appreciate the initiative you have shown in developing your regulatory reform bill; this bill is a good first step.

But, requiring CMS to publish its rules in a more organized fashion is only a small step toward resolving the problems facing our regulatory system. Far more fundamental questions must also be addressed.

I would argue that the federal government should not be allowed to impose any new rules unless it also pays for their implementation. I also would argue that CMS and the FI be held much more accountable for their performance in meeting congressional mandates. Finally, I would argue that providers would support additional funding for CMS -- if it is contingent on improved performance by CMS.

I recognize the important role the federal government has in setting standards for the health care system. However, there must be the kind of balance in this system that ensures that the interests of providers and consumers are both met.

Thank you.

Statement of Nicholas J. Wolter, MD, CEO
Deaconess Billings Clinic

May 28, 2002

Senate Finance Committee Field Hearing
on

“Regulatory Relief for Medicare – the Case for Cutting Red Tape”

Chairman Baucus, I appreciate this opportunity to discuss some of the challenges that physicians and health care organizations face in the ever growing and complex arena of government rules and regulations.

I am submitting these comments on behalf of Deaconess Billings Clinic. DBC is a not-for-profit, physician-led, community governed medical foundation serving Montana and northern Wyoming. It is composed of 170 physicians, located at 10 clinic sites, as well as a 272 bed hospital, a nursing home, and a research division. DBC also manages several small hospitals and nursing home facilities in towns with populations of less than 10,000.

DBC, like many other large health care organizations in rural states, serves a very large geographic region with primary, secondary and tertiary care services. It is common for patients to travel 90 minutes to Billings for a primary care visit, and five hours or more for a visit to one of our medical subspecialists. As part of a consortium of rural hospitals, DBC also operates a telemedicine network. DBC's mission is to improve the health of the communities we serve, and to support health care research and education.

I am Dr. Nick Wolter, the CEO of Deaconess Billings Clinic. I have spent most of my professional life practicing critical care medicine and pulmonology, and I still see patients today.

I'd like to start with several simple premises.

- Medicare should support the physician-patient relationship.
- Medicare should encourage quality, coordinated, and efficient care.
- Medicare regulations should be as simple and inexpensive to implement as possible.
- Medicare regulators should work in a cooperative, partnership manner with physicians and other providers.

Deaconess Billings Clinic believes that operating from these premises can provide Medicare beneficiaries, our patients, with the best care and the best value.

Better Guidance, More Coordination, and More Oversight from the National Level is Needed

Documentation, Billing, and Coding Guidelines

Physicians, hospitals, and other health care organizations face an enormous paperwork burden created by many regulations promulgated by the Centers for Medicare and Medicaid (CMS) and the Department of Health and Human Services. Much of this paperwork is unnecessary to the intended outcome and results in a waste of valuable resources that would be better spent on providing care and dealing with pressing new issues like the threat of bio-terrorism. Further, many of the regulations appear to be unnecessary and intrusive into the physician-patient relationship and many impose costs and burdens on health care organizations that far outweigh any benefit.

Example: Preventive Medicine Codes

Every day, patients, especially in our internal medicine practices, are confused by how they are charged for preventive care because of unclear and contradictory coding guidance from CMS and our local Medicare contractor on a preventive medical exam, versus a problem medical exam. Medicare does not generally pay for a preventive exam, the patient does. So this is an area of great patient interest, where clarity is important. Furthermore, preventive exams are common. Therefore, you would think that the guidance would be clear by now. What we find, however is the following:

- It is very difficult to determine, under current guidance, when a preventive medical exam becomes a problem exam.
- It is also very difficult to determine when a preventive exam becomes *both* a preventive exam *and* a problem exam, during the course of an exam. For instance, if the physician finds a potential heart problem or diabetes, when can billing be done for treatment beyond what would be done in the routine preventive exam? In this instance, we are faced with figuring out the correct billing procedure and making sure we do not charge the Medicare beneficiary for the part of the exam that should be billed to Medicare. This situation is extremely difficult to explain to the patient, even if we could get clear guidance from Medicare.
- Medicare now allows certain preventive tests for women (e.g. a screening pap smear, a breast exam and a pelvic) to be performed and billed to Medicare at the same time as a problem visit billed to Medicare. This is not the case in regards to screening for men. We may bill a preventive screening digital rectal exam to Medicare, but not at the same time as a problem visit billed to Medicare. This is difficult to understand and more difficult to explain to the patient.
- To make this issue even more confusing, we have been faced with differing interpretations from our Carrier and the Medical Director of our Carrier, as well as the Medicare Regional Office on these questions. There are no clear national guidelines in this area and this only perpetuates the confusion.

DBC recommends that this problem be solved by allowing covered preventive tests to be billed during any type of visit, as long as medically appropriate time frames are followed.

Example: Documentation of Patient Status: Inpatient, Outpatient, and Observation

Currently, the Medicare PRO in Montana has advised us that the initial documentation of patient status as an inpatient, outpatient, or observation patient controls for billing purposes, and may not be changed, even in the face of better information. The PRO claims it is following national guidance.

A good example is when an emergency physician admits a patient as an “inpatient,” then the hospitalist, upon further evaluation, determines that the patient should be held for “observation” instead. Currently, the hospital would not be allowed to change the patient’s status prior to billing, and, if it is determined that the patient did not meet inpatient criteria, nothing can be billed. Often, for complex patients, several physicians are involved in care. The case managers or UR nurses need time to review documentation, request clarification from physicians as needed and determine appropriate status. The current process, which does not allow this, is punitive.

Physicians should be able to change documentation to reflect better information about patient status as warranted during hospitalization and prior to billing of services (e.g., 48-72 hours post discharge) for the purpose of clarifying patient status.

Medicare Carrier Review Processes Must be Improved

Medicare has often taken a punitive, rather than an educational, approach to complex coding issues. One area of special concern has been efforts to collect so-called overpayments from physicians. For instance, extrapolation of overpayments made to physicians based on probe samples is unfair and inaccurate. Physicians and carriers must be able to take steps to rectify coding issues before formalizing an overpayment request, and such requests should be based on actual claims reviewed, not on extrapolation. CMS should ensure that repayment options for overpayments are practical and should provide adequate due process protections. Finally, CMS should ensure that physicians are appropriately educated about Medicare requirements and should act as the channel for communication between physicians and carriers.

We urge you to include language in S. 1738, the “Medicare Appeals, Regulatory, and Contracting Improvement Act of 2001” (MARCIA).

- Appropriately limit the use of extrapolation: When conducting post-payment audits, carriers should be able to use extrapolation only where there is either a sustained or high payment error rate, or the carrier’s documented education efforts have failed.
- Appeals Rights: Physicians should be able to appeal administratively the probe sample findings that carriers use during post-payment audits. Physicians should not be forced to undergo a more intensive audit just to maintain their appeal rights, but should have the right to appeal the probe sample audit itself.
- E&M Pilot Projects: Require CMS to conduct pilot tests of any new E&M documentation requirements before implementation on a nationwide basis. Physician organizations would have to be involved in the pilot project design, implementation and analysis.

Teleradiology

Medicare regulations should not inhibit expansion of teleradiology by organizations like DBC, using radiologist support from out-of-state sites to support local efforts by radiologists. As a clinical matter, the location of radiologists is irrelevant, given existing technology. DBC has built a secure, computer-based imaging network to address the crying need for radiology services in Montana. Small communities often can't support a radiologist, and certainly can't support subspecialty radiology expertise that is increasingly medically important. The technology exists to provide these services to underserved rural beneficiaries (and the physicians in those communities), but Medicare rules make it difficult to bill Medicare in Montana for the services of contracted radiologists. CMS should evaluate Medicare billing rules, as applied nationally, to encourage the rapid adoption of new teleradiology technology.

Local Medical Review Policies ("LMRPs"), "Medical Necessity" Determinations, and other Guidance (or lack thereof)

Medicare requires local Medicare contractors to decide what is medically appropriate care, within the context of national guidelines. The number of LMRPs varies enormously across the country by Medicare contractor, and the advice is often inconsistent. The effect is that beneficiary services vary from area to area because of the variations within Medicare administration. Quality may also be inconsistent. Medical evidence should drive Medicare's medical review policies, not variability in the opinions of local Medicare Medical Directors.

Nothing is more difficult for a practicing physician than to be told by the local Medicare contractor that the service he is providing or has authorized is not "medically necessary," especially when that payment denial decision is not supported by current medical evidence, is inconsistent with accepted practice, and threatens patient care.

Example: Air Ambulance

Let me give you one recent, extremely serious example in Montana right now, involving air ambulance services. DBC, like several other hospitals in the state that provide trauma and higher level medical services, owns and staffs an air ambulance. The medical director of that service refers to it as a "flying ICU." We can and do save lives because of air transport, especially in a rural state, where many of the health care facilities in smaller communities are not able to care for complex cardiac patients or serious trauma. However, since January 2000, our local Medicare Fiscal Intermediary has downgraded approximately thirty-nine (39%) of our air transports to land ambulance, claiming that air transport was not necessary. We understand similar denials are not common with Medicare FIs in other states. This has involved hundreds of thousands, if not millions, of dollars of losses to air ambulance providers, both in denied payments and in the operational costs of appealing hundreds of claims. These losses could threaten the long-term availability of air transport in some parts of Montana. For that reason, we have been fighting hard to assure services.

Let me give you two examples of downgrades that illustrate the seriousness of the threat to patient well-being posed by our local Medicare Fiscal Intermediary's extremely narrow view of when air transport is medically necessary:

- A 78 year old female sustained a huge intracerebral hemorrhage and was transported by air for neurological evaluation. Vital signs were stable enroute and the patient was confused with slurred speech. Upon neurological evaluation, it was determined by the neurologist that the patient would likely not survive the event. The family made decisions for comfort care and the patient passed away 4 days later. This flight was denied by Medicare, stating that the patient was stable and could have been transported via ground ambulance. Due to the extent of her intracerebral hemorrhage, she could have compromised her airway at any time and did in fact lose consciousness shortly after arriving at DBC. We have appealed this denial.
- A 68 year old male presented to the Emergency Department of a small hospital with chest pain. The patient had an abnormal EKG and elevated cardiac enzymes indicating that he had suffered a heart attack. He was stabilized and transported by air for cardiac evaluation, and was not in active pain during the transport. The admitting cardiologist decided that due to the recent myocardial infarction, it was best to perform cardiac catheterization the following morning. The patient underwent cardiac catheterization within 18 hours of transport and underwent multiple vessel coronary artery bypass later in his hospital stay. This transport was denied based upon the fact that the patient was stable during the transport. The FI stated that the patient must experience chest pain during the transport to establish the medical necessity of air transport. We are appealing this denial based upon the fact that you can never predict which patients will be stabilized and which will continue to evolve and extend their myocardial infarction.

Basically, the medical judgement of the physician responsible for a patient's care at the hospital that initiates air transport has been reversed by a person in the Medical Review department of the local Medicare Fiscal Intermediary looking at a paper record, apparently with an eye toward finding a reason to deny. In our experience, the local Medicare Medical Review department has consistently made decisions that, we believe as physicians, seriously threatens patients. For that reason, we have appealed a very high percentage of the air ambulance downgrades by our local Medicare Fiscal Intermediary. While appeals are expensive, we have also had a very high rate of initial downgrades overturned, so far. Unfortunately, while the rate of downgrades has lessened since January of this year, DBC is still experiencing an initial rate of downgrades of air ambulance to land of approximately 28%.

Senator Baucus, We appreciate your support and understanding on this issue, and understand that you intend to introduce legislation that would address our problems. Such legislation will save lives in rural communities in Montana. Thank you.

Improve the Performance of the Fiscal Intermediaries and Carriers

DBC supports the need to restructure Medicare contractors, with a primary objective of providing better service to providers, physicians, and other health care professionals. We believe this will require that providers and physicians have direct access to better information resources, either

through the FIs and Carriers, or directly through more adequate guidance from Medicare nationally. At the same time, any Medicare contractor for Montana must be well versed in how services are delivered in a very rural and large state. As you can tell from the previous discussion, it is frustrating, time-consuming and expensive for DBC to work within the current structure of Medicare contractors and regulations. Because of the volume and complexity of our claims, and because of our commitment to an effective compliance program, we often identify claims issues involving the Medicare contractors sooner than other providers in the state. Often our FI/Carrier lacks the internal resources to answer our questions in a timely manner. It also does not have a technology specialist on staff who can answer basic questions about electronic submission of claims or who can fix problems with their computer system. In our experience, any solution to the problems we have with Medicare, and specifically with our Medicare contractors, requires more resources.

We urge the inclusion in S. 1738 of contractor performance review utilizing results of monitoring the accuracy, consistency, and timeliness of information as obtained through consultation with provider organizations who help develop the standards.

Ineffectiveness of Dispute Resolution with Medicare

Physicians, hospitals and other health care providers need help getting our disputes with Medicare resolved in a more timely and cost-effective manner. We believe this requires reform at two levels.

First, as is the case with air ambulance, we expect to have hundred of claims in appeal. Many of them involve essentially the same material facts and the same question of medical necessity. We are confident that we will win on appeal before the administrative law judges, for those cases we aren't able to get reversed before that in the appeals process within the Medicare Fiscal Intermediary. But even if we win dozens of appeals before the ALJ, all involving the same issues, there is no way currently to force the Medicare Fiscal Intermediary to change its policies. It can continue to deny and downgrade claims without regard to success by providers in appealing those claims.

We have discussed this issue with you and your staff on the Senate Finance Committee, and understand that you intend to introduce legislation that gives providers avenues for making Medicare contractors change their policies in such situations. This involves both an amendment to Sec. 522 of BIPA to give providers standing under appeals reform initiated by Congress earlier, and a new provision that would allow providers to petition the Secretary to direct a Medicare contractor to make or revise local policies, taking into account actual success in front of ALJs. We appreciate your understanding on this issue.

Second, at this point, providers have no way to challenge the legality of regulations and conduct by the Department of Health and Human Services on an expedited basis. This is true even if the regulations and conduct are unconstitutional or violate the underlying statute enacted by Congress or the Administrative Procedures Act. It should be possible to challenge such regulations and conduct as soon as they occur, before they are implemented, on an expedited basis. However,

under US Supreme Court precedent in Shalala v. Illinois Council on Long Term Care, a provider is only able to challenge a regulation through an administrative process that requires that the provider first violate the regulation, in order to get standing to challenge it. Since penalties for violating Medicare regulations can include exclusion from the Medicare program, this puts providers in an untenable position.

Congress should revise Medicare law so that when providers dispute the legality of HHS' regulations or actions, they are entitled to bring an action in court, on an expedited basis, without having to first violate the regulation.. We would encourage inclusion of this provision in S. 1738.

Medicare Rules often Micromanage Care and Direct Physicians How to Practice Medicine and Impose Onerous Paperwork Requirements

A few examples should suffice to demonstrate the problem with overly prescriptive regulations that interfere in the physician-patient relationship:

The "Inpatient Only" Designation

Designation of "Inpatient Only" services was part of the Medicare Hospital OPPS rule, published April 7, 2000. The Inpatient Only procedure list attempts to replace clinical judgment with government regulation. The rule that Inpatient Only procedures will not be paid if performed on an outpatient basis conflicts with CMS requirement that patients be admitted as inpatients only if they meet clinical criteria. Admitting patients as inpatients to comply with the Inpatient Only procedure list may well result in hospitals admitting patients who do not meet clinical inpatient criteria. This puts the hospital at risk for have services denied for payment. It also may make an inpatient bed unavailable to a patient who really needs it.

The dictates of the Inpatient Only procedure list also conflict with many commercial insurance guidelines for what procedures should be performed on an outpatient basis. Hospitals are forced to base medical decisions on payment source rather than clinical needs. Conflicting standards are cumbersome for hospital registration, case management, nursing and coding staff.

The Inpatient Only procedure list is often obsolete. A list based on historical data, often several years old, cannot keep pace with the innovations in health care technology and delivery. Hospitals are penalized financially for advances in medical care that allow them to provide services in a more efficient and cost effective setting

The financial burdens of the Inpatient Only procedure list affect the Medicare trust fund, patients and hospitals. Since inpatient DRG reimbursement is generally higher than a corresponding outpatient APC payment, it costs the trust fund more if procedures safely performed on an outpatient basis must be performed on an inpatient basis. Patients may be financially burdened if the inpatient deductible is higher than the corresponding outpatient procedure co-payment would be. Potentially, the patient may bear complete financial responsibility for an outpatient hospitalization if he/she knowingly chooses to have an inpatient only procedure done on an outpatient basis.

Proposed solutions:

- Eliminate the Inpatient Only list and allow clinical criteria, standards of medical care, and risk of legal liability to determine the appropriate level of service.
- Allow hospitals to appeal Inpatient Only denials through Quality Improvement Organization or Fiscal Intermediary medical review channels. Medical Review findings could determine reimbursement for the case being reviewed and be used to improve timeliness of updates to the inpatient only list.

Physician Supervision of Diagnostic Tests (Program Memorandum Transmittal B-01-28, issued April 19, 2001)

This rule tells physicians, mainly radiologists, 1) when they must “generally supervise” a procedure, which means the procedure is furnished under the physician’s direction and control, but their physician presence is not required, 2) when they must “directly supervise, which means they “must be present in the office suite and immediately available,” but not in the room, or 3) when they must “personally supervise,” which means they must be in the room during the performance of the procedure. The supervision requirement has meant that patients requiring contrasts for MRI must be done under direct supervision of a physician. As a result, patients requiring that procedure frequently must wait for the procedure, sometimes for hours, sometimes for days, raising quality of care concerns. We looked at 10 years of data, and could find no evidence of any safety concerns for patients related to use of contrasts that could not be handled by the highly trained RNs and other staff present, with supervision by radiologists via highly sophisticated technology, that effectively put the physician in the room.

One-hour Rule for Review of Seclusion and Restraints in Psychiatric Facility

The Medicare Conditions of Participation, published in the Federal Register in August 2000, require physicians to physically see an inpatient who is placed under restraints or seclusion within one-hour. This rule has posed a significant operations problem for our inpatient Psychiatric Center in terms of staffing and psychiatrist burn-out, and it does not improve patient care. While proper oversight of restraints and seclusion is important, this level of micromanagement is not. This rule has had deleterious effects on DBC’s ability to retain psychiatrists in the acute, inpatient setting. This is especially challenging, given our critical role in the safety net for mental health services.

The one-hour requirement for needs to be deleted or changed to allow for more realistic and flexible management of the use of seclusion and restraint.

We question the need for medical micromanagement of medical judgement through Medicare regulations and the Conditions of Participation. When it occurs, it should be based upon sound medical advice and evidence, not upon individual instances where additional safeguards were needed to prevent a bad outcome.

Advanced Beneficiary Notices

The ABN regulations impose burden on physicians/providers that impede the delivery of care to patients. If physicians followed the encouragement of government to obtain ABNs, physicians are burdened with explaining Medicare regulations about coverage to their patients. Physicians/or representative are encouraged to present an ABN when there is a likelihood that Medicare may not pay for a particular service. In order to present the ABN when appropriate, physicians/representatives need to know or have an efficient way to know which tests or services are considered to be Limited Coverage Tests/services—which is variable among Medicare Carriers and Fiscal Intermediaries. Physicians need to know or be able to access a list of ICD-9 codes to see if the patient’s diagnosis codes are on the “list “ of codes that Medicare will pay for testing. If the patient’s diagnosis code is not on the covered list--- then an ABN needs to be presented. Why, if not required, would a physician with a busy practice take time to explain Medicare regulations? Many times, the result is that an ABN is not executed.

The ABN regulations target the wrong group. In the case of a laboratory test, in order for the laboratory to bill for Limited Coverage tests---the laboratory needs to submit a claim with a “payable code” or indication of a signed/properly executed ABN. Many times the patient is never at the laboratory that performs the test(s). And yet, the liability and responsibility to execute an ABN rests with the laboratory. The clinical laboratories are set up for failure.

Solutions: Either eliminate the ABN requirements for lab procedures or make it feasible for labs to comply. Even a partial elimination of the ABN requirement for frequent and relatively low cost services and procedures would be helpful.

Medicare Secondary Payor Rules

The Medicare Secondary Payment rules, which received substantial attention during the last Congress, continue to be a significant problem. This rule requires providers to ask 25 questions of Medicare beneficiaries about other payment sources. Initially, this rule required that providers gather this information on every encounter. At DBC, patients will frequently have several encounters in a day. The paperwork burden to DBC and patients, alike, was huge, and actually interfered in the process of care. At this point, our FI requires that we collect such information every two months, which is still too frequent. We understand that other FIs still require an MSP questionnaire be filled out on every encounter. More reform and more centralized guidance is needed.

Stark Self-Referral Rules (42 CFR 350 et seq., authorized under 42 U.S.C. 1395nn et seq.)

There are thousands of ways to engage in beneficial activity that violates the Stark laws and triggers punitive penalties. Regulatory reform could ameliorate some of the harsh consequences.

Under the Stark laws, any “compensation” between a physician and an entity must fall within one of the statutory or regulatory exceptions, or the entity is prohibited from billing certain federal

payors for “designated health services.” It is a strict liability law -- actual harm, actual intent don’t matter. Failure to meet every element of one of the exceptions carries potentially terrible consequences for the ability to provide health care, especially in rural communities, even if the failure is technical and harmless and the actions by the physician and entity are beneficial.

For instance, if a physician, who is not an employee of a small rural hospital, agrees to train hospital staff on a simple outpatient procedure that is going to be added to the services of the hospital, and is paid \$100 to do that training, under the Stark regulations, unless he has a written contract with that facility, both he and the facility have violated the law. As a result, the hospital would be precluded from billing Medicare for services that physician refers to that facility (for a period of time unspecified in the statute or rules), and, if that hospital provided and billed for services, it would be required to return any money it received once it discovered the technical Stark violation. This would be true even if the \$100 payment met all of the requirements of the fair market value exception to Stark, except the requirement of a written agreement, and all of the patients who got the procedures at the hospital needed them, and the physician and hospital were making a special effort to bring the procedure closer to home so people would not have to travel to distant hospitals. If this physician is the only physician who provides certain services in a community with a sole community provider hospital, the physician might not be able to continue to practice in the community because the hospital could not afford not to bill for the designated health services he refers to the hospital.

Although fundamental statutory reform of the Stark law is needed, the problem described above could be partially addressed through regulatory reform that removes the requirement of a written contract from the fair market value and personal service arrangements exceptions to the Stark law. The regulations should specify a very short time frame (e.g. no more than one month) during which services could not be billed to government payors as the result of a Stark violation, especially for an honest mistake or when there is no evidence of inappropriate referrals.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Based on expert outside consultation using a conservative approach DBC expects to spend three million dollars over the next few years complying with Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules. We support the intent of many of these rules but hope that simplification of the requirements is yet possible, and that recognition of the practical and financial implications of implementation will be taken into consideration.

We are pleased that HHS’ proposal to improve the consent process by replacing the current redundant written consent requirement with written acknowledgment. The proposal for written acknowledgement greatly improves the consent process for both patients and providers. It eliminates the barriers to care created by the previous requirement while retaining strong patient protections for non-routine uses of information. Montana has already adopted one of the most stringent laws in the country on protection of health information, which DBC believes in and

complies with. It doesn't require prior written consent, and yet, we simply have not seen in Montana the kinds of abuses of health information that have been a problem in other states. Our experience in Montana suggests that prior consent is not needed to fully protect patients. Requiring prior written consent in a state of vast spaces, where providers need to work together over telemedicine and telephone, could actually impair care, in addition to creating an unnecessary and expensive paperwork burden.

The Volume and Combined Impact of the Rules is Overwhelming

As the examples above illustrate, physicians, hospitals and nursing homes are drowning in a sea of government rules and regulations. Caregivers, driven by complex rules and regulations in the Medicare program, are forced to shift their focus from patient care to "crossing the t's and dotting the i's" of paperwork. In a study for AHA, PricewaterhouseCoopers found that physicians, nurses and other hospital staff spend on average at least 30 minutes on paperwork for every hour of patient care provided to a typical Medicare patient. In the emergency department, every hour of patient care generates an hour of paperwork – including complying with the vast array of federal, state and local health regulations. And, at a time when we face serious workforce shortages, many caregivers cite regulatory burden as among the downsides of their jobs.

The impact to DBC of the financial and human resource cost of responding to many of these regulations is becoming clearer to us at DBC and is huge. Staff salaries to support physician coding total \$500,000 alone. We expect to spend \$3 million dollars over the next several years on implementing HIPAA regulations.

Steps are need to reduce the impact of poorly conceived, unnecessarily burdensome, and poorly implemented regulations on physicians, hospitals, and other health care providers. We suggest the following:

Coordinate the orderly release of federal regulations to allow for more seamless compliance

- Government agencies need to release regulations in a coordinated manner so that implementation does not overwhelm health care personnel and systems. That means establishing a point of accountability to coordinate regulatory activity across major federal agencies, as well as within HHS. Secretary Thompson has ordered a top-down review of all HHS regulations to determine whether they are confusing, conflicting, impose unnecessary costs or penalties or are simply burdensome. In addition, HR. 3391 and S. 1738 include language requiring consultation between HHS and the Office Management and Budget to establish an orderly timeline for the publication of final rules.

Provide interpretive and advisory guidance on Medicare payment requirements

- Medicare requirements for provider participation and payment are increasingly voluminous and complex, making compliance difficult, while penalties for noncompliance are increasingly severe. CMS should establish query mechanisms for individual providers and

their associations on the appropriate interpretation or application of Medicare rules in specific situations. CMS' responses should be timely and readily available to others in an easily accessible format (such as an indexed file on the Internet). We urge inclusion of this provision in S. 1738.

Consult caregivers on rule development

- Early in the drafting 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. We support Secretary Thompson's recommendation that CMS pilot test new regulatory measures for workability before requiring them of providers nationwide.

The Congressional years of 2001 and 2002 have seen a flurry of activity in the area of regulatory reform, and increased Congressional attention to addressing recognized problems. The Department of Health and Human Services and the Center for Medicare and Medicaid Services have taken some steps to reduce the regulatory burden. In particular we applaud proposed rule changes to the HIPAA Privacy Rule, mentioned above, and to EMTALA rules.

I appreciate the opportunity to testify today and acknowledge where improvements have been suggested and highlight areas of continuing need for regulatory reform.

Thank you to you and your staff for your focused attention on these issues.

COMMUNICATIONS

STATEMENT OF THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY

Thank you for holding this hearing on regulatory relief for Medicare. My name is Philip Barney, MD, FASCP, and I am a former president of the American Society for Clinical Pathology residing in Missoula, Montana. I appreciate your efforts to highlight administrative concerns facing health care providers, and to find solutions to easing certain regulatory burdens that, if revised, may assist in improving the delivery of health care. I hope the information provided below may be of assistance.

The American Society for Clinical Pathology (ASCP) is a nonprofit medical specialty society representing 151,000 board certified pathologists, other physicians, clinical scientists (PhDs), medical technologists and technicians. It is the world's largest organization representing pathology and laboratory medicine. As the leading provider of continuing education for medical laboratory personnel, the ASCP enhances the quality of the profession through comprehensive educational programs and materials.

Diagnostic Information

Laboratory professionals do not directly control laboratory test utilization. Other health care providers order the tests that the pathologist and laboratory professionals perform. Ordering providers are responsible for the patient's medical record. Yet, laboratory professionals are responsible for providing the diagnostic information necessary in order for a Medicare claim to be paid.

The Balanced Budget Act of 1997 contains a provision that states, "... if the Secretary requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner." However, this provision has no enforcement authority, since the laboratory is ultimately responsible for the Medicare claim and the financial burden. It remains extremely difficult for the laboratory to collect the required diagnostic information.

The Institute of Medicine (IOM) published a report in December 2000, *Medicare Laboratory Payment Policy – Now and in the Future*, that discusses this dilemma. The IOM report recommends that the Health Care Financing Administration “discontinue use of the International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes as the basis for determining the medical necessity of clinical laboratory tests.” In place of these codes, the report suggests that alternative approaches be established for identifying or reducing unnecessary or inappropriate laboratory testing. ASCP would agree with this general approach.

Advance Beneficiary Notices

Similar to the unease with diagnostic information requirements, laboratories are expected to have Medicare beneficiaries sign advance beneficiary notices if there is a concern that the test about to be performed will not be covered under Medicare. This is expected even though the laboratory professional does not often see the patient and will generally not know the patient’s medical history. Considering the tremendous confusion over the appropriate use of advance beneficiary notices and its impact on Medicare payment, there is a strong need to clarify these policies and their use within the laboratory community. ASCP has been working with HCFA, particularly on the draft of the Medicare Part B advance beneficiary notice for laboratories, and many changes have been made to the draft form that will make it easier to read and easier to comprehend. However, the overall issue still remains a concern.

Medicare Secondary Payor

We appreciate the need for Medicare to ascertain when it does not have primary responsibility for paying the medical expenses for a Medicare beneficiary. However, there are some specific circumstances when this information collection process unduly burdens – both in time and financial resources – laboratories and laboratory professionals.

MSP questions must be asked at every inpatient or outpatient beneficiary admission or encounter, but there is a change under consideration by HCFA and the Office of Management and Budget that the MSP questions be asked at every initial encounter. For recurring patients, we understand that the change will have MSP information gathered or verified at the initial admission or encounter and just prior to the monthly billing. This is defined as not longer than 15 days prior to the date that Medicare claims are submitted, at the last encounter in the billing cycle, or as close as possible to the date of claims submission. This continues to pose some concern.

ASCP suggests that instead of requiring the lengthy, cumbersome MSP form for each encounter prior to the billing cycle that Medicare beneficiaries be required to sign a simple MSP statement affirming that Medicare is indeed their secondary payor. Perhaps, the beneficiary may simply “reaffirm” an initial form.

We have data to share that explains that even with the change in collection requirements for inpatients, outpatients, and recurring patients, there is an added burden for the patient and the laboratory. For example, in some settings, particularly outpatient clinics, the one laboratory employee responsible for drawing the blood, processing the specimens, testing the specimens, and indicating test results, must also sit down and complete the MSP form with the patient. This causes an increase in patient wait times and a delay in the turn around time for patient test results. The added burden of a cumbersome questionnaire often frustrates patients, and creates an unfair advantage for laboratories that are not required to complete such forms.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

CLIA mandated a level of quality assurance for all clinical laboratories. Standards for clinical laboratory testing such as quality control, quality assurance, personnel standards, proficiency testing, and site neutrality should not be eroded. CLIA has helped to raise the standard by which all laboratories operate. We recognize that some organizations may consider CLIA to be a burdensome regulation, so we are writing to recognize the benefit of such standards for clinical laboratory testing – no matter the site of service.

For example, according to April 1999, data from the then-Health Care Financing Administration, the most frequent survey deficiencies have decreased since the advent of the CLIA survey. The percentage of laboratories noted for not following manufacturer instructions, a part of quality control, fell from 19% in the first survey cycle to 10% in the third survey cycle. Also notable is the improvement of physician office laboratories, where the deficiency, in this instance, fell from 21% to 10%.

Studies, such as a recently published report in the *Journal of the American Medical Association* in February 1998, concluded that "testing personnel in many POLs (physician office laboratories) might lack the necessary education, training, and oversight common to larger facilities... patients should be aware that preliminary findings suggest that differences in quality of laboratory tests based on testing site may exist...(and) legislators may wish to reconsider the wisdom of further easing restrictions on those to whom we entrust our laboratory specimens." This 1997 California Department of Health Services study on physician office laboratories found that physician office laboratories had a significantly higher proficiency testing failure rate compared to non-physician office laboratories, and physician office laboratories that employ medical technologists.

The Office of the Inspector General (OIG) issued in June 1995, a report, *CLIA's Impact on the Availability of Laboratory Services*. The report concluded that "CLIA appears not to have affected physician ability to secure laboratory services for their patients." Of the 232 physician practices contacted by the OIG, 18 had closed physician office laboratories while eight actually opened new sites.

HCFA released data in September 1995, showing that CLIA has helped physician office laboratories improve their performance in carrying out laboratory testing for patients. Then-HCFA Administrator Bruce Vladeck, PhD stated, "With physician office labs making up 59 percent of the nation's clinical laboratories, improving the quality of testing is very important to patient care... erroneous test results can lead to improper diagnoses and treatment, which may ultimately cause unnecessary injuries and deaths..."

In March 1996, the *Morbidity and Mortality Weekly Report*, prepared by the Centers for Disease Control and Prevention, published a report, "Clinical Laboratory Performance on Proficiency Testing Samples - United States, 1994." The report found that "... physician office laboratories and other newly regulated testing sites had higher rates of unsatisfactory proficiency testing performance than previously regulated hospital and independent laboratories."

CMS found in a recent survey that 32% of waived laboratories failed to have current manufacturer's instructions, 16% didn't follow the manufacturer's instructions, 9% didn't follow manufacturer's storage and handling instructions, and 6% were using expired reagents and kits. This preliminary information is based on a survey conducted by HCFA from October 2000 to January 2001. The results showed overall that a substantial 48% of waived laboratories surveyed had quality testing problems. The survey results were produced from an expanded pilot project undertaken by the agency of 270 certificate of waiver laboratories and 190 provider-performed microscopy laboratories surveyed in eight states.

Thank you for the opportunity to share these views. We respectfully request that this statement be included in the hearing record. If you have questions or need additional information, please contact me or the American Society for Clinical Pathology at (202) 347-4450.

Luke A. Pluto, M.D.

Lewiston, ID 83501
May 22, 2002

Senator Max Baucus
United States Senate
Committee on Finance
Washington, D.C. 20510

Dear Senator Baucus:

I would like to express my views on the Regulatory Relief for Medicare - The Case for Cutting Red Tape hearing on May 28, 2002.

My name is Luke A. Pluto, M.D. I practice pulmonary, critical care, and sleep medicine in Lewiston, Idaho. A large portion of my practice is devoted to the care of Medicare patients. On January 23, 2001, the CIGNA Medicare Anti-Fraud Unit in Nashville, TN requested a statistically valid random sample, or full audit of my practice. I was not informed of the specific reason for the audit, or as to why a statistically valid random sample was requested. I was given 30 days to provide 279 patient records, which was insufficient. On July 23, 2001, I was given 30 days, or until August 22, 2001, to repay \$14,521. On August 16, 2001, CIGNA asked for \$14,853.78.

CIGNA scored my documentation using what they termed an "HCFA/AMA approved score sheet." My attorney requested a copy of the score sheets. CIGNA would not release the score sheets, citing Title 5 United States Code 552 (b). I do not know whether 1995 or 1997 score sheets were used, and do not have information which is vital in my efforts to code properly. In the request from July 23, 2001, extrapolation was applied to records which were not actually reviewed. The method was not actually valid, in that what is termed a statistically valid random sample does not accurately reflect the billing from records which have not been reviewed. I am currently waiting for the date of a hearing with an administrative law judge.

The audit disrupted my practice. There was no due process, and I was asked to repay almost \$15,000.00 based on records from which overpayment was never proved because the records were never reviewed. I have found that medical meetings too often focus on correct coding, and that trying to determine the level of service for each patient encounter detracts from the practice of medicine. Medicare regulatory efforts have become the biggest impediment to my ability to provide quality and efficient care to my patients.

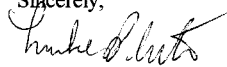
The most effective way to cut red tape would be to follow the recommendation of the HHS Advisory Committee on Regulatory Reform and eliminate documentation guidelines for Evaluation and Management services. In the meantime, if a statistically valid random sample is requested, the Medicare Integrity Program should finance an independent review. If a provider has been found to code at a lower level than the review indicates, the

service should be upcoded. When extrapolation is applied to the audit, upcoded services should be included if the sample is felt to be statistically valid. Such a system would encourage accurate coding.

Due process should be used during audits, consistent with Amendment VI, including the right of the provider "to be informed of the nature and cause of the accusation." The provider should be presumed innocent until proven guilty. For me, the most devastating aspect of my CIGNA audit has been the inability to give patients the attention they deserve when I am in a continued state of fear from future audits and the loss of my ability to practice medicine.

Thank you for this opportunity to present my views on Regulatory Relief for Medicare.

Sincerely,



Luke A. Pluto, M.D.

copies: Senator Larry E. Craig
Senator Michael D. Crapo