HEALTH CARE FINANCING ADMINISTRATION PAPERWORK BURDENS

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BEFORE THE

COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

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HEALTH CARE FINANCING ADMINISTRATION PAPERWORK BURDENS

WEDNESDAY, MAY 9, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 10:03 a.m., in Room 2360, Rayburn House Office Building, Hon. Donald A. Manzullo (chair of the Committee) presiding.

Chairman MANZULLO. Please come to order.

Our hearing today is about Health Care Financing Administration regulatory requirements burdening health care providers. This hearing will be the first in a series of hearings that the Committee will hold on reducing regulators burdens on health care providers. The next full Committee hearing is scheduled for July 11, when the Committee will examine a broad array of regulatory relief options for health care providers.

I would like to thank my colleague, the gentleman from Pennsylvania, Mr. Toomey, for the efforts he has made on that front, and would hope that he can find the time to testify at the July 11 hearing.

I am going to waive the reading of the rest of my opening statement, and defer to Ms. Velázquez and then Dr. Christian-Christensen. Both will have an opening statement.

Then I would like to ask Mr. Toomey to introduce his witness.

[Mr. Manzullo's statement may be found in appendix.]

Chairman MANZULLO. Ms. Velázquez.

Ms. VELÁZQUEZ. Thank you, Mr. Chairman.

Today the Committee begins working towards the reauthorization of the Paperwork Reduction Act. This landmark legislation was signed into law in 1980 by President Carter with the goal of reducing the overall burden and time small businesses spend complying with paperwork reporting requirements.

This Committee has long known that the overall Federal paperwork burdens fall disproportionately heavily on small businesses. Paperwork requirements and the associated costs are nearly twice as high for small businesses than corporate America.

The focus of this hearing is on the Health Care Financing Administration and the associated paperwork requirements that its regulations create. HCFA is the Federal agency charged with administering Medicare, and has been referred to as the country's largest health insurance provider. Oftentimes, it is the only health care option. The services they provide affect the lives of 38 million Americans nationwide.

Because of the nature of its work, oftentimes HCFA creates some of the largest and most complicated paperwork requirements. Out of the 30-plus Federal agencies, HCFA ranks sixth behind Treasury, Labor, and DOD in paperwork burdens.

While it is easy to simply lay the blame for onerous regulations on Federal agencies, the reality is that most of the paperwork burden that falls on small businesses are the result not of agency mandates, but due to legislative initiatives passed by Congress. I believe that if Congress truly wants to reduce paperwork burdens on small businesses, we need to look first at how we legislate.

In recent years, a great deal of attention has been given to HCFA regulations and the paperwork burden that it places on small businesses. It should come as no surprise that the industry affected most by these paperwork requirements are the medical professions. We often forget that many in the health care field are small businesses. As a matter of fact, small business loans to medical providers ranks in the top five under the SBA 7(a) loan program.

According to the American Medical Association, HCFA produces over 110,000 pages of medical regulations, requiring doctors to spend an estimated 20 percent to 50 percent of their time filling out forms, meaning many doctors are spending as much time with their accountants as they are with their patients.

Hopefully, today's hearing will shed some light on how we can streamline these processes, and what changes can be made to the Paperwork Reduction Act to ensure agencies report clear and concise regulations.

I look forward to hearing from the witnesses on how this Committee can find a balance between the need for accurate reporting requirements that do not overburden small businesses.

[Ms. Velázquez's statement may be found in appendix.]

Chairman MANZULLO. Thank you. We are going to defer Mrs. Christensen's statement until after the vote.

At this time, I would like to have Congressman Toomey to introduce his witness, and Congressman Baldacci can introduce his witness.

Mr. TOOMEY. Thank you, Mr. Chairman.

Chairman MANZULLO. After the introductions, the Committee will stand in recess until after the vote.

Mr. TOOMEY. Thank you, Mr. Chairman. I want to also thank you for your invitation to testify before the Committee on the July 11 hearing. I will certainly happily accept that invitation. I look forward to speaking with this Committee about my bill, H.R. 868, which has over 165 cosponsors already, the intent of which is to provide some due process reform for health care providers when they are dealing with HCFA in matters of dispute.

Today, of course, our topic is slightly different. I want to welcome our first guest on the panel, Dr. William Mahood. Dr. Mahood's wife and daughter live in Flourtown, Pennsylvania. I am delighted you could be with us today, and I appreciate your coming here to be with us.

I want to tell you a little bit about Dr. Mahood. He has a group practice in gastroenterology, has had a long history in being involved in public policy issues as they relate to health care in par-

ticular, and has been involved in numerous medical societies and organizations over the last 20 years.

A couple of noteworthy examples nationally, Dr. Mahood has been a member of AMA's board of trustees since 1996, and AMA's Council of Medical Service since 1991. He has also been very active on the local level. In Montgomery County, Dr. Mahood helped to create the county's board of health, and co-chaired a health task force for the county.

Dr. Mahood works in the trenches of providing medical care, but also understands our health care system in a broader context, so his input today is going to be very helpful. I am personally delighted you could be with us to join us and give us your views. I would like to welcome Dr. Mahood.

Chairman MANZULLO. Thank you, Congressman Toomey. Congressman Baldacci used to be a member of the Small Business Committee. We miss his presence. He and I used to exchange spaghetti recipes from our family restaurants.

Congressman Baldacci, will you introduce your guests here?

Mr. BALDACCI. I won't give you the recipe, but I will introduce my guest.

First, I want to thank you, Mr. Chairman and Ranking Member Velázquez. It is a pleasure to be here with all of you. This is a very important matter, and I commend you for taking this issue up and for coming forward with this hearing.

When we look at health care costs and look at the amount of money that is being spent on paperwork itself taking away from needed care to people, this is truly an important area that needs to be addressed.

Mr. Cummings is a good friend of mine. He is somebody who has been a health care leader in Maine. He has been the CEO of the Blue Hill Memorial Hospital. He serves on numerous boards. He has been the executive officer of the Blue Hill Memorial Hospital for over 10 years, and has contributed to the hospital's successes for over 20 years. He has been chair of the board of the Maine Hospital Association, and currently the director and vice-chair of the Maine Center for Public Health.

He had been representing the American Hospital Association on the Interagency Task Force on Rural Health Clinics, and is currently a member of the American Hospital Association Task Force on Regulatory Relief.

Bruce's commitment, his intelligence, tenacity, and energy have helped to mold Blue Hill Memorial Hospital into a first class hospital and health care provider in the community. He has helped other health facilities to meet the needs of the people of Maine. I have found his advocacy, especially for rural Maine, to be second to none. He truly represents the best of his profession. I appreciate his participation at this hearing.

Bruce and I met last week, along with other hospital administrators. Bruce had an example, and I am not sure if he is going to unfurl that stack of paperwork today, but he unfurled it for my benefit. It was good, because it leaves a lasting impression in terms of the amount of paperwork that people have to go through.

I want to thank the chairman for the opportunity, and look forward to hearing from the witnesses.

Chairman MANZULLO. Thank you very much. We are going to a recess so we can approve the Journal of the great things we did yesterday. Then we will be back in about 15 minutes.

[Recess.]

Chairman MANZULLO. The hearing will come to order..

We are going to have an opening statement from the gentlelady from the Virgin Islands and doctor, Mrs. Christian-Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

I want to thank you and the ranking member, Ms. Velázquez, for holding this hearing on the paperwork burdens of the Health Care Financing Administration.

As chairman of the Health Brain Trust, but especially as a physician who suffered from the complex and burdensome bureaucracy myself, I can say that a close scrutiny of this important issue is long overdue. I commend the Chair and the ranking member for recognizing the special plight of small businesses which are health care providers in bringing the issue of HCFA to this Committee.

It is an honor to welcome my colleagues and all of the representatives of health care provider associations who are with us this morning. I want to thank them for stepping in and providing information to this Committee on behalf of all of the health care providers of this country.

Based on the introduction of bills like H.R. 868, and many letters and statements, it seems that help is on the way. However, I would caution that to fix and not compound the problems, it is important that this Congress not follow the lead of HCFA, but instead, hear from and be advised by those who know the problems and its impact best, the providers.

We must be especially cognizant, as we do that, of the fact that indeed Congress is responsible for some of the confusion itself.

Several key leaders in both bodies are on record. In the House, three chairmen, Chairman Tauzin, Chairman Bilirakis, and Chairman Greenwood, in a letter to Secretary Thompson, stated their commitment to changing the system so health care professionals can better focus on improving quality of care. Both the President and the Secretary are on record in favor of reform, as well.

During several testimonies here on the Hill, I have committed myself to working on this issue. I have also signed on as a cosponsor of H.R. 868.

It is no wonder this agency is a mess. There are over 130,000 pages of regulations which, based on my experience, are interpreted differently in different parts of this country. Just a few examples:

A Medicare patient, at perhaps the very worst time, in the emergency room, can be faced with filling out over eight pages of Medicare forms; because of complexity and continuous changes, records have to be reviewed by at least four people to ensure compliance; OASIS, which is used to assess care at home health agencies, asks more than 60 questions; another tool used for skilled nursing facilities asks almost 200, which are not used for calculating, what the payment should be;

According to GAO, 40 extra minutes of a nurse's time is required just to do the initial OASIS assessment. For every hour of health

care provided, it takes anywhere from 30 minutes to an hour to do the paperwork.

HCFA is quick to point out that it is not ranked the worst in terms of record keeping, it is ranked sixth. But I have a feeling, having been a physician and having had to fill out the paperwork to take care of patients and do all the rest of the best of medicine, that we just do not complain. I don't think that the full record from physicians and health care providers is there for them to really be ranked as they should be ranked. I am sure if all the information was there, HCFA would be ranked higher than sixth as one of the worst regulatory agencies as far as regulatory burdens are concerned.

It is, therefore, no wonder that many physicians and other medical service providers choose not to participate in the Medicare program. Many in my district of the Virgin Islands do not, and not only because of the reporting requirements, but because of lack of fairness and timely responses, timely payments, and then the denials and medical necessity decisions.

I would like, Mr. Chairman, to ask unanimous consent to include in my statement a statement from one of our local physicians at home for the record.

As you have said, this is not going to be our only hearing on this issue, and I am really pleased to hear that. I look forward to hearing from our guests this morning. Hopefully this is the beginning of resolving many if not all of the issues that we have with HCFA.

Thank you, Mr. Chairman.

Chairman MANZULLO. Could you identify the name of the physician, for the record?

Mrs. CHRISTENSEN. Yes, Dr. Robert L. Booker. He is an endocrinologist in the Virgin Islands. He has served in the medical society.

Chairman MANZULLO. That statement and the full statements of all the witnesses will be admitted in the record, without objection.

Our first witness is Dr. William Mahood.

One of my constituents is the former head of the gastroenterologists. At one time I learned about the ENTs, but I am not even going to get into that now.

HCFA has been referred to as "Hell Can Find Anyone." We are coming off a big fight with HCFA back home where they fined three chiropractors $250,000. We got it down to $1,500. Then HCFA appealed it. Within a short period of time, they withdrew that appeal. My staff gave me a set of boxing gloves. On the right boxing glove it says HCFA. I should have brought them here. We know who the enemy is. We represent people, we don't represent the government, so you are among friends here.

Dr. Mahood, I look forward to your testimony. We are going to try to keep the testimony at 5 minutes apiece so we will have plenty of time for questions and interactions. Doctor.

STATEMENT OF WILLIAM H. MAHOOD, M.D.

Dr. MAHOOD. Thank you, Mr. Chairman.

My name is Bill Mahood. I am a member of the American Medical Association Board of Trustees and a practicing gastroenterologist from Abington, Pennsylvania.

We appreciate the Committee's efforts to address the burdensome Medicare regulatory requirements, and believe that the bipartisan Medicare Education and Regulatory Fairness Act, MERFA, will significantly decrease the burdens placed on physicians.

Two-thirds of physician practices qualify as small businesses, with less than 25 employees. Thus, these practices cannot absorb the costs imposed by the unfunded government mandates resulting from burdensome Medicare regulations.

In fact, in a recent AMA survey, more than one-third of the responding physicians spend one hour completing Medicare forms and administrative requirements for every one to four hours of patient care. These requirements shift physicians' time away from patient care.

Three examples. First, documentation guidelines require physicians to record information in a patient's chart that is not clinically relevant. These stringent documentation requirements force physicians to overload the patient's medical record with extraneous information that can actually harm patient care.

When a patient needs emergency treatment, for example, physicians must go through volumes of patient records to try to quickly determine what treatment is needed. It is like trying to find a needle in a haystack.

HCFA is developing clinical examples to illustrate the typical documentation that should be in a medical record. We understand that the initial draft of this clinical example is already 640 pages long.

Finally, even though these guidelines are a serious Medicare paperwork problem, and we know Medicare relies on them to ensure proper payment, the guidelines have never gone through the OMB clearance process.

We urge the Committee to review the paperwork burden imposed by the guidelines and to explore whether pilot projects using peer review designed to test the clinical relevance of the guidelines are not a more appropriate response to ensuring clinically relevant documentation standards.

Next, I would like to discuss the Medicare enrollment process. A physician cannot be reimbursed for providing treatment to a patient until he or she has a provider number, which is issued by Medicare upon completion of the Form 855 enrollment process. Carriers often take months to approve these enrollment applications, even though physicians have already undergone tremendous scrutiny to become licensed in the State and to have hospital privileges.

During this approval process, many physicians, especially in rural and smaller practices, are effectively precluded from treating Medicare patients.

Carriers should reserve temporary provider numbers, allowing licensed physicians to see Medicare patients while waiting for their permanent Medicare number.

Another problem with the enrollment process is HCFA's cost and time estimates required by the Paperwork Reduction Act. For example, HCFA's estimate for clerical employee wages, and attorneys' and consultants' fees for completing this form are severely under-

estimated. HCFA should be required to take into account the true costs of the Medicare enrollment process.

Another problem is a pending HCFA initiative under which all physicians would have to enroll in Medicare. Physicians also would have to revalidate this every 3 years. This is completely unnecessary and burdensome, and we urge the Committee to prevent HCFA from expanding the enrollment process.

The final issue I would like to address today is the serious conflict in Medicare policy between advanced beneficiary notices, or ABNs, and a requirement under the Emergency Medical Treatment and Active Labor Act, EMTALA.

When physicians see Medicare patients, to bill the patient for an uncovered or possibly uncovered service, the physician must request that the patient sign an ABN. It just states that the service may not be covered and that the patient will indeed pay if it is not covered.

Medicare obviously requires these be signed by the patient prior to ordering or performing a noncovered service, but under EMTALA, the patient must first be stabilized before you can even ask about their insurance. EMTALA prohibits a physician from complying with the Medicare ABN policy, and therefore, although the emergency service must be provided, the physician cannot bill or be paid for them.

We urge the Committee to recommend that HCFA immediately resolve this conflict. We thank the Committee for pursuing these regulatory relief efforts. We look forward to working with you in the future. Thank you.

Chairman MANZULLO. Thank you, Doctor.

[Dr. Mahood's statement may be found in appendix.]

Chairman MANZULLO. Our next witness will be Dr. Alan Morris. He is from St. Louis, Missouri, born in the great State of Illinois. We just wanted you to acknowledge that.

He is a graduate of the University of Illinois, the University of Illinois Medical School, and former Captain, U.S. Army Reserves. He has a practice in orthopaedic surgery. He is here to testify about how he loves to fill out forms.

Dr. Morris, you were trained to fill out forms and not practice medicine, is that correct?

STATEMENT OF ALAN MORRIS, M.D.

Dr. MORRIS. As I frequently tell my mother, this is not what you sent me to medical school for.

Good morning, Chairman Manzullo and members of the Committee. My name is Alan Morris. I am a practicing orthopaedic surgeon in St. Louis, Missouri. I have a small practice, six partners.

I am also chairman of the Council on Health Policy and Practice for the American Association of Orthopaedic Surgeons. On behalf of this association, which represents 18,000 board-certified orthopaedic surgeons, I would like to thank you for the opportunity to testify.

In our health care system, our number one concern, of course, should be to ensure quality patient care. Instead, we have managed to create a bureaucratic nightmare of paperwork, rather than focusing on spending time with the patients.

Let me share with you some examples of this onerous paperwork burden. Mr. Chairman, it is very important to stress to you that Medicare sets the standards, and other payers may follow these standards. Our practice is set up to comply with Medicare.

My practice is a rather typical orthopaedic practice. It can be characterized as a small business. We have 26.5 FTE employees for seven physicians. Seventeen are administrative staff. This does not include an outside company to whom we have outsourced our billing process. This, in reality, adds additional administrative staff to process paperwork. That is a lot of people to push paper.

My associates and I are required to comply with requirements, both directed centrally from HCFA and independently by Medicare carriers, who enter into contracts with HCFA to oversee the coding and billing practices of physicians and other Medicare providers.

These carriers operate with a great deal of discretion, and utilize their own specific policies and forms, in addition to those of HCFA, and are not required to comply with Federal government review. We are required to comply with new and revised policies distributed monthly through the bulletins by each Medicare carrier. This is in two areas.

These policies often vary from carrier to carrier, but my patients are pleased that my medical journals take priority over my reading of these bulletins, which come out every month. I am a little behind in reading those bulletins.

Adding to our paperwork this year, the HHS Office of Inspector General distributed to physicians guidelines to develop voluntary compliance plans. My practice invested significant time to comply with paperwork requirements, and took time away from patient care to train our staff to comply with these plans.

To participate as Medicare providers, as my colleague has already said, our practice is required to complete several lengthy Medicare enrollment applications. Each physician is required to apply for a separate individual Medicare provider number, and the practice is required to apply for a separate group practice number.

Medicare requires physicians to reapply for Medicare numbers each time they move from one practice to another. Recently, three members of my practice applied for Medicare numbers. Two of these partners just practiced down the street. They have been in practice for 20 years. They received their Medicare enrollment numbers approximately 6 weeks after they reapplied. For one of our orthopaedic surgeons who was applying for the first time, it took significantly greater time. In addition, the practice had to reapply for a new group number. It is important to say that we could treat Medicare patients during that time, but we could not submit a Medicare payment or could not submit a claim for Medicare payment.

In contrast, I just recently completed a Veterans Administration credentialing online form. It was done online. It took me 15 minutes. I received prompt approval. There was no hassles. There was no paperwork. It was very streamlined. I think HCFA could learn something from the VA.

I believe HCFA has seriously underestimated, under the requirements of the Paperwork Reduction Act, the time and cost involved to complete these enrollment forms.

Finally, I would just like to mention E&M guidelines. This is the most onerous paperwork burden in the Medicare program. These guidelines have never gone through, as was stated, the OMB clearance process. It takes nearly as much time for me to dictate the report as I spend face to face with my patient. Don't forget the time and cost for my practice's three typists to transcribe these reports into the medical record.

In closing, I don't know all the nuances of legislative and statutory approaches to solve these problems. I did try to address some of these in my written testimony. But one thing is clear, paperwork needs to be reduced, and the requirements need to be simplified and standardized. All government agencies, HCFA and its affiliates, Medicare carriers, need to come under the same requirements.

We look forward to working with you, Mr. Chairman, and the Committee to find solutions to the paperwork burdens that are imposed upon us.

Thank you very much.

Chairman MANZULLO. Thank you very much, Doctor.

[Dr. Morris' statement may be found in appendix.]

Chairman MANZULLO. Our next witness has already been introduced by his Congressman. He is hiding behind that stack of paperwork. I am sure you are going to make a notation that those papers are not there to balance the table.

Mr. Cummings.

STATEMENT OF BRUCE D. CUMMINGS, CEO, BLUE HILL MEMORIAL HOSPITAL, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION

Mr. CUMMINGS. Thank you, Mr. Chairman.

I am Bruce Cummings, the CEO of Blue Hill Memorial Hospital in Blue Hill, Maine. I am here today on behalf of the American Hospital Association's nearly 5,000 hospitals, health system network, and other health care provider members. We welcome the opportunity to testify before you on the complexity and burden of HCFA's paperwork requirements.

Blue Hill Memorial Hospital is a 25-bed hospital. It was established in 1924 to serve the residents of a small coastal village of Blue Hill. Since I am from a State with a long maritime tradition, I am going to borrow a cue from last summer's hit movie, the Perfect Storm, to frame my remarks.

The Perfect Storm is the true story of a small fishing vessel, the Andrea Gail, that was caught up and ultimately destroyed by the confluence of three major storms. Like the Andrea Gail, hospitals are facing an assault. It is an assault born of the confluence of several bureaucratic engines. First and foremost are the Federal Medicare regulations, and then a myriad of State and local laws; and last but not least, requirements from private payers and accreditation bodies.

Unlike the movie, this perfect storm is not a cataclysmic event, but an insidious assault gradually eroding the effectiveness of health care staff, driving caregivers from the field, and wounding the ability of hospitals, home health agencies, and other providers to care for patients.

To illustrate this problem, I have brought some examples with me. I would like to tell you about one of them right now. This is the largest one before me. It is known as the Medicare cost report. It costs us about $100,000 to prepare this report in a 25-bed hospital.

Chairman MANZULLO. Could you describe how thick that is for the record, Mr. Cummings?

Mr. CUMMINGS. I am not good at guessing. I would say at least a foot. Over a foot.

Chairman MANZULLO. Thank you.

Mr. CUMMINGS. Recently, Congress sought to improve the financial viability of small rural primary care facilities by creating the Critical Access Hospital Program. These hospitals, however, have continued to experience serious cash flow problems because of long delays by some fiscal intermediaries in settling the annual Medicare cost report.

Some fiscal intermediaries may not settle cost reports for 2 or more years. Our cost report, the one you see before you here, was filed last summer, and we still have not had it settled by our fiscal intermediary, even though it was declared complete months ago.

Worse yet, Blue Hill Memorial Hospital, which is operating at a deficit, is owed more than $2½ million over a period of 3 years. To compensate, we have had to take out a bank loan to meet our current obligations. These interest charges on the loan are approximately $120,000 a year. Those expenses, by the way, are disallowed by Medicare in the cost report. They are all avoidable. That is money we could have used to replace outdated equipment, start new programs for our community, or to help recruit and retain scarce health care personnel.

You have asked us to estimate the total paperwork burden imposed by HCFA on small hospitals. The AHA recently commissioned Price Waterhouse Coopers to ask some of America's hospitals about their paperwork experience. Their findings may shock you.

They 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, as you have heard already, about every hour of patient care generates at least an hour of paperwork.

We have provided a copy of that study for the record. While some paperwork is necessary for clinical purposes, there has been a significant increase in paperwork to document regulatory compliance. The problem is growing. Since 1997, more than 100 regulations affecting health care have come online.

We know Congress intended to address some of these issues when it enacted the Paperwork Reduction Act. What Congress did not anticipate is how some agencies would get around the law. For example, it is our understanding that HCFA violated the Paperwork Reduction Act by not receiving final clearance from OMB for the Medicare Secondary Payer form, which I have here.

The MSP form is intended to determine when a patient has insurance other than Medicare. As a result of this violation, HCFA does not formally require hospitals to complete the form. It merely requires that the hospital ask the patient the same 25 questions

contained in the form at every patient encounter. If a patient comes every day to the hospital to receive outpatient treatment and related testing for, say, cancer, or a serious infection, he or she will be asked the same questions each and every day.

We recommend that Congress create an intergovernmental task force to review the Paperwork Reduction Act, other similar laws, and make recommendations for corrective measures.

In conclusion, some regulations contribute to our efforts to provide quality patient care, but others simply drain resources away from that goal. Where Congress can make a difference is in reducing paperwork and bureaucracy. To assist you, the AHA has developed a list of reforms, both general and specific, for your consideration. We look forward to working with you to achieve meaningful regulatory relief.

Thank you for this opportunity, and I look forward to showing you additional forms, if you would like, during the question and answer period.

Chairman MANZULLO. I appreciate that.

[Mr. Cummings' statement may be found in appendix.]

Chairman MANZULLO. Before we get to our next speaker, let me make this announcement. If there are individuals in positions within HCFA that are not answering your correspondence, that are sitting on it, would you let us know? This Committee has the power of subpoena. I am not at all embarrassed to use that power in order to make these Federal agencies accountable, and to answer before this Committee and the Nation why it takes so long to do that.

I would also encourage the associations here to write to the Members, and not be hesitant to contact your Members of Congress; to have a continuing dialogue going on with your Members of Congress and people at HCFA.

What we have found out is in our last experience with HCFA, for 3 months they never answered a letter, for 3 months. Then we had to have an office meeting back in my district. That is when we found out that the Wisconsin Physician Service, WPS, that administers health care for the State of Illinois, really did not know the difference between an x-ray and the X files. It was totally embarrassing to see representatives from the government that had no idea what was going on. The only way you are going to able to get HCFA to move on some of these things is to contact a Member of Congress and to continually call and do everything possible you can to dislodge those forms that are there.

Dr. Robert Anderton from Carrollton, Texas, is a dentist, a Doctor of laws, a Master of laws, and probably a master of paperwork, which is one of the reasons why he is here to testify today. He has been a member of the Dallas County Dental Society, has obviously very impressive credentials, and Doctor, welcome to our Committee. I look forward to your testimony.

STATEMENT OF ROBERT M. ANDERTON, D.D.S., J.D., LL.M.

Dr. ANDERTON. Thank you, Mr. Chairman.

I am Dr. Robert Anderton, President of the American Dental Association. While these issues that affect dentistry are not quite as heavy in volume as those affecting the hospitals, they are quite critical to our practitioners. As you may know, dentists generally

have very small practices. Most offices have only four or fewer employees, so excessive paperwork is always a problem for us.

I would like today to discuss three areas where significant problems exist. One issue is in Medicare, the other in Medicaid, and yet another of our concerns is with the recently finalized HHS privacy rules.

The vast majority of dental services are not covered by Medicare. In fact, they are expressly excluded by statute. However, some dentists have been forced to file Medicare claims for noncovered services when requested to do so by one of their patients. These patients often mistakenly believe the services are covered. Other dentists have filed claims as a favor to their patients because supplemental dental coverage plans require a Medicare denial.

For whatever the reason, requiring dentists to submit a claim that they know will be denied is a waste of resources for all concerned. HCFA expends scarce agency resources on needlessly processing claims, patients are inconvenienced, and dentists are forced to spend staff time processing Medicare claim forms, which are very different, in most instances, from medical insurance claim forms.

More important, these dentists will also have to take the time to file applications to become Medicare providers just in order to process the claim. This is an important distinction because, unlike physicians, the vast majority of dentists do not participate in Medicare.

This predicament has occurred because of HCFA's rules that give each beneficiary an absolute right to cause the practitioner who has provided a service to file a Medicare claim. This can easily be fixed if HCFA would amend its rules so categorically excluded services are exempted from these requirements.

Dentists should be able to opt out of the Medicare program, also. At the present time, Medicare's private contracting law does not apply to dentists. Once providers have opted out of Medicare, they are no longer subjected to Medicare's rules. A simple expansion of the definition of "provider" to include dentists would not alter the mechanics of private contracting, but it would give dentists a simple means of avoiding the unnecessary paperwork requirements currently imposed by HCFA, especially in view of the fact that most dental services are not covered by the program, anyway.

With regard to HCFA's role in the Medicaid program, excessive paperwork requirements are a disincentive to participation in the program. Therefore, they present a needless barrier to appropriate health care for underserved populations.

Misinformation and confusion concerning HCFA rules and regulations remain, but the solution is simple: HCFA should clarify for the States exactly what their requirements are, and then encourage the States to simplify those requirements that are left to the States' discretion.

HCFA could assist States by facilitating the establishment of systems to ensure rapid confirmation of children's eligibility under Medicaid, or the State Children's Health Insurance Program.

Lastly, I would like to briefly explain our concerns about the final rule regarding medical records privacy. While the ADA generally supported many of the provisions of the proposed privacy

rule, the final privacy rule contains many new features that were added without input from the health care industry.

Frankly, we are concerned that the final rule generates more questions about compliance than it answers, and creates unnecessary paperwork. The final rule expanded coverage of the privacy provision to include oral communications. This provision could have the unintended consequence of limiting doctor-patient discussions at chairside, where proper patient care demands detailed communication.

Dental offices are designed to be patient-friendly, with most having open operatories. It would cost thousands of dollars to soundproof schools, clinics, and the average dental office just to comply with the privacy rule if these operatories had to be enclosed.

In addition, receptionists are usually located in waiting room areas where follow-up phone calls are made to patients after extensive procedures, and calls are also made to remind patients of their appointments and discussions concerning payment for treatment, which also take place at the receptionists' desk.

All of these are oral communications that would now be subject to the privacy rule. To comply with the rule, it appears that dentists would have to reconfigure treatment rooms and the manner in which the receptionist area opens up to the waiting rooms.

Finally, changes to the rule are so vague dentists may be uncertain as to how to comply. Many would have to go to great lengths to avoid potential criminal penalties. The ADA believes the final rule must be modified so dentists and other providers better understand their obligations and are not subject to unreasonable burdens.

Mr. Chairman, I want to thank you for the opportunity to be with you today. I would be happy to answer any questions, if I can.

Chairman MANZULLO. I can see why you had to go to law school to practice dentistry, Doctor.

[Dr. Anderton's statement may be found in appendix.]

Chairman MANZULLO. Our next witness is Craig Jeffries from Johnson City, Tennessee. He is the President and CEO of HEALTHSPAN Services, Incorporated, in Johnson City. They provide regional coordinated health and pharmacy service operations.

STATEMENT OF CRAIG JEFFRIES, PRESIDENT AND CEO, HEALTHSPAN SERVICES, INCORPORATED, ON BEHALF OF THE AMERICAN ASSOCIATION FOR HOMECARE

Mr. JEFFRIES. Thank you, Mr. Chairman. Thank you for inviting us to testify this morning.

My name is Craig Jeffries. I am president and CEO of HEALTHSPAN Services. I am testifying today also on behalf of the American Association for Home Care.

Healthspan is an independent, for-profit regional provider of home health care in the northeastern section of Tennessee, southwestern Virginia, and western North Carolina. A lot of our business is Medicare and Medicaid. Approximately 35 percent is Medicare, and 25 percent is with the Tennessee Medicaid program, so we feel the burdens from the requirements from HCFA very strongly with that percentage of our business.

The home health care that we provide is providing nurses and physical therapists in individuals' homes so that they are receiving the therapy in their own homes. We also provide medical equipment such as wheelchairs and respiratory equipment to those patients in their homes. In any one month, we are serving approximately 3,000 patients in that northeastern Tennessee area.

We appreciate the Committee for initiating this in-depth review and analysis of the regulatory requirements imposed by the Health Care Financing Administration. Mr. Chairman, I have heard from my folks in my office when they get a memorandum from HCFA that "Here come the Feds again," a different analogy than yours.

What I would like to do is focus on two areas. The first is the unfair burdens documenting medical necessity to support payment for medical equipment.

The CMN, Certificate of Medical Necessity, is a form to document the medical necessity of certain items. It is required by statute. The CMN forms were approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

A supplier, however, that submits a properly executed CMN, while they have satisfied its legal obligation to document medical necessity, HCFA and its contractors, the DMERCs, or the Medicare carriers, often require additional documentation. This additional documentation has not gone through the process of approval by OMB pursuant to the Paperwork Reduction Act. This additional documentation of medical necessity is a tremendous burden.

Mr. Chairman, you asked us to make comparisons with the private sector. I asked our folks at Healthspan. They estimate that an additional FTE is required for every 80 new Medicare patients per month that we are providing medical equipment to just to handle this burdensome CMN documentation requirement.

For example, after we receive an initial order from the physician, we need to call back that prescribing physician to get additional information for the CMN approximately 70 percent of the time for our Medicare patient. That compares to only 50 percent of the time for private orders. So it gets a margin of difference between private insurers and Medicare.

Additionally, once the prescription or the CMN is provided back to us from the physician's office, we need to call back or spend additional time; 95 percent of the time for private insurance it comes back complete, whereas only 70 percent of the time does it come back complete from Medicare patients.

This burden obviously is one that is imposed on us, but it also is a tremendous burden on the physician's office. I am sure the physicians here, while they did not specifically address this CMN requirement, would agree that there is a heavy burden imposed by that paperwork requirement.

The second area that I would like to address is for our home health agencies, which are providing nursing and therapy to patients in the home. They are required to fill in a new form, which was mentioned earlier by the Congresswoman and Dr. Christian-Christensen, called OASIS.

HCFA requires home health agencies to collect extensive sensitive personal information on an 80-question survey form, and they need to get this from every patient, regardless of whether they

seek Medicare or Medicaid coverage. We need to get this on admission of the patient, every 60 days when they are still on service, after any hospital discharge, and whenever there is a significant change in the condition of the patient.

There are two areas we are concerned with this OASIS form. One is that it is asking 80 questions when it appears that 18 to 23 are sufficient to support the claim for payment, so the additional questions do not seem to serve any purpose. The other requirement on OASIS that is extremely burdensome is that HCFA is extending the burden of collecting OASIS information to our non-Medicare and non-Medicaid patients.

In Healthspan's business, we specialize with a lot of patients who are young pediatric patients or developmentally disabled patients. None of those populations were considered when addressing the development of the OASIS form, so it really becomes a form that is irrelevant.

Mr. Chairman, I appreciate the opportunity to testify this morning. I look forward to answering questions.

Chairman MANZULLO. Thank you.

[Mr. Jeffries' statement may be found in appendix.]

Chairman MANZULLO. Ms. Velázquez.

Ms. VELÁZQUEZ. Thank you, Mr. Chairman.

I want to thank all of the witnesses for the important information and experiences they have shared with us.

Dr. Mahood, my first question is for you. You stated that you are encouraged by President Bush's and Secretary Thompson's commitment to decrease regulatory burdens on physicians, and that the President has acknowledged that Medicare is driving physicians from the program.

What are some of the President's initiatives to alleviate the burden that you support?

Dr. MAHOOD. To look at the privacy rule, for example, we are very concerned about that. While the rule was allowed to go into effect, Tommy Thompson has said that he will indeed take cognizance of the many problems that we still have with that privacy rule and make the needed changes before the effective date comes up in 2 years. That is one example.

Ms. VELÁZQUEZ. It seems like there are a lot of complaints against private insurance companies who contract with HCFA. In light of this, would you support privatizing Medicare?

Dr. MAHOOD. The American Medical Association has a policy which would indeed favor individually-owned and individually-selected health insurance, which essentially would eliminate the interference of the third party between the patient and physician. In essence, there would be long-term support for that.

Ms. VELÁZQUEZ. The American people benefit because of important regulations in the area of health and safety, the environment, and consumer protection, but we have to be very sensitive to the aggregate impact of those regulations. We need to make certain that they are done properly and the burden is minimized.

Congress creates the laws from which these regulations originate. Should Congress be reassessing these regulations on a periodic basis to determine if they are creating more benefits than burdens?

Dr. MAHOOD. Absolutely. We feel very strongly that—for instance, the proposed recommendation which HCFA is looking at to expand the enrollment of physicians and to have them recertified every 3 years is a perfect example of where the rule would far exceed the problem. It is absolutely a monstrous recommendation for an incredibly small problem in that area.

Let me show you, if I can, an example of a form which we use in our office to record a patient visit. The form is a 2-page form, and I seem to have misplaced it, but it is a 2-page form for each visit. In my practice, for many years I was able to accurately document the interval history between a visit, say, 3 months earlier, record my physical findings and my plan of treatment in 2 inches or 3 inches of written information on my chart. Thus, I could look at a page of my chart and see pretty much a year of the history of that patient. Now I have a form front and back filled out for every visit. I have another form for each telephone call that we receive. Thus, my chart quickly becomes inches thick of papers. Trying to find something in there is very difficult.

So the regulations definitely need to be looked at. We think Congress does have an oversight responsibility, and we encourage you to take a very close look at that.

Ms. VELÁZQUEZ. Thank you, Dr. Mahood.

Dr. Morris, you stated in your opening statement that your association would like to encourage our Committee to evaluate the possible regulatory reforms under the Regulatory Flexibility Act, in addition to the Paperwork Reduction Act.

Would you support bringing HCFA within the scope of SBREFA?

Dr. MORRIS. I am not that familiar with the abbreviation that you used.

Ms. VELÁZQUEZ. The Small Business Regulatory Enforcement Fairness Act.

Dr. MORRIS. Thank you, very much. Yes, in a very short answer. Yes.

Ms. VELÁZQUEZ. Let me ask a follow-up question.

In SBREFA, it is the kind of review process that applies to OSHA and EPA. Now we passed legislation last year in this Committee to include the IRS—the legislation was stalled in the Committee on Ways and Means, not by the Democrats, but by the Republicans. But that is another story. Whenever the EPA or OSHA is going to issue any regulations, they have to hear from the business community that it is going to impact.

My question is, how could we assure that HCFA's role on under SBREFA would not delay important activities to improve patient care under Medicare, Medicaid, and CHIP?

Dr. MORRIS. I think that regardless of the regulations, we as physicians, and my associate next to me, the hospital, are going to continue to take care of our patients. We are going to continue to submit the claims. Those claims may be very long in being responded to, but we are going to continue to take care of the beneficiaries and take care of our patients.

But I agree with you that HCFA should be aware of the regulations and the impact not only on we as providers and physicians, but also the patients, as we have also tried to point out.

Ms. VELÁZQUEZ. And I guess that Members of Congress, whenever we pass legislation that will mandate agencies such as HCFA to produce such regulations.

Dr. MORRIS. Absolutely.

Ms. VELÁZQUEZ. Thank you.

Mr. Cummings, when agencies circumvent the normal rulemaking process, small businesses have less opportunity to comment and participate in the process. How can we make certain that agencies follow the normal rulemaking process and not avoid executive and congressionally-mandated regulatory requirements?

Mr. CUMMINGS. I am aware of only the MSP form that I can point to as a specific circumvention of the Paperwork Reduction Act by HCFA, although I think it would be very instructive to have Congress, perhaps through the GAO or through an intergovernmental task force, really examine this question more fully. We think there are undoubtedly other examples.

I think for many of us in the field, whether we are practicing physicians or trying to run small hospitals, the burden of just getting through the day, in terms or meeting our clinical and administrative responsibilities, is such that we rarely have the time to look up in the Federal Register or participate in rulemaking.

Ms. VELÁZQUEZ. Mr. Cummings, the SBA National Ombudsman Program was developed by SBREFA to provide small businesses an opportunity to comment on agency enforcement activity. Through this provision, we have provided small businesses a forum in which to express their views and share their experiences about Federal regulatory activities. The national ombudsman receives these comments and reports these findings each year to us, to Congress. I am interested to know if you have utilized the regional advocates, and how do you think they could be more effective in reporting HCFA's enforcement activities?

Mr. CUMMINGS. I appreciate the Congresswoman bringing this up. I was unfamiliar with the SBA National Ombudsman Program, so no, we have not used this resource. Thank you for mentioning it to me.

Ms. VELÁZQUEZ. Have any of you had any experience with this?

Mr. JEFFRIES. I would note, I don't know what the current experience at HCFA is, but back at the 1980s there was an SBA liaison that was housed at the Health Care Financing Administration whose responsibility was to coordinate and act as a liaison for that. He served as a lightning rod, in some respects, because he received the input that you are suggesting should be provided from small businesses that are burdened by the activities of HCFA. So I would suggest looking at that.

Ms. VELÁZQUEZ. Thank you.

Thank you, Mr. Chairman.

Chairman MANZULLO. Thank you, Ms. Velázquez.

Let me submit this to you. I don't think there will ever be one package of legislation that can address every problem or just a portion of the problems that we are facing here. What I would suggest is this: If you get a form that is 25 or 28 pages of questions and you think you can do it in five or less, I would encourage you to contact my Committee. We will take that form plus your form and we will send it to the agency saying, "The Committee on Small

Business has jurisdiction over the Paperwork Reduction Act. As far as we are concerned, you are violating that. This is the suggested form. Would you comment on that in 7 days or less?".

We are going to have to pick away at this animal. This thing is totally out of control. The experience that I had with HCFA, it was not good at all.

To think that—she is not here, but the Democrats wanted to have HCFA in charge of pharmaceuticals for seniors. That is enough to raise the hair on the back of your head. Of course, Republicans want to create another agency. There is not much—I don't know where you are going to go on that.

But I would recommend you—you can do it on a one-by-one basis. Take one issue that you can identify, and please don't hesitate to use our Committee.

And in addition, the Small Business Administration has what is called the Office of Advocacy. Ms. Velázquez and I, along with another Committee, were able to use that office to complain to the Department of Defense that the 104,000 hats that the Air Force had requested should not have been contracted out to the Government Printing Office because the Air Force thought that hats are printed and not manufactured. We were able to cancel a contract with the manufacturer, who was going to have a Chinese factory manufacture those American hats.

So the SBA has an in-house law firm. We also have I think about six lawyers on staff with the Committee on Small Business, and we really want to help you out question by question, and inch away, regulation by regulation, to get you back into the business of providing for health care.

I just have a couple of questions. I want to give a tremendous amount of time to Dr. Christensen because of her background. Mr. Toomey will be after her.

Mr. Jeffries, my mother was a home health care patient, a great beneficiary of a tremendous way to utilize experts as they came to her assisted living center at a fraction of the cost had she been hospitalized: I am distressed about the fact that every time you pick up 80 patients, you have to hire a full-time employee. First of all, those full-time employees are difficult to train, they are hard to find.

I don't know if home health care has been picked out or singled out for all of these onerous forms, but fill me in, is there some kind of a program to eliminate home health care by drowning you in all these forms?

Mr. JEFFRIES. One would think so from the forms that are required by the Health Care Financing Administration. I think home health care, as you well know, is well-liked by patients. I think physicians see it as a very viable way of keeping the independence of that individual.

Chairman MANZULLO. It worked with my mom, because she went from home health care to hospice, and she passed away at the assisted living center, which was her home for years.

What forms are not necessary?

Mr. JEFFRIES. Part of what you have heard here—and I can reemphasize, when a form goes through the process of approval and then HCFA, through its Medicare carriers, the DMERCs, allows

them to add additional requirements, it is very difficult to meet those requirements. You think you have done it when you have the OMB-approved form, but then they require all those things.

I think just focusing, from an oversight function, the spotlight on what are those additional documentations—and I will work with the American Association of Home Care to provide you some specific examples of that—I think that would be an important investigatory area, who are those additional requirements and why don't they go through the Paperwork Reduction Act process?

Chairman MANZULLO. My point person on staff is, to my right, Barry Pineles. He is an expert on regulations. He stays up on Saturday nights in front of the fire and he reads all these books on regulations. He has a real heart for people that are hit heavy by it. He is an expert on regulations and regulatory reform.

Dr. Christensen, let us use the 5-minute rule, and then when everybody here has completed their time, I would like to go back to you for additional questions after that.

Dr. Christensen.

Mrs. CHRISTENSEN. Thank you.

I think we have had some great questions already, as well. That cuts down some of the questions I have to ask. I am really impressed with some of the very concrete recommendations, though, that we have from this panel on how we can proceed to address some of the burdensome HCFA regulations.

Let me start with Dr. Mahood. I know we are going to discuss H.R. 868 later on, but I see an article that indicated that the IG at the Department of Health and Human Services had criticized very strongly this bill, saying that it would dramatically reduce accountability for Medicare claims.

Are you familiar with statements made by the Inspector General at the Department of Health and Human Services? If so, how would you respond to those criticisms?

Dr. MAHOOD. It does not change the accountability at all. What it does is it limits the preclaim audits so that they are not random. They can still do audits and they can do prepayment audits, but they should do them for cause or for a rational reason, not just randomly.

There is no intention of any part of the act to interfere with the search and identification of true fraud or abuse. So I would say that they are off the mark.

Mrs. CHRISTENSEN. All right.

There has been a lot of discussion about medical errors. I would ask the first three panelists, Dr. Mahood, Dr. Morris, and Mr. Cummings, to what extent do you think the burden of paperwork and the regulatory burden in general impacts on quality of care? Can there be a relationship between the amount of paperwork burden and the medical errors that have been reported?

Dr. MAHOOD. I don't think there is any doubt about it. As a gastroenterologist, I am called on in the middle of the night to see a patient who has suddenly started to have a massive gastrointestinal hemorrhage. I have not seen the patient before. I am a consultant.

I go to the chart. While the patient is bleeding and receiving blood transfusions, I have to find out the best I can what might be

the cause and what the appropriate next step is, whether it is an emergency endoscopy or what. It often takes 20 or 30 minutes or longer to go through just the last few days of the patient's care, because every physician who sees that patient has to fill out such an extensive documentation.

So there is no doubt in my mind that it does interfere with proper care.

Dr. MORRIS. I would respond to that by saying I don't think it adds the additional paperwork. That is not going to prevent a medical error. Many of the errors are due to process, but it is not due to the medical records.

The Orthopaedic Association has instituted a sign-your-site program several years ago wherein, when we are seeing the patient before surgery, we write with an indelible pen on the area where we are going to do our surgery. We don't depend on looking through the pages of the chart to be sure which side we are going to operate on.

It may seem very simplistic, but it is extraordinarily easy to do and effective.

Mr. CUMMINGS. Congresswoman, in your opening statement you alluded to the OASIS form. Mr. Jeffries also spoke to this during his remarks.

I brought a copy of it with me, and with the chairman's permission, I would like to be able to just show it to members of the Committee. Then I will answer your question about how it affects patient care.

This is the form that our home health agency must complete. It takes our nurses, if they were to do this by hand, about 90 minutes. We have provided them with laptop computers so they are able to do this in only an hour. There are 43 additional pages of forms not attached here that they also must fill out for that initial patient visit.

As Mr. Jeffries mentioned, home health agencies must do this, whether the patient is a Medicare beneficiary or not. Where we see this affecting patients is that our nurses are unable to provide any care to the patient until they have completed this form.

Being in a rural area, the average distance between our home health patients is 20 miles. The average age of our patients is 78. They typically have two or three chronic conditions. Congestive heart failure is the leading diagnosis. The patients often have skin lesions, and 33 percent have severe anxiety.

Before the nurse can lay a hand on that patient, she must complete this OASIS assessment. The patient can beg for help and she cannot help him. So I think that is where we see this: with frail, elderly, uncomfortable patients for whom that nurse cannot provide any assistance until she has completed this paperwork.

Chairman MANZULLO. Is this one form? It appears that page 7 of 11—it gets down to what is your favorite color, those types of questions.

Mr. CUMMINGS. Mr. Chairman, it combines several forms required by Medicare. One is the OASIS form, which is the lion's share of this.

Chairman MANZULLO. This has to be asked of one person?

Mr. CUMMINGS. Yes. There are also certain State laws that must be fulfilled during this initial assessment visit, and certain accreditation requirements. So this represents, then, the confluence of these various requirements.

So although not all of them are OASIS-related, all must, in fact, be completed on every patient when they are first brought in for care to an agency.

Chairman MANZULLO. There is duplicative material, questions?

Mr. CUMMINGS. Yes.

Chairman MANZULLO. Can I throw out a challenge to you? Could you create your own form that would consolidate all this information into one and get that to us, and we will send it over to HCFA and challenge them to accept that form, as opposed to this one?

Mr. CUMMINGS. I would be happy to go back to my nurses and confer with the Visiting Nurse Association of America and the National Association of Home Care.

Chairman MANZULLO. Then we can bring that before the Committee and bring you back again, and explain why it takes all of this to perhaps put down in 10 or 12 pages what you would like.

Mr. CUMMINGS. Thank you. We will try.

Mrs. CHRISTENSEN. Let me just ask a follow-up question.

Chairman MANZULLO. Sure.

Mrs. CHRISTENSEN. I am sure it is going to take a brief answer.

Mr. Jeffries, is there any justification at all—has any justification at all been given for questions that are not related to calculating payment?

Mr. JEFFRIES. Job security has been talked about a lot. There are a lot of people at HCFA that probably benefit by the additional questions, because there is additional analysis.

I think it is hard to justify the additional information. As others have testified, there is probably some value at some point, but it is a question of cost and resources, and diverting focus to what we are all trying to do, and that is, maximize patient outcomes by providing good care.

Mr. Chairman, just to follow up on this form, remember that this is being imposed by HCFA for us to use with non-Medicare and non-Medicaid patients.

Chairman MANZULLO. That is interesting, because there is no jurisdiction for that. Would you send us a letter on your letterhead, and we will get that to the SBA Office of Advocacy, and have HCFA give us a legal opinion as to whether or not that is possible?

One of the things we want to do at the Office of Advocacy in this Congress, hopefully, is to give it the power to start a class action lawsuit, class action lawsuits against Federal agencies. Of course, it costs $1 million every time you challenge a regulation.

Mr. Toomey.

Mr. TOOMEY. Thank you, Mr. Chairman.

If I could just comment briefly on this outrageous absurdity of paperwork that is required, from what I have heard from the physicians in my district about E&M forms and other documentation, I cannot help but reflect on the fact that this obviously detracts from the time that physicians could be spending with patients.

It is obviously an effort by HCFA to verify that these services were, in fact, provided. We have to step back and recognize, I

think, that we have such a profoundly flawed system that this kind of battle will always go on. We have to keep fighting it, but we are never going to win this until patients are the people that are in control of this process in verifying that services were provided. The patient knows. A third party bureaucrat in Washington will always demand unreasonable and excessive information to try to verify something they cannot know but something that the patient knows.

If we move in the direction of giving the patient the control of the money that is spent on their behalf, putting the patient in the role of the consumer, so many of these problems go away. I hope we will move in that direction. I realize that is beyond the scope of this hearing today.

Let me ask a more direct question. I would direct this first to Dr. Mahood, but anyone else may make a comment and would be welcome.

When you consider the magnitude of this regulatory burden, I was wondering, Doctor, if you could share with us your thoughts on the extent to which solo practitioners and small group practices are basically forced to join large groups or become employees of hospitals.

To what extent do you see the gradual reduction, if not the elimination, of the solo practitioner and the small group practice that so many patients prefer to have?

Dr. MAHOOD. Let me give you a quick example. We did refer to, in our testimony, the enrollment form for Medicare participation.

This is a copy of the application. It is over 30 pages in length. As I implied——

Chairman MANZULLO. Excuse me. Is that per person, per patient?

Dr. MAHOOD. No, this is an enrollment form for physicians to be a participating provider in the Medicare program.

Chairman MANZULLO. Thank you.

Dr. MAHOOD. For a physician going into private practice by themselves, or particularly in a rural area where there are more Medicare or Medicaid patients percentagewise—they would be in practice for anywhere from 2 to 6 months before they could submit a bill for reimbursement for the patients they have seen. That is prohibitive. So physicians coming out today do indeed tend to join larger practices.

Our practice is 14 gastroenterologists just outside of Philadelphia. We recently had a world class gastroenterologist from Temple, head of a program there, join our practice. We were flattered. She had to get a new enrollment number. It took our practice 4 months before we could finally submit any bills for her care to the Medicare population.

Now, that was possible in our practice, with some difficulty, because of the work of other physicians supporting her income. But clearly, it could not have been carried out by her alone. So that is an example of how it interferes in the individual or small group development.

Dr. MORRIS. If I might follow up on that, I have with me an HMO application form which is standardized in the State of Missouri. This is double-sided, but this is eight pages. It is the same information, to allow a physician to be credentialed.

I would also like to follow up, if I might, about the home care issue. That I think is a real detriment to patient care. The home care nurse, the person out at the home, if they have a question about this form and they have to call the physician, they have to speak with the physician personally. They cannot get the information, according to Medicare regulations, from an office nurse or a PA, a physician's assistant, or any sort of physician's extender.

Also, if you are a private practitioner, be it primary care or a surgeon, you are obviously not in the office all the time. So I ask you, what happens with that home care nurse who is out in the home at that time trying to fill out this form, and has a question about a diagnosis or about something that has been happening? She cannot take that information or that order from a physician extender and has to wait for the doctor. The doctor is not there. The doctor is in surgery.

That happens all the time. That has been explained to me very clearly as a real problem to the home care nurses. Thank you.

Mr. TOOMEY. Thank you, Doctor. I yield the balance of my time.

Chairman MANZULLO. Dr. Anderton.

Dr. ANDERTON. I would comment also on the small, solo practitioners. As you know, about 80 percent of the practicing dentists in this country are solo practitioners. They are overburdened with this same type of paperwork.

If I can shift gears for just a minute and go to Medicaid, where most dentists are involved, we have some States that require an application that is 50 pages long just to participate in Medicaid. This is causing severe problems for us in getting providers to even sign up for the programs. Not only is the paperwork burdensome and voluminous, it is the contracts these providers have to sign.

It was mentioned earlier about fraud and about probable cause. Most of you are aware, in order for a provider to sign up to participate in these programs, they have to essentially sign away their fourth amendment protection against unreasonable search and seizure.

This allows the Justice Department to come in, as was mentioned earlier, on random audits to seize records and to do those kinds of things. In fact, there are instances where physicians have been handcuffed in their offices and their records seized for no probable cause. Those things are unduly burdensome, and it is really hindering our efforts to go in and provide access to care for people who really need it.

Also, as I testified earlier, a dentist very often has to sign up for Medicare just to file a claim for a patient who requests it. By HCFA rules, they are required to do so, even when they know the claim is going to be denied. They have to go through all of this paperwork with only four or fewer employees in their office. So it is a critical situation.

Mr. CUMMINGS. I wonder if I could respond to Mr. Toomey's question, also, an additional perspective.

In my rural area, we, the hospital, employ all of the rural physicians. There are 14 of them. They used to be in private practice. They were unable to continue to be in private practice primarily for two reasons. One is the dearth of health insurance in our area. We

have no large employers—almost 45 percent of the patients who came to this small practice had no insurance of any kind.

But the other reason was to deal with the paperwork. We were able to obtain something called a rural health clinic designation for each of our practice sites, for which we are very appreciative, and this helps improve the payment from Medicare and Medicaid to these rural primary care doctors.

But the paperwork burden has not gone away. This is the manual that each rural health clinic must have. I have taken this from one of our sites, the Island Medical Center. By the way, for reasons I don't understand, we are never to take the manual from the premises, so I am sure I have committed some egregious HCFA violation by bringing it here.

We have to have one of these, regardless of the size of the practice, so each——

Chairman MANZULLO. Could you describe the dimensions and the pages, the number of pages, for the record, approximately? It is about eight inches thick?

Mr. CUMMINGS. Six inches thick, maybe, and several hundred pages.

Dr. MORRIS. It weighs about 10 pounds.

Mr. CUMMINGS. The smallest practice we have is one doctor and a family nurse practitioner. The largest we have are four doctors and a nurse practitioner, so you can see, we are talking about very small practices, but each of them have to have one of these.

Chairman MANZULLO. Thank you.

Mr. Phelps.

Mr. PHELPS. Thank you, Mr. Chairman. Thank you for calling this hearing and these distinguished people to be here to give us input.

I don't think there is a Federal official who is not aware of overregulation, especially in the health care industry. I have chaired the Health Care Committee in the Illinois House for 4 years, and was astonished at what we found in many of our investigations there.

I represent an extremely rural area, the largest congressional geographic district east of the Mississippi. It covers 27 counties, and small counties, as much as 4,000 and 5,000 population only, so I am aware of the value, and could say nothing better about how I feel about home health care.

I know it is a challenge to try to balance how we have access, create access, for especially senior frail elderly people who need to have care at the most vulnerable time of their lives, and make it affordable and make it protected to the consumers and the taxpayers.

I guess what I am interested in asking, for fear of duplicating what has already been explored and maybe will be gotten into, how did we arrive at where we are? We make the laws. We ask agencies that we create by appropriations, by law, to carry them out.

Now, in the Illinois legislature, there was one time when I actually voted to repeal my own bill, because by the time the agencies that made the rules to implement the bill that I passed, with the intent that I made clear on the House floor, a matter of Journal record, I did not even recognize my own bill.

I guess my point is, has there ever been what you feel, and maybe not you individually, but the associations you represent, any clear inclusion of people talking to make it clear to HCFA, now, this law has passed by Congressman whoever, and we need to know from the standpoint of those of you who deal with it every day in the field, how can a health care provider that wanted to rip off the taxpayer through fraud and abuse—that is what I assume these laws were made to try to protect from happening. We need professionals, people that know—the FBI, the way they know about counterfeit is they call in those convicted counterfeiters and learn from them how they were able to do this.

I guess what we need to know is from people who can help us identify what we can prevent from happening without stacks of regulations. Can you, in this form, tell someone in HCFA, that there are about 10 pages or less that actually get to the heart of what you are after. The rest of it is enough, or makes no sense and creates too many jobs for taxpayers to subsidize, and could possibly hurt funding for the home care program itself.

I happen to believe that home care can be proven to prevent costs in both the government and the private sector. I have seen it happen.

Is there not that kind of inclusion, and could we not prevent some of this nonsense?

Dr. MAHOOD. If I could respond to that, you know, your point is well made. Speaking for the physician community, a large number of physicians are scared. They get reports like this from their carrier four times a year. They get bulletins monthly. They get special letters. Each one has rules and regulations buried in them, and they don't know what they are responsible for, and they can't find out easily.

They can make a phone call to the carrier, and the person on the other end of the line says, this is the way to do it. If they do it that way, they may subsequently find that it was the wrong way, and they have no evidence, no proof. We rarely get anything in writing with a signed statement. It is a cottage industry.

Mr. PHELPS. I don't want to cut you off, but I know you are answering the question as vaguely as I put it.

But what I want to know is before it becomes regulation and law—and we know there is some sort of congressional effort because of 60 Minutes or 20/20 or some news that brought it to our attention—people are getting ripped off; these old people are paying, in their matching funds as well as the government—they are getting ripped off. We all rush up here and have a press conference and say, as a good guy, here is what I am going to do. No one ever asks, after we pass that, what are the consequences for carrying out and enforcing what we have passed into laws.

Before that becomes implemented, one of the reasons how it should be implemented would be to include people like you to sit around the table with HCFA and say, "Instead of getting those notices, you had better be doing this right. Before we put this in implementation, what do you think?" that has not ever been done, as far as you know?

Mr. JEFFRIES. Congressman Phelps, I would suggest that as part of your review of the Paperwork Reduction Act, one of the require-

ments in that process might be to have HCFA look at what the private sector does.

There is an encouraging trend, it is not overwhelming, but an encouraging trend to go back to the simple reliance on what the physician wants in the prescription, and stop second-guessing from home health prescribing or DME prescribing. I think that is a good private sector initiative that HCFA ought to address when they are coming up with new rules pursuant to a new law.

Dr. MAHOOD. Just a quick response. Participating in the process with HCFA, people within the HCFA program who have medical backgrounds understand the need to make things simple, but they are outvoted by other departments within HCFA; for instance, the program integrity group. We have different departments within that very agency which add layers and layers of complexity on the forms. So it is a very difficult problem to resolve when you are dealing with an agency of that size.

Mr. PHELPS. Yes, sir.

Dr. MORRIS. My members would have two words to answer that: oversight and accountability.

Mr. PHELPS. Thank you very much, folks.

Mr. CUMMINGS. Mr. Phelps, if I could add to my colleagues' comments, in the report prepared by the American Hospital Association, a copy of which is being made available to all of you, are eight specific recommendations to improve the process by which regulations are created. We have six recommendations on specific regulatory in need of reform.

One of those eight is the very issue that you have just raised, which is to have greater input from the field, from hospitals, have health nurses and practicing physicians before a form is generated. That does not happen right now.

The other is that there is really no one in charge of the regulatory apparatus. These are created by different divisions, bureaus——

Mr. PHELPS. What I was getting to——

Mr. CUMMINGS. Divisions within HCFA, and no one is looking at them in terms of the totality.

Mr. PHELPS. We need to know somewhere in the oversight process, once there are those who are capable of giving input and pointing out things, instead of being outvoted, there needs to be a process where they come back to a Committee such as this to say, "Why is this not being accepted? What are your reasons?" we need more oversight.

Ms. VELÁZQUEZ. Congresswoman Tubbs Jones.

Mrs. JONES. Good morning. I want to give you a quick background and ask you some quick questions.

I come from Cleveland, home of the Cleveland Clinic, the University Hospital. We are in the midst of a competitive issue on hospitals. I spend a lot of time working with the physicians in my community, in the health care area.

For the record, I just have to say that a number of the physicians have said to me the reason they have gone out of private practice is because hospitals often make it inconvenient for you to be in private practice, other than to be associated with the hospital in your

community, because of the competitive issues. I need to lay that on the record.

I empathize with each of you about this paper process. I came to the Committee on Small Business for the purpose of trying to assist you. I wonder if you would contemplate how terrible it is for the senior citizens in our communities across this country to deal with the medical process, as well? Is universal health care a solution for much of the paperwork that you put on the table or raise?

I need short answers, because I have all of 5 minutes.

Dr. MAHOOD. If universal health care is a single-payer, absolutely not, because what that would be expanding the regulatory hassles throughout the whole medical system.

Mrs. JONES. Let me back up. What percentage of your practice comes through the process we are talking about right now?

Dr. MAHOOD. Approximately 60 percent of my practice is Medicare. Now, a percentage of that is managed Medicare, so it is not all the regular Medicare.

Mrs. JONES. Health maintenance organizations?

Dr. MAHOOD. Yes.

Mrs. JONES. In my community, a health maintenance organization has no requirement to enter into a contract, so what has been happening to the people in my community is all of a sudden, the health care maintenance organization goes out of business and the people have no health care.

What happened when a hospital closed down in my community, it had a health maintenance organization. The hospital left. There are people running around with no place to go, and two hospitals within 2 miles of that one hospital that closed down because there was no HMO service there, and these people had no health care service.

Is that the result, to have an HMO that can come and go whenever they want to and not give people any health care?

Dr. MAHOOD. No. I think the insurance commissioner should have more oversight and responsibility for plans that develop programs within areas so that they do have the resources to serve those clients.

Mrs. JONES. I don't mean to make light. I hope you understand. The issue is so much more complicated than the paper reduction process that we are discussing here. The health care issue is so much more complicated.

I would hope that in addition to the paper reduction process that we are talking about here, that we can come to the table to talk about the delivery of health care and access to health care for all folk, with or without money, being 44 million out there without any health care at all.

I am supportive, and I am going to do what I can to help you reduce paper, but also I am asking you to step up and say what are we going to do to deliver health care to the folks?

I guess I am out of time. I am sure you had an opportunity. I have your preparation.

I am from Cleveland, Ohio, with the University Hospital, the Cleveland Clinic. If you are ever in the area and I can be helpful, please call me.

One more question, are any of you from urban centers? Two of you. Do you do diversion when an emergency room closes down for lack of beds in your hospitals?

Dr. MAHOOD. Infrequently, but yes.

Mrs. JONES. Is that a practice? And this is not only for me, but is that a practice that is put together by a panel of physicians or health care providers as to how you do that diverting process, and when you open up and close back down?

Dr. MAHOOD. I am unfamiliar with how it works in the hospital. I believe it is an administrative decision based on a lack of beds, as you said. But it is very infrequent in our hospital that that happens.

Mrs. JONES. Thank you so much. I look forward to working with you on future issues.

Ms. VELÁZQUEZ. Do you have any other questions?

On behalf of the chairman and myself, I want to thank you all for being here today.

This meeting is adjourned.

[Whereupon, at 11:54 a.m., the Committee was adjourned.]

Congress of the United States

House of Representatives

107th Congress

Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515–0315

Statement of Donald A. Manzullo
Chairman
Committee on Small Business
United States House of Representatives
Washington, DC
May 9, 2001

Our hearing today is about healthcare regulatory requirements burdening healthcare providers. This hearing will be the first in a series of hearings that the Committee will hold on reducing regulatory burdens on healthcare providers. The next full committee hearing is tentatively scheduled for July 11 when the Committee will examine a broad array of regulatory relief options for small healthcare providers. I would like to time to thank my colleague from Pennsylvania, Mr. Toomey, for the efforts that he has made on that front and would hope that he can find the time to testify at the July 11 hearing. The Committee then expects to have a third hearing in which Thomas Scully and John Graham, the nominees to head the Health Care Financing Administration (HCFA) and the Office of Management and Budget's Office of Information and Regulatory Affairs will testify about regulatory and management solutions to the problems identified at today's hearing, the hearing on July 11, and any hearings that the Committee's Subcommittee Chairmen decide to hold on the regulatory burdens facing healthcare providers.

Today's hearing will focus on one particular aspect of regulatory burdens imposed on healthcare providers – reporting and recordkeeping requirements imposed by the Health Care Financing Administration (HCFA), the agency within the Department of Health and Human Services charged with operating the Medicare and Medicaid programs. I am troubled that health care providers devote significant resources to complying with these recordkeeping and reporting requirements rather than devoting their energies to tending to the needs of their patients.

According to the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), the Health Care Financing Administration has 219 approved collections of information. The total number of annual responses is about 1.7 billion which consume nearly 105.8 million hours to complete. OIRA estimates that the annual cost of completing these forms is $57.4 million. Plus, the data may not accurately reflect the true costs of the paperwork burden. First, as the witnesses will describe, HCFA and OIRA's determinations of the time for completing forms lack substantiation. HCFA and OIRA believe that a physician can complete a 30 page form in 15 minutes. Second, during the month of April, OIRA approved 5 new forms requiring an additional 9,000 responses consuming an additional 306,000 hours to complete. Yet, the total cost of the paperwork burdens estimated by OIRA **did not change**. Thus, it appears that HCFA and OIRA do not pay much attention to solving the paperwork problems affecting healthcare providers. Let me assure the witnesses here today that I take my oversight responsibilities with respect to OIRA and its implementation of the Paperwork Reduction Act very seriously.

Healthcare providers appear to be drowning under a torrent of paperwork -- paperwork that disproportionately affects small businesses. Under the Small Business Administration size standards, approximately 96% of the offices of physicians, 99.9% of dental practices, 61% of

hospitals, and 91% of home health agencies qualify as small businesses. The Paperwork Reduction Act was enacted in 1980 and strengthened in 1995 to minimize the Federal paperwork burdens on small businesses. The Act was supposed to eliminate paperwork burdens that were unnecessary or duplicative. Obviously, the statistics from OIRA and the witnesses who have taken time from their busy practices to testify here tell a story that the Paperwork Reduction Act is not reducing paperwork burdens. Either the Act needs further strengthening or OIRA needs to more strictly enforce the requirements of the Act. The Committee will continue to examine the Paperwork Reduction Act and its implementation by OIRA to determine what corrective action may be required. I am very interested in the testimony of the witnesses with regard to that subject and look forward to working with them in trying to reduce the paperwork burdens they face.

Even efforts at administrative simplification and reduction of paperwork appear to create more paperwork. Congress enacted the Health Insurance Portability and Accountability Act of 1996. The Act required HCFA to develop standards that would permit the use of standardized, electronic transmission of transactions required for participation in the Medicare program. The "simplification" resulted in the production of 4,200 pages in guidance documents for healthcare providers. That does not seem like simplification to me.

The ultimate beneficiaries of this effort will not be small businesses that provide healthcare. It will be patients who benefit the most because healthcare providers will devote their time and energy, not to completing paperwork, but tending to the sick and infirm.

Before recognizing the ranking member, let me welcome my friend, the distinguished gentleman from Maine – a former member of the committee who is here to introduce his constituent, Mr. Bruce Cummings. Now I will recognize the ranking member of the full committee, the distinguished gentlelady from New York, for her opening statement.

DONALD A. MANZULLO, ILLINOIS NYDIA M. VELÁZQUEZ, NEW YORK

Congress of the United States

House of Representatives

107th Congress

Committee on Small Business

2361 Rayburn House Office Building

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Congresswoman Nydia M. Velázquez
Statement in front of the Committee on Small Business
at the hearing on Health Care Financing Administration
Paperwork Burdens
May 9, 2001

Mr. Chairman.

Today the committee begins working towards the reauthorization of the Paperwork Reduction Act. This landmark legislation was signed into law in 1980 by President Carter with the goal of reducing the overall burden and time that small businesses spend complying with paperwork reporting requirements. This committee has long known that the overall Federal paperwork burdens fall disproportionately heavy on small businesses. Paperwork requirements and the associated costs are nearly twice as high for small businesses than Corporate America.

The focus of this hearing is on the Health Care Financing Administration and the associated paperwork requirements that its regulations create. HCFA is the federal agency charged with administering medicare and has been referred to as the country's largest health insurance provider. Often times, it is the only health care option. The services they provide affect the lives of 38 million Americans nationwide. Because of the nature of their work, often times HCFA creates some of the largest and most complicated paperwork requirements. Out of the 30 plus federal agencies, HCFA ranks sixth behind Treasury, Labor and DOD in paperwork burdens.

While it is easy to simply lay the blame for onerous regulations on federal agencies, the reality is that most of the paperwork burden that falls on small businesses are the result not of agency mandates, but due to legislative incentives passed by Congress. I believe that if Congress truly wants to reduce paperwork burdens on small businesses, we need to look first at how we legislate.

In recent years, a great deal of attention has been given to HCFA regulations and the paperwork burden that it places on small business. It should come as no surprise that the industry affected most by these paperwork requirements are the medical professions. Often times we forget that many in the health care field are small businesses.

As a matter of fact, small business loans to medical providers ranks in the top five under the SBA 7(a) loan program. According to the American Medical Association, HCFA produces over 110,000 pages of medical regulations requiring doctors to spend an estimated 20% to 50% of their time filling out forms --- meaning many doctors are spending as much time with their accountants as they are with their patients.

Hopefully, today's hearing will shed some light on how we can streamline these processes and what changes can be made to the Paperwork Reduction Act to ensure agencies report clear and concise regulations. I look forward to hearing from the witnesses on how this committee can find a balance between the need for accurate reporting requirements that do not overburden small businesses.

DONNA M. CHRISTENSEN
DELEGATE, VIRGIN ISLANDS

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CONGRESSWOMAN DONNA M. CHRISTENSEN
OPENING STATEMENT BEFORE
THE HOUSE COMMITTEE ON SMALL BUSINESS
HEARING ON HEALTH CARE FINANCING ADMINISTRATION (HCFA)
MAY 9, 2001

Thank you Chairman Manzullo and Ranking Member Velazquez for holding this hearing on the paperwork burdens of the Health Care Financing Administration. As chair of the Health Brain Trust of the Congressional Black Caucus, but more especially as a physician who suffered under the complex and cumbersome bureaucracy, I can say that a close scrutiny of this important issue is long overdue. I commend our chair and ranking member for recognizing the special plight of small businesses that are health care providers, and bringing the issue of HCFA under our purview. It is an honor to welcome my colleagues and the representatives of the Health Care Provider associations who are with us this morning. Thank you for stepping up to the plate on behalf of all of the health care providers in this country.

Based on the introduction of bills, like HR 868, several letters and statements, help is on the way. However, to fix and not compound the problems, it is important that this Congress not follow the lead of HCFA, but instead hears from and is advised by those who know the problem and its impact best -- the providers. And we must also be especially cognizant of the fact that, indeed, Congress is responsible for some of the confusion that now exists. Several key leaders in both bodies are on record. In the House, Chairmen Tauzin, Bilrakis, and Greenwood in a letter to Secretary Thompson, stated their commitment to "changing this system so that healthcare professionals can better focus on improving patients quality of care." Both the President and the Secretary are on record in favor of reform as well. During several testimonies here on the hill, I have committed myself to working on this issue, and I have signed on as a co-sponsor of HR 868.

No wonder this agency is a mess. It is governed by over 130,000 pages of Regulations, which based on my experience seems to be interpreted differently in different parts of the country. Just a few examples and in the words of Joe Friday, just the facts:

- Because of the complexity and continuous changes medical records must be reviewed by at least four people to insure compliance.
- OASIS, used to assess care at home care agencies asks more than 60 questions, and the tool used for skilled nursing facilities asks almost 200, not used for calculating payment. The OASIS form may have to be completed up to three times in each 60-day period of care.
- According to GAO 40 extra minutes of a nurse's time is required to do just the initial OASIS assessment.
- For every hour of care in various health care sites, it takes anywhere from 30 minutes to 1 full hour of paperwork.
- According to some estimates, administrative cost due to the proliferation of paperwork adds up to $ 1,000 per person.

HCFA is quick to point out that it is not ranked the worst in terms of record keeping and reporting requirements. In fact it is 6th. I suspect rather than this being an accurate reflection of the burden imposed on providers, there may not be a full review of HCFA in this regard, because input from providers may have been limited. After filling out the reams of paper, and doing our very best to take care of patients we are to tired to do anything else, including register complaints, especially against the formidable federal government.

Is there any wonder that some medical service providers choose not to participate in the Medicare program. I know that many in the Virgin Islands do not, not just because of the reporting requirements, but also because of the lack of fairness in terms of denials, medical necessity decisions, slow responses and payments and other issues. We have no functioning home care agency in my district because of BBA '97, and the HCFA morass.

Mr. Chairman, I have a statement from one of my local physicians, Dr. Robert Bucher, which I would ask unanimous consent to include in for the record.

Healthcare providers comprise a large segment of our nation's small business population. HCFA has recognized that most rural Medicare providers and suppliers are small businesses. For this reason, the members of this committee along with SBA need to continue to work to ensure that their policies are responsive to small businesses.

Mr. Chair and Ranking member, I hope that this will be only the first of many hearings on these issues. I look forward to hearing form our guests this morning. I hope that from this hearing we can begin to identify the key problem areas, and the reforms needed to improve and streamline the Medicare reporting requirements.

DMCGVI00,

From: R.L. Bucher [rlb@islands.vi]
Sent: Monday, May 07, 2001 9:29 PM
To: DMCGVI00,
Subject: HICFA

Delegate Christiansen:

A few thoughts:

1. Something needs to be done to increase Medicare funding for home health care in the USVI. We now have 22 mostly elderly people who are permanent residents in the hospital, some of whom could be at home with Medicare services. Numerous other Medicare patients are forced to stay in the hospital for wound care which is no longer available at home. I have no idea how much money this is costing Medicare/Hospital/Territory but I bet it is a lot more than what "they" saved by putting our only home health care agency out of business.

2. Please clarify what we "Providers" can charge Medicare recipients for filling out the forms required for our patients to receive the free diabetes supplies they now deserve by law. This has become big business. The DME providers get a guaranteed fee. The patients get free supplies. The doctors' offices get nada for taking about 20 minutes per claim to authorize the transaction. And, the doctor who makes a clerical mistake is the one who will be prosecuted for Medicare Fraud. Hmm.

3. Why doesn't Medicare create a web site where we can submit claims, settle disputes and carry on all the other time-consuming things we lose money doing to be compliant?

4. Why doesn't Medicare put DME ordering and distribution on the Web? Amazon.com could probably get an electric hospital bed to the VI in 48 hours.

I'm trying to be constructive here. Medicare and all the other insurance companies have made it impossible to see patients in our office more than two afternoons a week without hiring two or three more people.

I'd like to think I should spend my time using what I've learned in the 32 years I've been a physician helping people in need - not employing people in the Health Care Industry.

Maybe you can voice some of Chris and my ideas if you agree.

Thanks for all you are doing to improve health care in the USVI!

B

SUE W. KELLY
15TH DISTRICT, NEW YORK

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Opening Statement of the Honorable
Sue W. Kelly
Committee on Small Business
Hearing on Health Care Financing Administration Paperwork Burden

Good morning. Mr. Chairman, Ranking Member Velazquez, I would like to thank the witnesses for being here today to testify before the Small Business Committee.

The onerous paperwork burden health care providers face when dealing with the Health Care Financing Administration is inexcusable. The simple fact is that for every hour that a doctor or other health care provider spends treating a patient, he or she spends nearly the same amount of time completing paperwork.

The paperwork requirements imposed by HCFA, with the intention of reducing fraud and abuse, have a detrimental effect on patient care. There are more efficient ways to combat fraud and abuse than by overburdening providers with unnecessary paperwork. The more time and labor it takes to fill out lengthy and often duplicative paperwork, the more it costs providers to maintain their offices. In the long run, this cost is passed on to consumers in the form of higher health care costs and less time devoted to patient care.

We need to make sure that the health care provider documentation process is as streamlined as possible, so that patients get the care they need, quickly and efficiently. Patients' lives depend on it. We need to adequately measure the amount of time health care providers spend filling out certain forms and adjust cost estimates accordingly. Providers need to be educated on how to properly complete required paperwork and not penalized for voluntary compliance efforts.

HCFA is an agency in need of reform. The medical community, the Secretary of Health and Human Services, and the President have acknowledged this. That is a good first step. I look forward to working with Secretary Thompson and the new HCFA Administrator to reduce paperwork burdens for healthcare providers and to improve our nation's health care system.

I am pleased that this hearing is the first in a series of hearings the Small Business Committee will hold to address HCFA paperwork reform. I look forward to a productive dialogue today and in the hearings to follow.

Statement of

Congresswoman Stephanie Tubbs Jones

Health Care Financing Administration Paperwork Burdens:
The Paperwork Reduction Act As A Prescription For Better Medicine

House Committee on Small Business

Wednesday, May 9, 2001

Stephanie Tubbs Jones

Mr. Chairman, Ranking Member Velazquez, and Invited Guests:

Thank you for bringing this matter to the Small Business Committee for consideration. The regulatory burden imposed on health care providers is of grave importance in both urban and rural settings, as we seek solutions to increase access to healthcare.

I represent the Eleventh Congressional District of Ohio. Within my District, we have experienced several hospital closings, which have seriously affected my constituents' access to healthcare. I have convened the Eleventh Congressional District Taskforce on Healthcare to hold dialogues with the community involving physicians, nurses, other providers, and administrators. We have examined these issues and, as a group, planned ways to improve access.

Therefore, I am familiar with the burden imposed on doctors by excessive paperwork. Like other regulatory scenarios, these burdens reflect policy choices that weigh costs and benefits. But unlike other small businesses, the regulatory burdens imposed on health care providers affect not only their revenue, but more importantly, their ability to care for patients.

I have heard from many physicians who have complained of the record-keeping and paperwork burdens imposed by HCFA. While caring for patients, many doctors encounter situations in which time spent in patient

care is matched by time spent filling out forms in an effort to comply with regulations. This has a clear effect on the time available to provide care. Excessive paperwork also affects a provider's ability and willingness to provide care for Medicare and Medicaid patients. The regulatory burden affects not only doctors, but filters throughout a community. Thus, more regulation may mean that poor and elderly persons may end up with less access to healthcare.

In weighing the need to regulate, we must consider whether information is truly needed in order to prevent fraud, or if the information can be obtained in an easier format than long and possibly duplicative forms. The system clearly needs reform. Physicians and dentists have enough demands on their time without being buried under paperwork.

It is imperative upon Congress to help ease this burden because we must also address the needs of more than 40 million people without health insurance. It is my hope that this hearing will lead to improved systems of collecting data and information. Considering the widespread use of computers, we should encourage electronic filing and data collection, and work to ensure that patient privacy is protected. Let's keep what is good about our health care system but remove the barriers that rob the system of efficiency.

I look forward to working with my colleagues on the Small Business Committee to address this issue.

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Congress of the United States
House of Representatives

Congressman Mike Ross
Statement in front of the Committee on Small Business
at the hearing on Health Care Financing Administration
Paperwork Burdens
May 9, 2001

Mr. Chairman.

I appreciate the Chairman and the Ranking Member for convening today's hearing, which will explore the Health Care Financing Administration's (HCFA) paperwork burdens. I am particularly interested in today's hearing for two reasons. First, I am a small business owner. I know what it is like to meet a payroll every Friday for 15 employees. I know what it is like to deal with paperwork requirements from the federal government and from employee-related issues. Second, the business that I own, along with my wife, is a pharmacy and home medical equipment business, Holly's Health Mart. As owner and manager of Holly's Health Mart for seven years before coming to the Congress, I dealt day in and day out with Medicare regulations.

HCFA has the enormous responsibility of managing not only the Medicare program with its 39 million beneficiaries but also the Medicaid program. Because of the nature of its work, often times HCFA creates some of the largest and most complicated paperwork requirements. When that small business is a doctor, pharmacist, home health agency or other health care provider, there comes a point when regulatory necessity causes potential harm to patient care. Indeed, the American Medical Association estimates that HCFA has produced over 110,000 pages of Medicare regulations. As a result, many physicians have reported that they spend 20% to 50% of their time fulfilling Medicare paperwork requirements.

I am pleased that HCFA has recognized that most health providers and suppliers, especially in rural areas, are small businesses. As a result the agency is working with the Small Business Administration to ensure HCFA regulations and policies are responsive to small business owners.

However, more can be done. I am a cosponsor of the Medicare Education and Regulatory Fairness Act (MERFA; H.R. 868). MERFA will require HCFA to document the costs of its regulations to health care providers and educate providers about proper documenting and billing. Additionally, several House committees have held hearings about HCFA's regulatory role and Health and Human Services Secretary Tommy Thompson has expressed support for increased

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funding for building and modernizing HCFA's infrastructure. These efforts will go a long way toward relieving health care providers of paperwork burdens. However, to effectively create real regulatory reform, we need to recognize where the most of the HCFA rules come from—Congressionally mandated laws.

I look forward to hearing today's witnesses and working with my colleagues on the Committee and in the Congress on commonsense and efficient regulatory reporting requirements.

Tom Udall (NM-03)

Statement of Congressman Tom Udall
Small Business Committee Hearing on "Health Care Financing Administration Paperwork Burdens: The Paperwork Reduction Act as a Prescription for Better Medicine."
May 9, 2001

Mr. Chairman and Ranking Member Velazquez thank you for having this hearing today to examine the Health Care Financing Administration (HCFA) Paperwork Burdens that are placed on physicians and providers all over the United States, especially in rural areas.

Those in the medical profession who I have talked to in my congressional district and throughout New Mexico tell me that HCFA's requests for information, as essential as the information is to ensuring the quality and availability of patient care, takes an enormous amount of time to provide. Time that could be better spent on providing healthcare to those who need it.

For example, most Medicare patients, according to the American Hospital Association, arriving at the emergency room for treatment are required to review and sign eight different

forms, just for Medicare alone. Moreover, the hospital must complete a 30-item questionnaire to assure the patient has no other health insurance.

Year after year new regulations, rules, and legislation add to the already hundreds of provisions which HCFA, Health Agencies, medical providers and patients must abide. Some interest groups have even suggested reforms to give health care providers and suppliers more influence on HCFA regulations, especially those that takes critical time away from patient care.

I am particularly interested in Dr. Robert Anderton's testimony where he states that only 1-in-5 children receive mandated preventive dental services and part of the problem is due to State compliance with complex Medicaid administrative and excessive paperwork requirements. Making sure our children receive the proper medical and dental services is a high priority for all of us. Especially those who represent rural or urban districts with low-

income families many of whom have no health insurance.

I look forward to listening to the testimony today to help us find ways where we can ease the paperwork burden that is placed on our physicians and patients so that the 20% to 50% of a physician's time which is currently spent on Medicare paperwork requirements---would be better served treating and giving health care to their patients.

American Medical Association
Physicians dedicated to the Health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Statement

to the

Committee on Small Business
U.S. House of Representatives

RE: Health Care Financing Administration Paperwork Burden

Presented by: William H. Mahood, MD

May 9, 2001

Division of Legislative Counsel
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Statement

of the

AMERICAN MEDICAL ASSOCIATION

to the
Committee on Small Business
U.S. House of Representatives

RE: HEALTH CARE FINANCING ADMINISTRATION PAPERWORK BURDEN

Presented by: William H. Mahood, MD

May 9, 2001

Thank you for the opportunity to appear before the Committee today to discuss our views concerning the overwhelming regulatory burden imposed on physicians and health care providers by the Health Care Financing Administration (HCFA).

Physician practices generally are organized as small businesses. Indeed, AMA data shows that two-thirds of physician practices have 25 employees or less. Thus, as small businesses, these practices do not have the economic and other resources necessary to absorb the administrative burdens and costs imposed by continual unfunded government mandates resulting from paperwork and other regulatory requirements.

Physicians are very frustrated by needlessly complex and overly-burdensome Medicare policies and regulations. We have reached the point where there are now over 110,000 pages of Medicare rules, policies, and regulations. In a recent AMA survey, more than one-third of the 653 responding physicians report spending one hour completing Medicare forms and administrative requirements for every 1-4 hours of patient care. Further, the majority of physician respondents (52 percent) indicated that Medicare's rules and requirements decrease their willingness to see Medicare patients.

We appreciate the efforts of the Committee in addressing the Medicare regulatory and reporting requirements being placed on physicians. Indeed, Representative Patrick Toomey (R-PA), a member of the Committee, has been extraordinarily helpful in working on these matters, and we are especially thankful for his leadership in introducing (with Representative Shelley Berkley (D-NV)) the bipartisan *Medicare Education and Regulatory Fairness Act of 2001* (MERFA), H.R. 868. This bill, which would make the carrier and fiscal intermediary audit process more equitable and increase Medicare education efforts regarding program rules and policies, currently has 143 cosponsors. We believe the Committee should take a special

interest in this legislation since several provisions would relieve some of the burdens placed on small physician and provider groups. **We thank those members of the Committee who have co-sponsored the MERFA legislation, and urge all other Members of the Committee to become a co-sponsor as well.**

We are also encouraged by the commitment of President Bush and Health and Human Services Secretary Thompson to decrease the regulatory burden on physicians. The President recently acknowledged that "Medicare is burdened by bureaucratic complexity . . . Medicare's regulations are 3 times longer than the U.S. tax code, driving physicians from the program." Secretary Thompson reiterated the Administration's commitment to this matter when he too acknowledged that "patients and providers alike are fed up with excessive and complex paperwork. Rules are constantly changing. Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses and other health care professionals out of the program."

There are a number of regulatory issues that are extremely burdensome to physicians, and there are too many to detail before the Committee today. Our testimony, therefore, focuses on certain issues that illustrate the complex and burdensome paperwork requirements and other regulatory burdens that shift physicians' time away from patient care.

The paperwork requirements discussed below are unique to the Medicare program. Although with respect to some of the issues discussed below, the private sector does not have similar paperwork requirements, physicians cannot continue to meet the burdensome paperwork demands placed on them by both the federal government and the private sector. We urge the Congress to focus on the burdensome and unnecessary paperwork requirements imposed by federal programs and to encourage the private sector to mirror any paperwork reductions.

EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES

Evaluation and management documentation guidelines (E&M guidelines or guidelines) continue to be an extremely burdensome problem for physicians. HCFA implemented these guidelines to establish requirements that physicians must meet when recording in their medical records the items and services they provide to a patient. This documentation is used to validate the physician's claims to the Medicare program for certain office, hospital, or outpatient visits and consultations (E&M services). For example, if a carrier requests a patient's medical record and determines that the record does not justify the specific coded services being billed to Medicare (based on a review of the extent of the physical exam provided and the kind of medical decision making involved), the physician may be required to refund the program thousands of dollars for that and other similar visits.

In the AMA survey referenced above, one-fifth of respondents identified these guidelines as the most onerous and egregious of the Medicare requirements. Many physicians regard the guidelines as "overly complex" and "unworkable." We have reached the point where physicians create documentation in their patients' charts often not for the benefit of the patients' care, but purely to meet the government's demands. These regulatory requirements

have resulted in voluminous charts filled with layers and layers of extraneous information. In fact, this additional documentation in patients' charts can actually hurt patients since care is unnecessarily delayed while physicians are forced to search through pages and pages of documentation to identify the truly relevant information. It is like trying to find the needle in the haystack, and when a patient needs emergency treatment, for example, physicians do not have the luxury of researching voluminous patient records. The pertinent medical information needs to be immediately available so that the patient can be treated appropriately. The current E&M documentation requirements make this nearly impossible.

Despite the serious problems with the guidelines, Medicare carriers rely on them when auditing physician practices, as does the HHS Inspector General (IG) when it conducts its annual audit of HCFA. If a physician's claims are not supported by documentation in the patient's chart, as required by the guidelines, then a carrier audit will likely determine that the physician has been overpaid. Further, the recent IG audit for the year 2000 noted that a payment was improper because the physician had documented "only" 19 of the 23 exam elements that are required in the documentation guidelines. Unfortunately, this rigid adherence to the minutiae of Medicare policy and paperwork requirements is far from an isolated incident.

Even though physicians identify the E&M guidelines as the most serious Medicare paperwork problem and Medicare relies upon them as an important tool for ensuring compliance, none of the guidelines currently in effect have ever gone through any type of OMB clearance process. These guidelines have never been scrutinized to assess the degree to which they increase the unnecessary paperwork burden on physicians and their patients or comply with the government's paperwork reduction rules.

Current HCFA Developments with the E&M Guidelines

Currently, physicians must follow one of two sets of E&M guidelines that were developed in 1995 and 1997, respectively. These guidelines have been extraordinarily problematic and unworkable and thus have not been acceptable to the physician community. HCFA, therefore, has been developing yet a new set of guidelines.

HCFA has contracted with Aspen Systems to develop "clinical examples" that are intended to illustrate to the physician community and Medicare carriers the typical documentation that should be in a medical record to support each type of service provided during a physician visit. These clinical examples are being extracted from paid claims and will be reviewed by medical specialty societies. At a meeting held last week to provide an update on the project, Aspen staff indicated that the draft clinical examples are 640 pages in length.

Physician Concerns with the Current E&M Guidelines

Since physicians will be severely impacted by the clinical examples developed by Aspen, most physician groups, of course, would prefer to be involved in their development rather than surrender that responsibility to a payer. Yet, there was no opportunity to do so. **The medical community was not asked to participate in the development of the E&M clinical**

examples, and, further, only twenty national medical specialty societies were asked to review them.

Physicians are also concerned that although they may voluntarily agree to participate in the pilot programs (that will test the clinical examples), they could be held liable for honest billing "errors" when any such "errors" simply would be the result of learning how the new guidelines apply. Physicians should not be penalized for participating in what is essentially a learning experience, yet HCFA will not grant them "immunity" from liability.

Finally, physicians are concerned that some carrier staff may not have the educational and other experience needed to effectively understand and apply the guidelines to claims submitted by physicians.

We urge the Committee to review the paperwork burden imposed by these E&M guidelines and explore whether "pilot" projects, designed to test the clinical relevance of E&M guidelines, are a more appropriate response to ensuring clinically relevant documentation standards.

HCFA ENROLLMENT FORM 855

There are deeply-rooted problems in Medicare's policy for physicians' enrollment in the program through Form 855. This Form must be completed by physicians and submitted to HCFA to enroll as a Medicare provider. We urge the Committee to review the paperwork burden imposed by this Form and to prevent HCFA from implementing its plan to expand extensively the circumstances under which this Form must be submitted, as discussed below.

As of this year, physicians will be required to fill out one or more versions of Form 855, depending on their type of practice. Most physicians will need to fill out Forms 855I (individual physicians), Form 855R (for reassignment of benefits to an entity), and Form 855B (if they own a physician practice). Many of HCFA's requirements for Form 855 apply across the board to all versions of the Form. Below we will generally refer to Form 855, unless otherwise indicated.

General Problems with the Enrollment System

A physician cannot get paid for treating Medicare patients until the physician has a provider number, which is issued by the program upon completion of the Form 855 enrollment process. Yet, in many regions, physicians must wait for months to receive enrollment approval under Form 855. During this time, physician practices cannot submit claims to receive Medicare payment for services provided to beneficiaries, and thus are effectively precluded from treating Medicare patients This is an extremely difficult situation for physicians who are just beginning to establish themselves in a community, and especially in rural communities that may have difficulty recruiting new physicians.

This lengthy waiting period is also challenging for the practice that the new physician is joining. Physicians who have just completed their residency training must spend several

months assembling their documentation for state licensure, which often includes records from high school through residency. Once the correct documents are submitted, licensure normally occurs within six weeks. Only when they have their state licenses can physicians apply for hospital privileges, which generally take three months to obtain. Only after receiving state licensure and hospital privileges, can physicians submit their Form 855 to Medicare to obtain provider identification numbers. After all of this prior licensure activity, carriers often take more than six months to process Form 855 before enrolling physicians in Medicare.

The AMA has strongly urged HCFA to ensure that its Medicare carriers shorten the processing times for provider enrollment forms by allowing physicians, for example, to enroll via an online version of Form 855 and to mail relevant attachments to HCFA. Physicians currently cannot submit Form 855 or any changes to the Form electronically.

Further, HCFA should prohibit carriers from sending an incomplete or incorrectly completed Form 855 back to physicians, which restarts the processing timelines. Under the Medicare Carrier Manual, carriers are required to process enrollment applications within 45 calendar days, absent extenuating circumstances. Often, however, carriers wait until the end of the 45-day period and then return the application to the physician citing minor information that is missing. Clearly, carriers should contact the applicant as soon as possible, preferably by telephone, to request any missing information, without restarting the approval process timeline. Only during this period when the carrier is waiting to receive these materials in the mail should there be a temporary pause in the processing period.

The AMA also has advocated strongly that physicians receive temporary provider numbers during the enrollment application period. By the time a new physician submits Form 855, he or she has already undergone tremendous scrutiny to become licensed in a state. In these instances, licensed physicians should be reimbursed for the services they provide while waiting for the carriers to process their permanent provider identification number. **Identifying and reserving a limited number of temporary provider numbers would help facilitate a smooth transition for patients, physicians, and practices during the enrollment process.**

HCFA's New Enrollment Form

HCFA recently released a new version of Form 855, which would actually lengthen the time that carriers have to process the application from 45 days to 60 days. **At a minimum, we urge the Committee to recommend that HCFA clarify that this means 60 calendar days, not 60 business days, and that HCFA hold its carriers to this deadline.**

The AMA is also very concerned about the requirement in the new 855 Form that physicians must submit changes to the Form, even when they are nonmaterial in nature, within 30 days. We strongly believe that the goal of updated information could be more reasonably met by requiring quarterly reports of new material information. Otherwise, physicians will continuously have to send in new forms to their carriers as changes in their practices occur. **A quarterly reporting requirement is a less burdensome solution that still accomplishes the same goals of transmitting information changes.**

HCFA's Underestimated Costs under the Paperwork Reduction Act

HCFA has provided time and cost estimates regarding its Form 855 Enrollment Form which seriously underestimate the true time and costs incurred by physicians in completing these forms. First, HCFA's fifteen minute estimate to complete the 855R is a woeful underestimate. Reading the directions which accompany the application alone would take longer than 15 minutes.

In addition, HCFA's estimate for clerical employee wages and attorneys' and consultants' hourly fees for completing this form are several years, or in some cases, several decades behind the times. For example, HCFA's estimate that clerical staff salaries are $12 per hour is far from correct and somewhat irrelevant. Because of the potential liability for physicians and providers who provide incorrect information on the Form, office managers — not clerical staff — by necessity, have to be responsible for completing or reviewing the form. Office managers are paid on average $20 per hour. In addition, neither this $20 average office manager hourly wage nor the $12 hourly wage HCFA has estimated for clerical workers includes fringe benefits paid by most physician practices to their employees. These fringe benefits increase hourly wages by approximately one-third.

Further, HCFA's estimate of $75 per hour for attorneys' and consultants' fees seriously underestimates current market realities. Although there is no absolute per hour average for attorneys' fees available, Lawyer.com reports on its website that average attorneys' fees range from a minimum of $75 to over $300+ per hour. It is also inaccurate to assume, as HCFA has done, that physicians will not require attorneys' or consultants' services to complete the 855I. This is especially true if the physician is a solo practitioner who must complete the entire Form 855I, rather than only part of the Form (if she or he is part of a group practice). **HCFA should take into account the true costs that enrollment in the Medicare program will impose on physicians' practices.**

HCFA's Proposed Expansion of the Form 855 Enrollment Process

Under the existing Medicare enrollment system, most physicians will have to complete Form 855I, Form 855B, and Form 855R. The time and costs to physicians in completing these forms are substantial. Yet, HCFA is attempting to expand the scope of its enrollment efforts by requiring all physicians to enroll in the program. Previously only physicians who have enrolled in the Medicare program after 1996 have had to complete the Form 855. The agency is also seeking to require physicians to revalidate this application information every three years.

This would affect physicians who have been providing care to their communities for decades, but have not filled out the more than 30-page application form. **The AMA strongly believes that the Medicare enrollment program should not be expanded since it would place an enormous additional burden on physicians across the country with respect to costs and time needed to complete the forms.** Some physicians, such as anesthesiologists, have to have a separate Medicare number for each hospital where they practice. Further, it is not

clear that carriers are ready to assume this responsibility, or that it would not disrupt the delivery of care to Medicare patients.

Accordingly, we urge the Committee to scrutinize this pending HCFA initiative that could negatively affect physicians' willingness to reenroll in the program, and to prevent HCFA from implementing any plans to expand the enrollment process.

CONFLICT BETWEEN ADVANCED BENEFICIARY NOTICES AND EMTALA REQUIREMENTS

When physicians have questions about Medicare coverage policies, current law dictates that in order to bill a patient for the service, the physician must request that the beneficiary sign an ABN stating that (i) the beneficiary understands the service may not be covered and (ii) the beneficiary will pay for the service in full if Medicare does not cover it. Medicare coverage policies are extremely confusing, however, and physicians very frequently do not know, when they order an item or service, whether Medicare will cover it. This is necessary to preserve the right of the physician or other provider (laboratory) to bill for services for which Medicare will not provide payment.

ABNs have long been a problem and have created unnecessary burdens and conflicts for physicians and health care providers. Indeed, surveys have shown that physicians consistently list this requirement as imposing a barrier in the physician-patient relationship as well as an administrative burden on physicians. We are encouraged that HCFA recently released a new one-page ABN, and we are working with the agency to provide physician community feedback on the new form.

Although there have been many problems with lengthy and confusing ABN forms and process, the particular issue on which we wish to focus today is the serious conflict between ABN and EMTALA requirements. Under Medicare ABN policy, physicians must abide by carrier instructions that require ABNs to be signed by the patient prior to ordering or performing a test or service that the physician knows or believes may not be covered by the Medicare program.

In contrast to this policy, however, under EMTALA requirements, the hospital/physician must first stabilize the patient before asking about the patient's insurance coverage. Thus, the physician is prohibited by EMTALA from discussing Medicare coverage of services that need to be provided and whether the patient is willing to pay for non-covered services. Yet, if a service is provided in the emergency department that is subsequently not paid by the Medicare program, because physicians are prohibited by EMTALA requirements from having the patient fill out an ABN form, the physician cannot bill the patient or be paid for the service.

This result is particularly detrimental considering that many hospitals' emergency departments are struggling or closing due to financial considerations. Further, in rural areas, which often have a higher Medicare population, it is very difficult for physicians and hospitals to absorb these losses.

We urge the Committee to recommend that HCFA immediately resolve the conflict between ABN and EMTALA Medicare policy.

SECLUSION AND RESTRAINT

HCFA's regulations on seclusion and restraint of patients are extremely and unnecessarily burdensome and do not promote quality patient care.

In July 1999, HCFA isolated certain seclusion and restraint provisions from a 1997 proposed rule on hospital conditions of participation for purposes of Medicare and Medicaid and published them in an interim final rule. This regulation included a new so-called "one-hour" rule that requires physicians to conduct a face-to-face evaluation with the patient within one hour of an order to restrain or seclude a patient in the behavioral management setting.

HCFA did not include the one-hour rule in the initial 1997 proposed rule, and thus the physician community never had a chance to comment on it before it was implemented.

Moreover, HCFA never issued a final rule responding to the thousands of comments and strong clinical objections it received on the interim final rule. Nor has the agency ever responded to findings from both the Small Business Administration's Office of Advocacy and a Federal Court that HCFA did not comply with the Regulatory Flexibility Act in promulgating this rule, as all federal agencies are required by law to do.

The "one-hour" rule is over-prescriptive, does not reflect the current or the best practice of medicine, and places an undue and unfair burden on all hospitals, especially psychiatric, small, and rural hospitals.

Although a timely evaluation should occur when a patient is restrained or secluded, the one-hour rule amounts to the unlicensed practice of medicine by federal bureaucrats who have never seen nor have any knowledge of the patient involved. A face-to-face evaluation within one hour by a physician is not clinically or medically necessary in every instance where a patient is restrained or secluded, especially when the physician has frequently treated the patient, as is often the case. Evaluations can routinely be made over the telephone by discussing the patient's condition with the nurse or other caregiver attending to the restrained or secluded patient. The physician, based on this discussion, can then make a professional medical decision as to whether a face-to-face evaluation is needed.

Accordingly, we urge the Committee to recommend that HCFA withdraw the one-hour rule and re-promulgate the regulation in consultation with the medical community and in compliance with the Regulatory Flexibility Act.

Further, in January 2001, the Clinton Administration published an interim final rule governing the use of seclusion and restraint in psychiatric residential treatment centers. With this latest rule, mental health providers must now comply with at least four different sets of requirements governing the use of restraint and seclusion. These myriad rules are confusing,

often duplicative, extremely costly to implement (without any offsetting payment for compliance costs) and may result in less access to important medical care for patients.

We further urge the Committee to recommend that HCFA review the various rules that have been published governing the use of seclusion and restraint in various settings, and to conduct meetings with affected physician and provider groups to design a reasonable and consistent policy for use of restraint and seclusion in all facilities.

CERTIFICATES OF MEDICAL NECESSITY

Physicians are required to complete a certificate of medical necessity (CMN) when ordering certain items and durable medical equipment for Medicare patients. CMNs must be completed, for example, each time a physician orders a cane, crutches or a walker, and frequent re-certification is required for patients who have a lifetime need for durable medical equipment.

In a recent AMA survey, 39 percent of physician respondents identified CMNs as posing one of the greatest problems under Medicare. This is especially true for physicians practicing in rural areas. During the last year, 45 percent of physicians have had more than 10 percent of the CMN forms returned with a request for more information, while 20 percent of physicians have had more than 25 percent of the forms returned for more information. These survey results confirm the importance of reviewing the CMN process and working to achieve acceptable solutions to the enormous problems posed by CMN requirements.

HCFA recently agreed that problems caused by the CMN process would be a top priority for the agency. **We urge the Committee to recommend that HCFA review the CMN process to resolve overall problems with CMNs in consultation with the medical community, including reduction in the use of CMNs and streamlining the different forms used by each of the carriers.**

We thank the Committee for its interest and efforts in these important regulatory matters and look forward to further work with the Committee to achieve reasonable solutions to the problems discussed above.

American Medical Association
Physicians dedicated to the health of America

FOR IMMEDIATE RELEASE **May 9, 2001**

AMA TO CONGRESS: UNFUNDED GOVERNMENT MANDATES OVERBURDEN PHYSICIAN PRACTICES

Small Physician Practices Lack Resources to Accommodate Government Demands

WASHINGTON - The American Medical Association (AMA) told Congress today that unfunded government mandates resulting from burdensome Medicare paperwork and other requirements are taking time away from patient care.

"Two-thirds of physician practices qualify as small businesses with less than 25 employees, and these practices cannot absorb the costs imposed by unfunded government mandates resulting from burdensome Medicare requirements," William H. Mahood, AMA trustee, testified before the House Small Business Committee. "In fact, in a recent AMA survey, more than one-third of responding physicians spend one hour completing Medicare forms and administrative requirements for every one to four hours of patient care."

Dr. Mahood's testimony highlighted three examples of burdensome government requirements:

1. Evaluation and management documentation guidelines require physicians to record information in patients' charts that is not clinically relevant.
2. The Medicare enrollment process prevents physicians from being reimbursed for treating Medicare patients until he or she has a provider number — which is issued by Medicare upon completion of the Form 855 enrollment process. This process can take months.
3. The serious conflict in Medicare policy between rules that say a patient must first be stabilized before a physician can ask about insurance coverage, while at the same time requiring physicians to ask a patient to sign a guarantee of payment before any non-covered medical service can be performed.

"These requirements shift physicians' time away from patient care. We thank the Committee for pursuing these regulatory relief efforts," Dr. Mahood said.

For more information, an interview or Dr. Mahood's testimony, please call:

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American Academy of Orthopaedic Surgeons | AAOS American Association of Orthopaedic Surgeons

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Testimony of
Alan H. Morris, MD
Chair, Council on Health Policy and Practice
American Association of Orthopaedic Surgeons
Before the
Committee on Small Business
U.S. House of Representatives

Health Care Financing Administration Paperwork Burdens:
The Paperwork Reduction Act as a Prescription for Better Medicine
May 9, 2001

Good morning Chairman Manzullo and Members of the Committee, my name is Alan H. Morris, MD. I am a practicing orthopaedic surgeon in a small practice with six partners based in St. Louis, Missouri. I am also chair of the Council on Health Policy and Practice of the American Association of Orthopaedic Surgeons (AAOS).

On behalf of the AAOS, which represents the interest of 18,000 board certified orthopaedic surgeons, I would like to thank you for holding this hearing to seek input from physicians and other providers regarding recordkeeping and reporting requirements imposed by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services.

Our number one concern is the quality of orthopaedic care that we provide to our patients. We believe that the health care infrastructure of this country is in critical need of an overhaul. We have lost sight of ensuring quality patient care, and have managed to create a bureaucratic nightmare of paperwork rather than focusing on spending time with patients. Both the federal government and private insurance providers should be focused on directing resources to ensure an appropriate balance of paperwork to patient care.

Over the past year and a half, the AAOS has been pleased to work with you Chairman Manzullo to address these paperwork and regulatory reform issues. We appreciated your efforts, along with Representative Collin Peterson, in initiating a Dear Colleague letter during the 106th Congress, signed by 60 of your colleagues, requesting the Chairmen of the Ways and Means and the Commerce Committee to hold hearings to examine Medicare regulatory reform issues.

AAOS is also encouraged that the Small Business Committee is reviewing these regulatory reform issues from a small business perspective by evaluating possible opportunities for enforcement under the jurisdiction of the Committee such as changes to the Paperwork Reduction Act, the Regulatory Flexibility Act, and other laws.

The growth in Medicare regulations generated from the Health Care Financing Administration (HCFA), as well as requirements from the Medicare Fiscal Intermediaries and the Carriers, has imposed significant paperwork burdens on physician practices and consumes an enormous amount of manpower, time and resources of these practices. The AAOS, like others, in proposing the reduction of paperwork stresses the need to streamline and simplify the forms and

reports that must be completed by those being regulated, and to consolidate those forms and reports to avoid unnecessary duplication when several agencies, or entities within agencies, may be requiring similar or overlapping information. We are also concerned that HCFA may be liberally applying exemptions under the Administrative Procedures Act (APA) and other laws to circumvent the review and clearance procedures required to approve regulations effecting paperwork reporting and recordkeeping requirements.

Majority of Orthopaedic Practices are Small Businesses

The average orthopaedic practice in this country can be characterized as a small business with 6.3 full time equivalent (FTE) orthopaedic surgeons and most practices have between 4 and 10 orthopaedic surgeons. I am part of a practice of 7 orthopaedic surgeons. Most practices average 25 to 35 employees excluding physicians. Staffing can include nurse practitioners, physician assistants, registered nurses, physical therapists, occupational therapists, surgical assistants, radiological technologists, orthopaedic technologists and a high number of administrative staff.

In my office we employ 26.5 FTE employees for the 7 physicians or 3.8 FTE's per physician. This is a rather typical average across the country as indicated by the Medical Group Managers Association (MGMA) data. My office employs 9.5 FTE medical staff and 17 FTE administrative staff. Of that 17, 3 FTE employees are transcriptionists who type our dictations into the medical record, 3 FTE employees do nothing but obtain precertification for managed care organizations (Medicare Managed Care Organizations require more staff and time than

other MCO's) and schedule procedures, and 3 FTE staff handle the printing preparing the charts for office visits.

Over the past 3 years, due to regulatory requirements increasing over what they had been, we have had to hire more personnel. In addition to the above, we have an outside company to whom we have "out sourced" our billing processes. The outside company estimates that they use approximately 8 to 10 FTE staff to process the paperwork from our practice. This additional administrative cost would be borne by our office (additional staff hires) should we have billing processes "in house." Our fee to the billing company includes a company representative that reviews each patient charge to ensure that a proper diagnosis code accompanies each procedure code. While the latter is a process that each physician and his staff perform, it is double checked by the billing company out of fear that an inadvertent error will have been made which would cause a Medicare audit. Our entire office management is directed by an administrator who, of necessity, must have medical, financial, legal, and personnel experience. Our administrator has a masters degree in health services management.

Medicare Carrier Reporting Requirements and Discretion

Regarding Medicare recordkeeping and reporting requirements, Medicare health care providers are required to comply with requirements both directed centrally from HCFA and independently by the Medicare Carriers. Medicare Carriers are health insurance carriers such as Blue Cross Blue Shield, Aetna, United Healthcare and others who enter into contracts with HCFA to oversee the coding and billing practices of physicians and other Medicare providers. Carriers operate

with a great deal of discretion and many policies and specific forms generated from the Carriers are not required to comply with federal government review.

In our practice of 7 physicians, because some of our orthopaedic surgeons practice in both Missouri and Illinois, we are required to comply with the requirements of 4 different Medicare Carriers: the Missouri Medicare Carrier, the Missouri Railroad Medicare Carrier, the Illinois Medicare Carrier, the Illinois Railroad Medicare Carrier.

Processing our paperwork involves coding review, medical billing, processing claims, explanation of benefits review, mail, posting cash, appeal of payment denials, customer services, accounts receivable management and resolutions, processing of refunds for overpayments, development of compliance manuals and other training material for staff, development of templates for staff use in patient evaluation documentation requirements and review procedures for ensuring that patient information is properly recorded. We are required to comply with new and revised policies distributed periodically through single Carrier bulletins released by each of the 4 Carriers where these policies can often vary from one Carrier to another.

This past year, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) distributed to physicians guidelines for developing "voluntary" compliance plans (Compliance Program Guidance for Individual and Small Group Physician Practices). Significant time and cost was invested in the training and paperwork requirements, including the time needed to write a manual and closing the office for staff training. Additionally, ongoing paperwork will include quarterly audits of our practice to ensure implementation of the seven

elements of the plan as defined by the OIG and the conduction of two hours of annual review training for each staff member.

Medicare Enrollment Process

In addition to a uniform physician identifier number, which is used universally across all public and private health care plans, each physician is required to apply for a separate individual Medicare provider number. The Medicare application for the individual provider number (Form 855I) is approximately 30 pages long and has taken up to 6 months for some Medicare Carriers to process. Practices are also required to apply for a separate Medicare number for the group practice (Form 855B)– this application is approximately 9 pages, and the practice needs to receive an individual enrollment approval for each physician before qualifying for the group practice number.

Medicare requires physicians to re-apply for Medicare numbers each time they move to a new practice or begin practice under a new Medicare Carrier. Recently 3 members of my practice applied for Medicare numbers, where two of my partners, who had been in prior practice down the street, received their Medicare re-enrollment numbers approximately six weeks after they applied. For one of our orthopaedic surgeons applying for the first time for a Medicare number, it took a significantly greater amount of time. In each case, the practice had to also re-apply for a new group number for each Carrier these physicians would be practicing under. Physicians are precluded from submitting claims to receive Medicare payments until they receive these provider numbers.

Additionally, in the early 1990s, HCFA established separate Durable Medical Equipment Regional Carriers (DMERCs) to manage the paperwork reporting and recordkeeping requirements for durable medical equipment and other medical supplies. We are also required to comply with the policies of the DMERCs assigned to this region and to also apply for separate DMERC Medicare numbers. The typical application required by a managed care health plan is generally 2 pages long for the physician, and generally takes less time to process.

We believe that HCFA has seriously underestimated, under the requirements of the Paperwork Reduction Act, the time and cost involved to complete the Form 855 Enrollment Form. HCFA estimates that it takes a physician no more than 15 minutes to complete this form, and uses outdated salary rates for estimating the costs involved for administrative and clerical involvement in the processing of the application.

HCFA is currently extending the Medicare enrollment system to require all physicians to enroll in the system. Currently, only those physicians who enrolled after 1996 have to complete the Form 855. AAOS believes that it is reasonable to require HCFA to first solve existing enrollment application processing problems, shortening the backlog and response time, before extending these requirements to all physicians.

Evaluation and Management (E&M) Documentation Requirements

HCFA has made two attempts (1995 and 1997) to develop evaluation and management (E&M) documentation guidelines to help physicians bill and code correctly for services to Medicare beneficiaries. Physicians have questioned both the accuracy and complexity of both sets of these guidelines relative to services provided and view the E&M documentation requirements as among the most onerous paperwork burden in the Medicare program. These guidelines have never gone through any type of Office of Management and Budget (OMB) clearance process.

The structure of the E&M system is based on a single-system examination environment that does not transfer well into a specialty environment. Under this single-system approach, while it may take the orthopaedic surgeon the appropriate time to analyze the patient's specialty diagnosis, such as a herniated lumber intervertebral disk, the physician is obligated to review and document several of the patient's systems in order to be adequately compensated for the specialty diagnosis.

Because the E&M guidelines require extensive documentation and HCFA has not provided a template, physicians and their administrative staff have spent a great deal of time and resources to develop their own templates to satisfy these requirements. HCFA's focus seems to be inappropriately placed on providing quantitative information, often through a basic "check-off" reporting process, rather than providing any documented evidence of quality patient care.

Typical of other practices, our administrator's paperwork preparation for the E&M coding has also required a great deal of time to create transcription templates to ensure the orthopaedic surgeon captures a broad range of the patient's systems. It then takes the orthopaedic surgeon a great deal of time to review these basic systems with each patient and to document this information with the patient, cutting into the time the orthopaedic surgeon has to examine the patient's orthopaedic problem. Private managed care plans do not have comprehensive coding and billings requirements comparable to the E&M structure.

Advanced Beneficiary Notice

Under the Advanced Beneficiary Notice (ABN), physicians are required to receive signed consent from patients for those services not covered by Medicare. The ABN takes time with the patient, slows down the process, while, in the long run, not really making much difference when it comes to seeking compensation for the service. The steps require that, before any care is delivered, the patient first receive an explanation of all services covered and not covered by Medicare, be given the option of declining services, and sign a consent form indicating what services they have agreed to. While the majority of patients will sign the consent form, many patients often don't recall later what was covered and what was not. This is really a needless requirement because it does not improve patient care, and can only result in an adversarial relationship with the patient.

Certificates of Medical Necessity

HCFA, in establishing the Durable Medical Equipment Regional Carriers (DMERCs), required physicians to complete a certificate of medical necessity (CMN) for certain medical equipment and items that their patients may require. This puts physicians in the position of "policing" the activities of medical suppliers and responsible for paperwork and recordkeeping activities that perhaps should be done directly by the supplier and monitored by the DMERCS, rather than putting the physician in the middle. The current arrangement also places all responsibility on the physician to know not only what medical equipment is appropriate for a patient's diagnosis, but also to know the condition of equipment approved for patient use -- something the supplier should be in a better position to know. This is especially problematic in those instances where the patient may need equipment, such as a wheelchair, throughout their lifetime.

Recommendations

I am a physician, not an expert on paperwork reduction or regulatory reform, but it seems to make sense that third party intermediaries should be covered under the same laws as the federal agency they answer to. This can ensure appropriate and consistent communication and uniformity in policies and practices, while streamlining paperwork requirements for reporting and recordkeeping responsibilities.

The AAOS believes that the Paperwork Reduction Act, as well as other laws that fall under the jurisdiction of this Committee such as the Regulatory Flexibility Act, the Small Business

Regulatory Enforcement and Fairness Act, and the Congressional Review Act, give the Small Business Committee the authority to address many of the concerns that I have raised here today.

We suggest that Medicare third party intermediaries come under the Paperwork Reduction Act as agents of HCFA. Applying the same scrutiny of paperwork requirements across all agents of HCFA imposes some degree of oversight to ensure that the reporting and recordkeeping requirements of the Medicare Carriers are reasonable and consistent with HCFA policies. Standardizing information across all Medicare Carriers will go a long way in holding the Carriers accountable.

The AAOS regularly comments on proposed Medicare regulations under the notice and comment procedures established by the Administrative Procedure Act. Seldom, however, are the actual reporting forms part of the review process or available to allow for timely review and comment from the provider community. Forms and data collection requirements initiated by Medicare Carriers should be subject to review by the Office of Information and Regulatory Affairs in the Office of Management and Budget as established by the Paperwork Reduction Act.

This holds true for many of the forms also generated directly by HCFA. Providers also do not get to adequately comment on the appropriateness of these Medicare forms that are generated out of HCFA headquarters. The review process should be scrutinized for its reasonableness and timeliness.

HCFA policy and regulations should also be scrutinized for compliance with the Regulatory Flexibility Act. This law requires independent regulatory agencies and executive agencies to prepare analyses indicating how their regulations would impact smaller entities, including businesses. Under the law, HCFA would not have to abandon the regulations, but rather they would have to find less burdensome ways to allow small businesses and small not-for-profit entities to comply with federal requirements.

HCFA should also be required to comply with the Small Business Regulatory Enforcement and Fairness Act. Subtitle A of this Act requires that small businesses receive assistance in understanding and complying with agency regulations from both the agency and the Small Business Administration. Subtitle E of this Act, also referred to as the Congressional Review Act, requires agencies to submit new regulations to Congress and the General Accounting Office (GAO) prior to implementation demonstrating that they have complied with various review requirements, including conducting a cost benefit analysis of the regulations. The Act also builds in more accountability for enforcement actions by providing small entities with an opportunity for redress of arbitrary enforcement actions.

To also build more accountability into the Medicare system, it might be reasonable to require HCFA and other relevant agencies, who have any oversight authority over health care providers who qualify as small businesses, to publish in the Federal Register, on an annual basis, a list of the information collection requirements that are applicable to health care providers who qualify as small businesses. HCFA and these other agencies could be required to establish a point of

contact for all small business concerns and to examine and demonstrate, on an annual basis, efforts to streamline paperwork requirements for small businesses.

Medicare Education and Regulatory Fairness Act

AAOS commends and appreciates the efforts of Representative Pat Toomey (R-PA), a member of this Committee, for working with a range of physician specialty societies, the American Medical Association, and other provider groups in introducing the Medicare Education and Regulatory Fairness Act of 2001 (MERFA). This legislation makes important changes to Medicare operations in an attempt to create a more inclusive, nonadversarial system for addressing the complexities of Medicare coding and billing recordkeeping and reporting requirements and related regulations imposed on physicians, hospitals, home health care and other providers. Among the issues addressed, MERFA codifies requirements for developing reasonable E&M documentation requirements, as well as addresses the lack of HCFA accountability by broadening the scope of judicial review of regulatory activity.

AAOS believes that support among legislators to address these regulatory reform issues is widespread as evident by the high number of cosponsors already supporting the MERFA legislation. We encourage this Committee to continue to examine these issues and to support legislative action to ensure that HCFA addresses many of these problems in a timely way.

Both HCFA and the Office of the Inspector General (OIG) have indicated that many of the concerns addressed in the MERFA legislation, as well as issues discussed here today before this

Committee, can be addressed without legislation. Our concern is that while HCFA believes that legislation is not necessary and that they already have the jurisdiction to address these issues, these changes are not getting done. Legislative action provides assurances that policymakers are serious about these issues.

Conclusion

The AAOS encourages the Members of this Committee to challenge HCFA to demonstrate the necessity for the scope of recordkeeping and reporting now required by HCFA as well as the Medicare Fiscal Intermediaries and Carriers. HCFA should be required to justify these requirements from a cost-benefit and quality patient care perspective. We believe the agency needs to strike a reasonable balance for reporting on Medicare beneficiary services that allows physicians to spend time with their patients focusing on the services for which the patient was referred.

On behalf of the AAOS, we appreciate your willingness Chairman Manzullo and Members of this Committee to hold this hearing, and we look forward to working with you to find solutions to the paperwork burdens imposed on Medicare providers.

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Testimony
of the
American Hospital Association
before the
United States House of Representatives
Committee on Small Business
on the
Health Care Financing Administration Paperwork Burdens:
The Paperwork Reduction Act as a
Prescription for Better Medicine
May 9, 2001

Mr. Chairman, I am Bruce Cummings, CEO of Blue Hill Memorial Hospital in Blue Hill, Maine. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network, and other health care provider members. We welcome the opportunity to testify on the complexity and burden of the Health Care Financing Administration's (HCFA) reporting and record keeping requirements.

Blue Hill Memorial Hospital was established in 1924 as a small, rural hospital serving the residents of the coastal village of Blue Hill. We have evolved to become a nationally recognized rural primary care system that provides a broad range of services to 13 rural communities and 18,000 residents of and visitors to western Hancock County, Maine. Our integrated primary care system includes: a 25-bed federally certified, state-licensed "critical access hospital" (CAH), the first CAH in New England and one of the first in the US; a home health agency and Medicare-

certified hospice; and a non-profit medical group practice which operates five federally-certified Rural Health Clinics, three of which are located 18 or more miles away from Blue Hill.

DROWNING IN A SEA OF RULES AND REGULATIONS

Since I am from Maine, a state with a long maritime tradition, I am borrowing a cue from last summer's blockbuster movie and the book which inspired it, "A Perfect Storm", to frame my remarks. "A Perfect Storm" is the true story of a small fishing vessel, the Andrea Gail, caught up in and ultimately destroyed by the extraordinary confluence of three major storm systems off the Grand Banks.

Like the Andrea Gail, hospitals are facing an assault, but one that is man-made. It is the confluence not of three storm systems but of several bureaucratic engines: federal Medicare regulations (now numbering more than 130,000 pages); a myriad of state and local laws; and, requirements from private payers and accreditation bodies – usually uncoordinated, almost always duplicative, and occasionally contradictory.

Unlike the movie, this "Perfect Storm" is not a cataclysmic event but an insidious, relentless assault that is gradually eroding the energy and effectiveness of health care staff; driving skilled nurses, doctors, technicians and therapists from the health care field; and wounding the ability of hospitals, home health agencies and other providers to care for patients. We are drowning in a sea of regulation; we are being crushed by tidal waves of paperwork.

To illustrate the tumultuous seas we must navigate, I would like to share with you Blue Hill Memorial's experience with the Medicare cost report. Not long ago, Congress wisely sought to

ensure that rural residents have continued access to essential routine health care services by improving the financial viability of small rural primary care facilities. As a result, Congress created the Critical Access Hospital program.

Unfortunately, Congress' intent has been frustrated and some critical access hospitals continue to experience serious cash flow problems because of long delays by some fiscal intermediaries in settling/closing the annual Medicare cost report required of all hospitals whether large or small, urban or rural. As you may know, the fiscal intermediary uses this compilation of documents and attachments – tantamount to a "super-sized" tax return – to calculate both interim rates and final payments to CAHs. Rather than process and settle the cost report in a business-like and timely manner, some fiscal intermediaries may not settle a cost report for two or more years. Our cost report for fiscal year of April 1, 1999 to March 31, 2000, for example, still has not been settled by the fiscal intermediary even though it was declared complete months ago.

Worse yet, Blue Hill Memorial Hospital – which is operating at a deficit – is owed more than $2.5 million on a combined basis from the Medicare and Medicaid programs, going back over a period of three years (three cost reports). Because of this long-time horizon – and the resultant cash flow pressures that devolve upon an already fragile organization – we have had to take out a line of credit from a local bank in order to meet our payroll, pay our vendors and meet other current operating obligations. These interest charges are approximately $120,000 a year – all of them avoidable and unnecessary. Had that money been available to us, we could have used it for replacing outdated equipment, starting new programs to better serve our community, or improving our ability to recruit and retain scarce health care personnel. To add insult to injury, the interest expenses caused from having to borrow money from a bank are disallowed on the

Medicare cost report by the fiscal intermediary! And to top it all off, whenever the fiscal intermediary chooses to settle up with us, it routinely withholds 20 percent of the Medicare funds owed to Blue Hill Memorial Hospital – a hedge, we are told, in the unlikely event our 25-bed hospital might someday owe money back to the fiscal intermediary. So, instead of being paid the full cost of caring for Medicare patients and receiving this payment on a timely basis – as Congress intended when it authorized the creation of critical access hospitals – we continue to be overburdened, underpaid and paid late.

I will give you one more example of excessive paperwork. This case revolves around Blue Hill Memorial's home health nurses when they visit a homebound patient. HCFA requires that all home health agencies, large and small, complete the same Outcome and Assessment Information Set (OASIS) form upon admission, at specified intervals thereafter and upon any significant changes in the patient's condition for all Medicare and non-Medicare patients alike. The purpose of the form is to assess the health status of home health patients and to classify episodes of care for payment purposes.

Our typical home health patient is 78 years old and approximately 37 percent live alone. Most have heart disease; indeed, most have multiple chronic illnesses. One third have severe, clinically-evident anxiety. Open wounds are a common acute problem. A Blue Hill nurse drives an average of 20 miles between patients over difficult and at times dangerous roads. She cannot treat her patient – no matter how ill or uncomfortable – until she has completed all 17 pages of the OASIS form, which takes roughly 90 minutes to complete on each new patient, many of whom are confused and anxious. Finally, let's take a closer look at the OASIS form. It has close to 100 questions, of which only 22 are used for payment purposes. HCFA claims that the

roughly 70+ questions remaining are needed for outcome analysis. We would argue that a less burdensome data gathering process would result in more reliable data and better outcome analysis. After our home health nurse completes the OASIS instrument, she still has 43 pages of additional forms required by Maine state law, the Joint Commission on Accreditation of Healthcare Organizations, or by other federal requirements. Given these paperwork burdens, it's little wonder that hospitals are facing a worker shortage.

PAPERWORK VERSUS PATIENT CARE

You have asked us to estimate the total paperwork burden imposed by HCFA on small hospitals. The AHA recently commissioned PricewaterhouseCoopers to ask some of America's hospitals, including small hospitals, about their paperwork experience. It may shock you that 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. The study examined a typical episode of care for a Medicare patient suffering from a broken hip. Figure 1 (on page 17) examines the paperwork burden for caregivers treating this type of injury. We have provided a copy of the study for the record (see attachment).

While the PricewaterhouseCoopers report did not evaluate the paperwork requirements placed on hospitals by the private sector, we do know that the private sector mirrors the paperwork burdens imposed by HCFA. And it is equally important to note that in the private sector there are many payers, each with their own set of requirements with which hospitals must comply.

Complete records and documentation are necessary for patient safety and quality care. But complying with the numerous regulations issued by HCFA and other federal, state and local regulatory agencies should not dominate a caregiver's day. While some paperwork is necessary for clinical purposes, there's been a significant increase in paperwork needed to document regulatory compliance. And the problem is growing. Since 1997, more than 100 regulations affecting health care have come on the books. Every new rule brings more paperwork and training and education for nurses, physicians and others, shifting the focus and resources away from patient care. For example, several medical privacy provisions in the Health Insurance Portability and Accountability Act (HIPAA) rules are estimated to cost hospitals up to $22 billion over five years.

The HIPAA administrative simplification rule is intended to streamline the processing of health care claims, reduce the volume of paperwork and create cost savings. HHS estimates that the cost of the administrative simplification provisions – including the transaction standards, code sets and national identifiers – will be about $3.5 billion for providers, occurring over the first three years of implementation. Hospitals alone would face costs estimate at about $1.4 billion to come into compliance. However, according to the Clinton administration estimates, administrative simplification is expected to ultimately save the health care field $30 billion over 10 years, with savings of $16.7 billion accruing to health care providers.

Recent studies by the Blue Cross and Blue Shield Association suggest that HHS has seriously overestimated these savings and underestimated the costs for hospitals. For example, according to the Blue Cross study, HHS has underestimated the costs for hospitals by a ratio of 3:1 or $3 billion. That's why the AHA is asking the Congress to adjust Medicare payments through a full

market basket increase and to provide grant monies to accommodate additional HIPAA information system costs.

PAPERWORK ...AND MORE PAPERWORK

Administrative burdens, driven by complex rules and regulations, shift the focus from patient care to paperwork. In fact, some of HCFA's paperwork requirements make little or no sense. We know that Congress intended to address some of these issues when it enacted the Paperwork Reduction Act. What Congress did not anticipate is how some agencies would circumvent some of the act's requirements. For example, it is our understanding that HCFA violated the Paperwork Reduction Act when it failed to obtain final clearance from the Office of Management and Budget for certain parts of the Medicare Secondary Payer (MSP) questionnaire. (The MSP form is intended to verify that Medicare patients do not have other sources of insurance coverage that could be considered primary for payment purposes.) As a result of this violation, HCFA cannot formally require hospitals to complete the form, but the agency does require that the hospital ask the patient the same 25 questions contained in the form at every patient encounter. If a patient comes to the hospital every day for a week to receive outpatient treatment and related testing for, say, cancer or a severe infection, he or she will be asked these same 25 questions each day. It is our experience that the employment status of most 80-year-olds rarely changes, especially from one day to the next. We believe that the MSP example illustrates the need for Congress to create an inter-governmental task force to review the Paperwork Reduction Act and other similar laws to assess how well agencies are complying with their requirements.

Listed below are a few other examples of simply wasteful paperwork:

- A Medicare patient arriving at the emergency department is required to review and sign eight different forms – just for Medicare alone.
- Each time a physician orders a test or a procedure, the physician documents the order in the patient's record. But HCFA requires additional documentation to prove the necessity for the test or procedure. Although the physician made a clinical judgment, the decision making process - which resulted in the medical order - must be documented using an established diagnosis assignment process mandated by the government.
- Because of the complexity and continuous changes in the Medicare program requirements, medical records must be reviewed by at least four people to ensure compliance.
- The Minimum Data Set (MDS), the patient assessment tool used in skilled nursing facilities, has almost 200 questions about patients that HCFA does not use for calculating payment.

Hospitals are drowning in this sea of government rules and regulations. Lost is a sense of fairness, due process and common sense. And the real victims are patients, because regulatory burdens are impeding the efficient delivery of health care. It is time to make the regulatory process make sense. We are not the only ones who feel this way. Health and Human Services (HHS) Secretary Tommy Thompson echoes our concerns. In his confirmation hearings, he expressed strong views about Medicare's regulatory overload. "Patients and providers alike are fed up with excessive and complex paperwork... Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses and other health professionals out of the program," he said. It is important to note that the regulatory burden is a contributing factor to the health care staff shortage the United States is experiencing – nurses, doctors and technicians are leaving health care professions in pursuit of other opportunities.

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

IMPROVE THE REGULATORY PROCESS

Enable providers to challenge questionable policy action in court. Unlike other federal agencies, Medicare program policy decisions made by the Secretary of HHS are insulated from judicial review. Health care providers are required to exhaust all administrative processes and remedies before they can file suit against HHS. However, there is no such process to exhaust on policy questions about whether the Secretary has exceeded his authority or failed in his duty. This effectively means that providers can bring a suit only if they violate Medicare requirements so significantly that they are thrown out of the Medicare program. HHS policy decisions should be subject to the same level of judicial review as other federal regulatory agencies.

Coordinate the orderly release of federal regulations to allow for more seamless compliance. Government agencies with jurisdiction over hospitals need to release regulations in a coordinated manner so that implementation does not overwhelm hospital personnel and systems. That means establishing a point of accountability to coordinate regulatory activity across major federal agencies, as well as within HHS. As the predominant federal regulator of hospitals, HHS should periodically evaluate its overall federal regulatory framework applied to health care providers for clarity and expected behavior from providers.

Include the cost of implementing significant regulations into Medicare payment updates. The cost of caring for patients continues to increase as a result of complex regulations such as HIPAA and greater technological advances in such areas as pharmaceuticals and blood products. Currently, the initial cost of implementing significant new regulations is not captured by Medicare prospective payment rate updates. Like new technology and productivity improvements, these costs should be required to be taken into account when the Medicare Payment Advisory Commission (MedPAC) makes its annual rate update recommendations to Congress. Therefore, MedPAC should be required to annually aggregate the estimated impact of a regulation on providers' payments and costs, and to incorporate this aggregated impact into the Medicare inflationary market basket update. The costs incurred by hospitals to comply with federal regulations and standards are simply part of our costs to provide care to patients.

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 compliance failures are increasingly severe. HCFA should establish query mechanisms for individual providers and their associations on the appropriate interpretation or application of Medicare rules in specific situations. HCFA's responses should be timely and readily available to others in an easily accessible format (such as an indexed file on the Internet).

Seek greater provider input on new rules and regulations; assess patient impact. Federal regulators need to become more acquainted with real-world hospital operating environments so that practical implementation issues can be minimized on staff and patients before a regulation goes into place. Agencies should conduct outreach efforts to obtain early input from the health

care field, including publishing notices of intent; making relevant databases, cost estimates, assumptions, and methodologies publicly available early on; holding field hearings; and conducting site visits. There are significant differences in the size, complexion and available financial and human resources throughout America's hospitals. Despite their obvious differences in size of and the roles they perform within the health care system, a 25-bed rural critical access hospital, a 200-bed community hospital, and a 500-bed teaching hospital all must meet the same relevant federal regulations. Agencies need to appreciate, therefore, that a "one size fits all" approach to regulation is inherently unfair and falls hardest on those least able to hire the additional specialized personnel or expensive consultants with which to respond to the latest new regulatory initiatives. Take HIPPA, for example. My 25-bed hospital is unable to afford the estimated $80,000-$120,000 in consulting fees we believe would be needed just to assess our readiness to meet the new HIPPA standards.

Enhance the communications of regulatory requirements to health care providers. Providers are finding it difficult to monitor, identify, absorb and comply with Medicare requirements because of the complexity of the program, the pace of change in requirements, and the numerous ways that HCFA issues policy and administrative requirements. HCFA should more actively communicate these changes and use contemporary technologies to provide free and easy access to a well-organized database of all requirements issued through any means.

Enact the Regulatory Fair Warning Act. Today's highly regulated health care environment demands that federal rules and regulations are issued in a timely manner, and made available and understood not just by those who are regulated by them, but also by those who enforce them. Passage of bipartisan legislation similar to the Regulatory Fair Warning Act, introduced by Rep.

George Gekas (R-PA) in the 106th Congress and reported favorably by the House Judiciary Subcommittee on Commercial and Administrative Law, would help stop ambiguous and conflicting regulatory pronouncements. Specifically, the Regulatory Fair Warning Act would prevent federal agencies from penalizing businesses or entities for alleged violations if:

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

Restrict use of interim final rules. HCFA has increasingly issued new rules as interim final rules; that is, issued and implemented before the agency takes public comment. To reduce the disadvantages of this approach – which negates the public comment process – HCFA should be required to issue final rules within a year after the interim final rules so that public comments are taken into account on a timely basis.

PROVIDE RELIEF FROM SPECIFIC REGULATIONS

Revise the HIPAA privacy regulation and offer grants to help hospitals with the huge costs of complying with the HIPAA rules. The AHA supports meaningful medical privacy standards. But the new HIPAA privacy rule is so complex and prescriptive that it's unworkable – or worse – for patients and for hospitals. As I mentioned earlier, an AHA-study looking at hospital costs alone, found that the cost of only three key provisions of the proposed rule could be as much as $22.5 billion over five years. We must fix HIPAA now and provide funding to help hospitals comply.

Streamline the Medicare cost report. The Secretary of HHS should evaluate and overhaul the cost report, reducing its size and complexity. It should be adjusted to differentiate between those providers for which Medicare payment is based on prospectively set rates from those that are cost-based reimbursed. The arcane Medicare-specific cost accounting principles should be modified for all providers, whether paid on a prospective or cost-basis.

Prohibit the denial of payment by FIs for emergency services provided to Medicare beneficiaries that are required by EMTALA. As a participating provider in the Medicare program, Blue Hill Memorial is required to screen any individual who comes to the emergency department to determine whether that person has an emergency medical condition or is a woman in active labor and, if so, to stabilize him or her. (This is mandated by the Emergency Treatment and Active Labor Act.) To adequately screen and stabilize the patient, we often employ ancillary services that are routinely available to the emergency department.

Medicare sometimes denies payment for the services furnished emergency departments because they exceed the local medical review policies (LMRPs) or utilization guidelines for coverage and frequency established by the Medicare fiscal intermediaries (FIs). However, hospitals are prohibited from billing beneficiaries for such services unless we notify patients in advance that the service may not be covered (advanced beneficiary notice). Conversely, we cannot notify patients in advance because the Inspector General interprets this advance notification of possible non-coverage as a delay in screening and stabilization. Hospitals, caught in a Catch-22, are often left with an unpaid bill for emergency care. The solution is simple: If hospitals must provide the services, Medicare should pay.

Limit data collection to what is necessary for payment and quality. Prospective payment systems should be simple, predictable and fair. Unfortunately, the patient assessment tools for skilled nursing, rehabilitation and home health are far from ideal. In fact, HCFA has devised three separate instruments, OASIS, MDS, and MDS-PAC, which collect much extraneous information, lack statistical reliability, and are extremely burdensome on hospitals. Recognizing the need for greater consistency and standardization, Congress last year asked the Secretary to study the development of a common patient assessment instrument and report back in five years. In the meantime, though, providers need immediate relief from the excessive burdens and often irrelevant information requirements imposed by these assessment tools, and HCFA needs to follow a rigorous process for changing or adopting new requirements.

Improve Medicare FI and carrier customer service performance. Communication and interaction between FIs/carriers and providers/practitioners is critical to a successfully administered program. Give FIs and carriers specific customer service performance objectives, and allow providers and practitioners to participate in performance evaluations. Enhance accountability by making FI and carrier performance evaluations public.

Revise the Medicare Secondary Payer Provision. Stop the burdensome requirement that patients must fill out the 25-question Medicare Secondary Payer (MSP) form every time they come to the hospital for recurring services, such as chemotherapy or blood work. Altering this requirement to require completion of the MSP every 90 days for recurring services would be a substantial improvement. We commend Rep. Saxby Chambliss (R-GA) for his efforts in convincing HCFA to no longer require a MSP questionnaire be completed for <u>every</u> outpatient

rehabilitation therapy encounter. However, the agency has yet to implement this improvement and some FIs still require completion of the MSP.

COMPLIANCE COSTS ARE HIGH

Complying with this growing mountain of rules and regulations comes with a high administrative price tag. Imagine the federal tax code. Now imagine something two-and-half to three times more voluminous. That's the size of the maze of Medicare rules, regulations, and interpretive guidelines.

Earlier in my testimony I told you about the Medicare cost report. My little 25-bed hospital employs one full-time individual at a cost of more than $65,000 annually just to *organize* the data that is required to complete the Medicare cost report and maintain the necessary supporting documentation. We then incur an additional $43,000 in fees paid to an independent auditing firm to check our calculations and to assure that the forms are properly filled out before we submit the cost report to the fiscal intermediary. That's more than $100,000 in direct expenses just to prepare the Medicare cost report. We incur other costs for accounting, billing, coding and supervision of our fiscal services personnel which now total more than 30 FTEs at a cost of $1 million per year – all this for a 25-bed hospital.

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

greater job satisfaction. Constantly training and educating new staff in the intricacies of these burdensome regulations is another hidden cost that hospitals must bear.

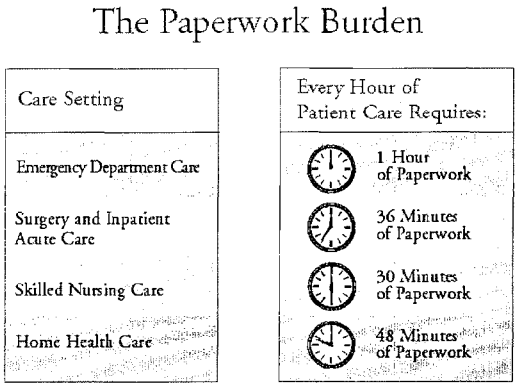
CONCLUSION

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

Mr. Chairman, we all agree the health care industry should be regulated. There are valid reasons why HCFA, the Joint Commission on Accreditation of Healthcare Organizations, the Internal Revenue Service and Occupational Safety and Health Administration should monitor hospitals' activities. However, the strain of 30 or more organizations issuing thousands and thousands of pages of often conflicting and complex rules, instructions and laws is hurting the health of our nation's hospitals. There is no coordination among agencies that regulate providers, and rules appear to be issued in a vacuum with no regard to the fiscal consequences of compliance, the impact on our daily operations, and last but not least, the effect on our patients.

The AHA is ready and willing to continue our work with HHS, HCFA and other agencies to improve the way rules and regulations are promulgated and implemented. We pledge to do all we can to help make the regulatory system work better not just for hospitals and health systems, but also for the patients and communities we serve. But we need the assistance of the regulatory agencies and Congress to achieve this goal. I thank the Committee again for the opportunity to describe the regulatory difficulties hospitals face, and for your tireless work on behalf of Maine hospitals, home health agencies and other providers too. I welcome any questions you may have.

Figure 1



Source: PricewaterhouseCoopers survey of hospitals and health systems.

Patients or Paperwork?
The Regulatory Burden Facing America's Hospitals
AHA

PRICEWATERHOUSECOOPERS

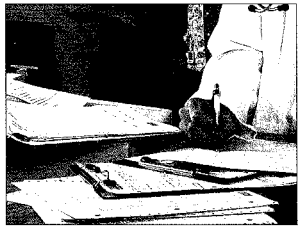
PricewaterhouseCoopers (PwC) was commissioned by the AHA to ask some of America's hospitals about their patient care and paperwork experience. PwC provides objective analysis to support AHA policy development. As a research and consulting organization, the AHA does not advocate for or endorse positions on specific policy issues.

AHA

The Case for Regulatory Reform and Relief in the Health Care Field

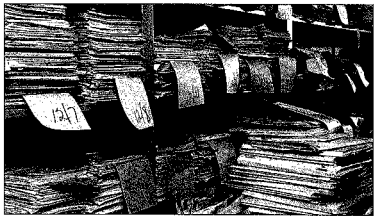
Perhaps no human service touches the lives of all of us so deeply as health care. Our society holds a special place for the people and institutions responsible for it. They are closely monitored and evaluated by local, state and federal regulators, who are charged with protecting the public and, in some cases, ensuring that public funds are spent wisely and in the public's best interest.

But those who give care—hospitals, physicians, nurses and others—are increasingly concerned that health care regulation is out of control and has lost a sense of fairness and common sense. It is time for dramatic change. Should all regulations be eliminated? **No.** The issue is not whether to regulate, but how. Just as hospitals, physicians and nurses constantly work to ensure that what they do benefits patients first and makes prudent use of resources, government must do the same.



The issue is not whether to regulate, but how.

A Sea of Paperwork



The people who take care of people know first-hand that many of today's health care regulations are too complex and inefficient, yet new ones are imposed on the system every-day. Health care workers strive to keep up with these regulatory requirements but are frustrated when their time and energy is diverted from their primary purpose—providing quality health care to patients—to trying to decipher and comply with the bureaucratic controls that often seem detached from good care and efficient use of resources.

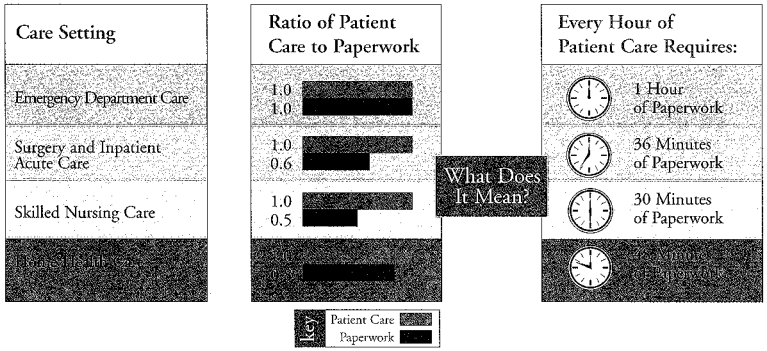
But how much time does a physician spend on paperwork and regulatory compliance, beyond writing diagnoses, medical orders and prescriptions? Or a nurse, a physical therapist, or any of the other professionals caring for the ill and injured?

Because hospitals, health systems and their caregivers are increasingly frustrated with regulatory red tape, the American Hospital Association (AHA) asked PricewaterhouseCoopers (PwC) to survey hospitals and assess the significance of the paperwork burden. The study illustrates a typical episode of care—an elderly woman who falls and fractures her hip—and the resulting patient care—and paperwork—which ensues (see appendix for details).

The results? For the various stages of care of a typical patient, paperwork adds at least 30 minutes to every hour of patient care provided and, in some settings, **adds an hour of paperwork to every hour of patient care**. The burden is simply too heavy—at the expense of patient care.

Paperwork can add an hour to every hour of patient care.

Study Results: The Paperwork Burden *fig. 1*



Source: PricewaterhouseCoopers survey of hospitals and health systems (see appendix for more information).

A Precious Resource: People

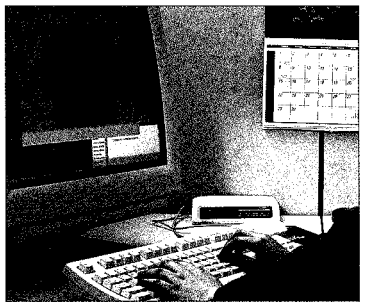
In an era of serious health care worker shortages, particularly when nurses, pharmacists and medical technicians are needed, we must use our caregivers' time as efficiently as possible. When less time is devoted to bedside care and more time is spent on regulatory paperwork and compliance, recruiting and retaining experienced, caring professionals—much less attracting future health care workers—becomes difficult.

Simply Wasteful Paperwork

Complete records and documentation are necessary for patient safety and quality care. They promote coordination, continuity and consistent quality improvement. But complying with the numerous regulations issued by local, state and federal regulatory agencies should not dominate our health care workers' day. Although some of this paperwork is directly associated with clinical care, there has been a significant increase in paperwork needed to document regulatory compliance. This administrative burden, driven by complex rules and regulations, shifts the focus from patient care to paperwork. In fact, some of these paperwork requirements make little or no sense.

Some paperwork makes sense, but did you know...

- A Medicare patient arriving at the emergency department is required to review and sign eight different forms—just for Medicare alone.
- Each time a physician orders a test or a procedure, the physician documents the order in the patient's record. But the government requires additional documentation to prove the necessity for the test or procedure. Although the physician made a clinical judgment, the decision-making process—which resulted in the medical order—must be documented using an established diagnosis assignment process mandated by the government.
- Hospital staff must complete a 30-item Medicare Secondary Payer questionnaire every time a Medicare patient comes to the hospital—whether for inpatient or outpatient care. The purpose? Make sure the elderly Medicare beneficiary still has no employer-sponsored insurance, or other coverage, that should be the primary payer.



- Because of the complexity and continuous changes in Medicare program requirements, medical records must be reviewed by at least four people to ensure compliance.
- OASIS, the Medicare patient assessment tool used in home health agencies, asks more than 60 questions that the Health Care Financing Administration (HCFA) does not use for calculating payment. Staff must complete the OASIS form an average of two to three times per 60-day episode of care.
- According to the General Accounting Office, OASIS requires 40 additional minutes of a nurse's time to complete the initial assessment. Additional staff time is required for supervisory review and data entry.
- The Minimum Data Set (MDS), the patient assessment tool used in skilled nursing facilities, requires almost 200 questions that HCFA does not use for calculating payment.
- Most skilled nursing facilities must designate one full-time employee to coordinate the collection and entry of MDS-required data.
- Each time a patient is discharged, even if only from the acute unit of the hospital to the on-site skilled nursing unit, multiple care providers must write a discharge plan for the patient. This documentation, as long as 30 pages, applies to all patients, regardless of the complexity of care received within the hospital or required post-hospital setting.
- Many forms, such as the "Activities of Daily Living," must be completed daily by clinical staff to submit to the government to justify the care provided to skilled nursing facility patients.

These are a few examples from a long list of how regulations pile on additional paperwork and documentation. Too often, these rules are implemented with no consideration for increased paperwork. The Appendix further illustrates the burdensome effect regulatory compliance and documentation has on paperwork.

There has been a significant increase in paperwork needed to document regulatory compliance. [5]

The Ripple Effect

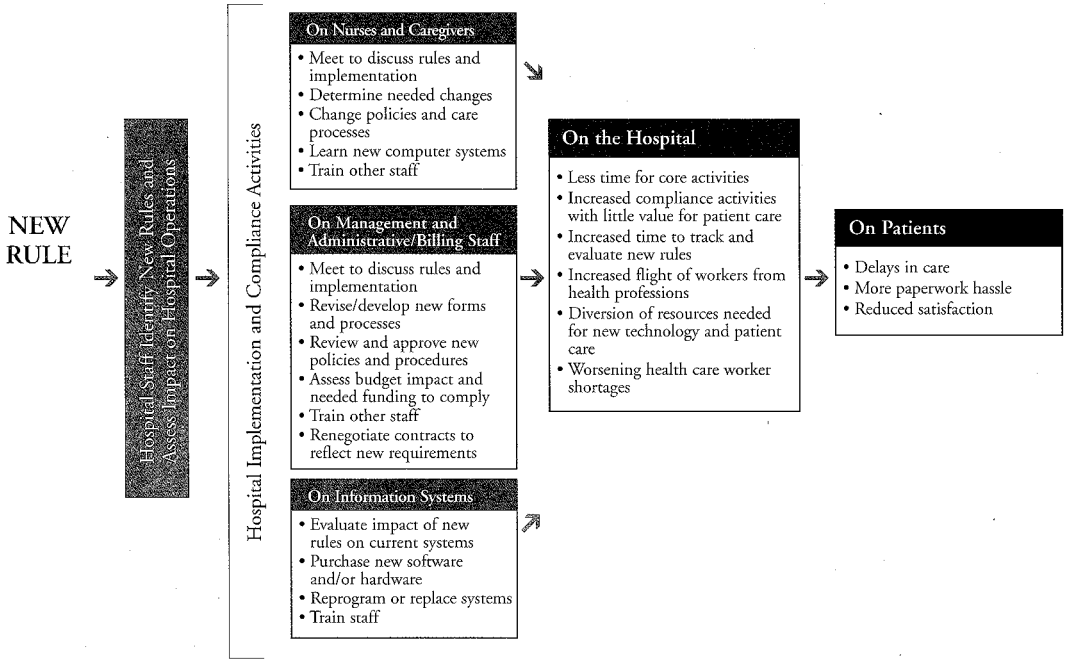
The PwC survey obtained information from hospitals about the patient care and paperwork time directly associated with a specific episode of care. It did not include what occurs when a new or revised rule, regulation or guideline is issued. Each new requirement—affecting either patient care and/or paperwork—demands a growing number of compliance and implementation activities by hospital personnel.

Each new regulation requires that a health care entity learn about the rule; conduct an analysis to determine how it changes current procedures; obtain approval for revised operating policies and systems; train staff; revise vendor contracts, if necessary; and establish methods for compliance documentation.

Figure 2 illustrates many of the activities needed to implement a regulatory change. Virtually every activity in a hospital is connected to another. Implementing and complying with just one regulation can cause a ripple effect, affecting operations and the care process throughout the hospital.

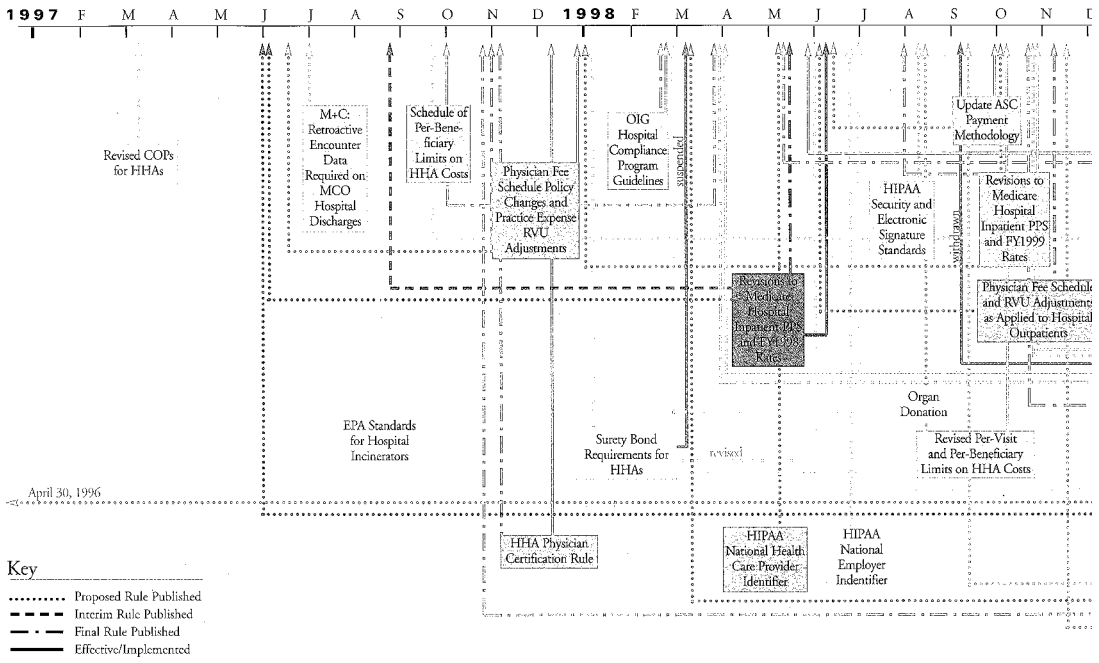
Just one regulation can cause a ripple effect.

One Rule, Many Changes—Many Rules, Countless Changes *fig. 2*



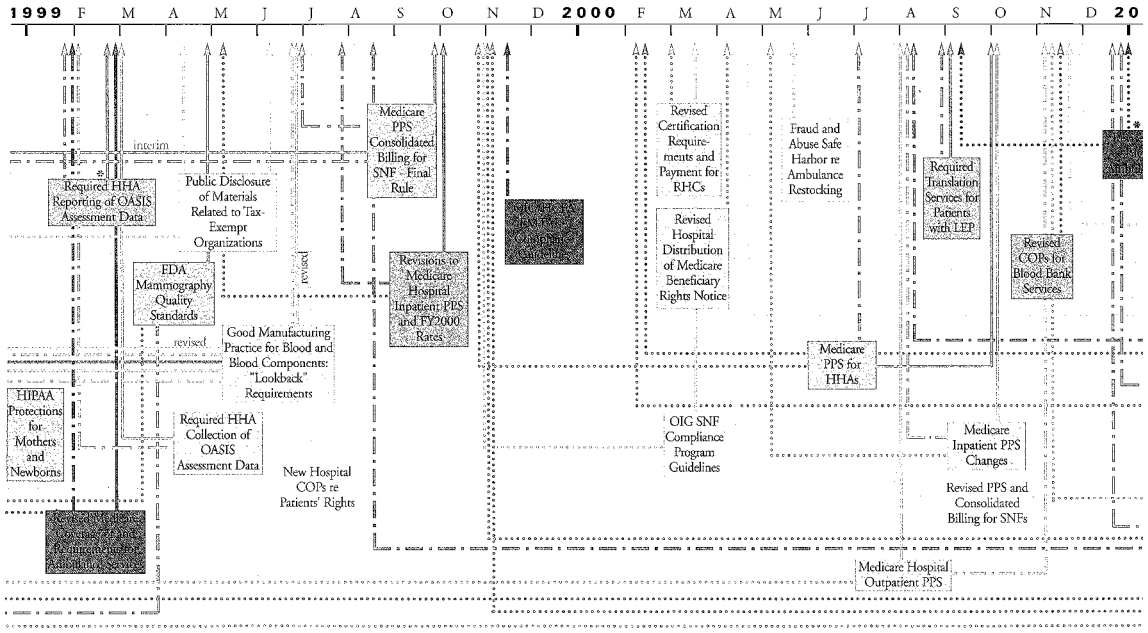
Added government regulation imposes unfunded costs on hospitals. 7

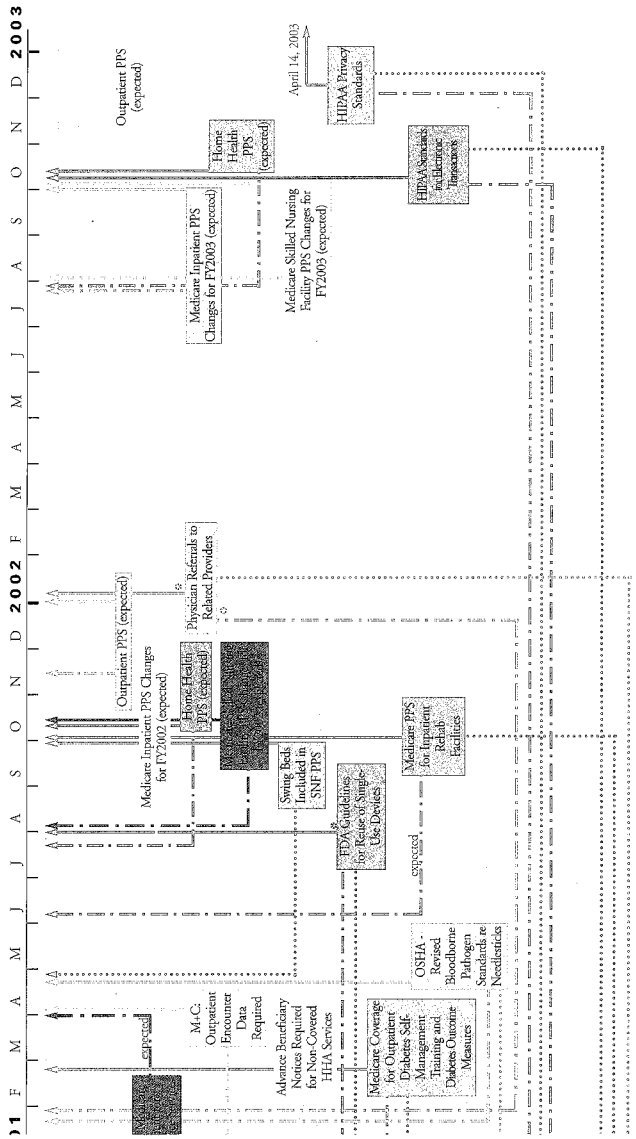
Health Care Regulation Timeline – 1997 to 2002:



* This regulation includes alternate effective dates for some sections of the rule.

A Period of Rapid, Massive Change for Hospitals




2003
Outpatient PPS (expected)
April 14, 2003
HIPAA Privacy Standards
Home Health PPS (expected)
Medicare Inpatient PPS Changes for FY2003 (expected)
Medicare Skilled Nursing Facility PPS Changes for FY2003 (expected)
HIPAA Standards for Electronic Transactions
Outpatient PPS (expected)
Physician Referrals to Related Providers
Medicare Inpatient PPS Changes for FY2002 (expected)
Home Health PPS (expected)
Swing Beds Included in SNF PPS
FDA Guidelines for Reuse of Single-Use Devices
Medicare PPS for Inpatient Rehab Facilities
OSHA - Revised Bloodborne Pathogen Standards re Needlesticks
M+C Outpatient Encounter Data Required
Advance Beneficiary Notices Required for Non-Covered HHA Services
Medicare Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measures
2002
01

What's the Count?

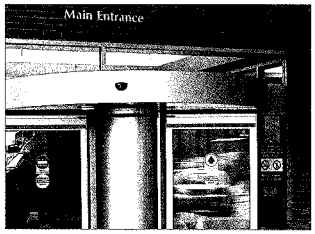
Multiply what a hospital has to do to implement a new rule by the number of new or revised rules affecting health care and it begins to paint a picture of the time and dollars devoted to compliance with new regulations. After reviewing almost 100 new or revised requirements issued by federal agencies since 1997, the AHA selected 57 of the most significant to create the Health Care Regulation Timeline. While it illustrates only a portion of the rules issued, the pace of change is clear. Also, consider that just three provisions in one of those rule—the privacy provisions in the Health Insurance Portability and Accountability Act (HIPAA)—are estimated to cost hospitals $22 billion over five years. The Health Care Regulation Timeline demonstrates why hospitals are saying, "Enough is enough."

A Dictionary of Terms

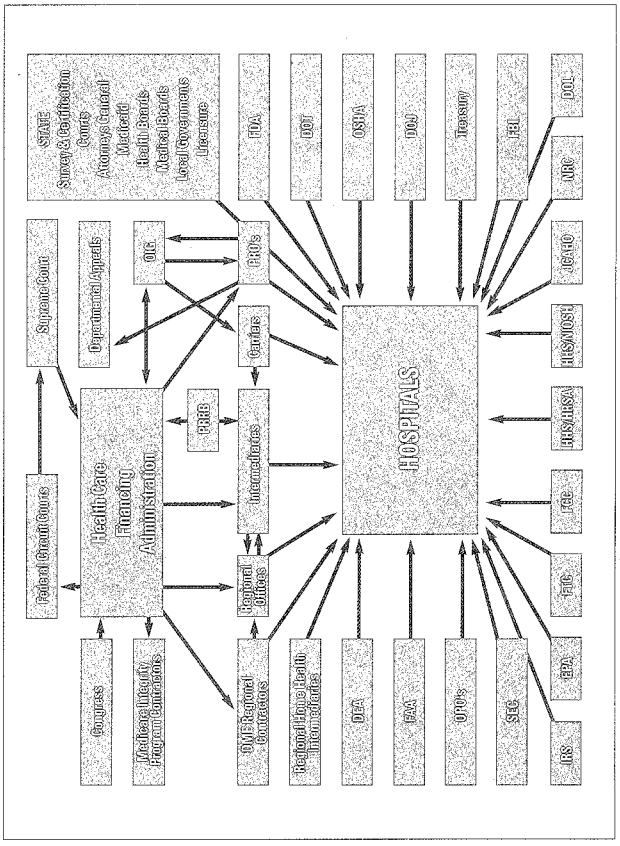
Acronym	Full Name
SNF	Skilled Nursing Facility
PPS	Prospective Payment System
COPs	Conditions of Participation
EMTALA	Emergency Medical Treatment and Labor Act
HIPAA	Health Insurance Portability and Accountability Act
HHA	Home Health Agency
ASC	Ambulatory Surgery Center
RVU	Relative Value Unit
LEP	Limited English Proficiency
MCO	Managed Care Organizations
M+C	Medicare+Choice

Who's on First?

But this is only federal-level regulation. Hospitals also are regulated by local and state agencies, as well as other private accrediting organizations. Figure 3 shows how many agencies are involved in regulating hospitals—almost 30 at the federal level alone. Almost no coordination exists among various federal agencies or between similar agencies at local and state levels, and private-sector accreditation. Even within the Department of Health and Human Services (HHS)—the major federal regulator of hospitals—there is little coordination among its different divisions. HCFA, for example, has trouble coordinating its Medicare and Medicaid rules and instructions—more than 130,000 pages. (That's three times the size of the Internal Revenue Service Code and its federal tax regulations.)



Government Regulation of Health Care Today:
Complex, Cumbersome and Confusing *fig. 3*



Overdue: Regulatory Reform and Relief

The AHA, its member hospitals and health systems, and the millions who work within these facilities urge the Administration and Congress to work together to ease the regulatory burden confronting health care providers. A necessary first step is to create a more common sense approach to developing and issuing future regulations. Equally critical, though, is the need to quickly provide relief from the most burdensome, inefficient or ineffective regulations—those that take away from critical time spent with patients.

What We Need

Improve the regulatory process:

- **Enable providers to challenge questionable policy actions in court.** Unlike other federal agencies, Medicare program policy decisions made by the Secretary of HHS are insulated from judicial review. Health care providers are required to exhaust all administrative processes and remedies before they can file suit against HHS. However, there is no such process to exhaust on questions about whether the Secretary has exceeded his authority or failed in his duty. This effectively means that providers can bring a suit only if they violate Medicare requirements so significantly that they are thrown out of the Medicare program. HHS policy decisions should be subject to the same level of judicial review as other federal regulatory agencies.
- **Coordinate the orderly release of federal regulations to allow for more seamless compliance.** Government agencies with jurisdiction over hospitals need to release regulations in a coordinated manner so that implementation does not overwhelm hospital personnel and systems. That means establishing a point of accountability to coordinate regulatory activity across major federal agencies, as well as within HHS. As the predominant federal regulator of hospitals, HHS should periodically evaluate its overall federal regulatory framework applied to health care providers for clarity and expected behavior from providers.

- **Include the cost of implementing significant regulations into Medicare payment updates.** Currently, the initial cost of implementing significant new regulations is not captured by Medicare prospective payment rate updates. Like new technology and productivity improvements, these costs should be required to be taken into account by the Medicare Payment Advisory Commission (MedPAC) when it makes its annual rate update recommendations to Congress.
- **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 compliance failures are increasingly severe. HCFA should establish query mechanisms for individual providers and their associations on the appropriate interpretation or application of Medicare rules in specific situations. HCFA's responses should be timely and readily available to others in an easily accessible format (such as an indexed file on the Internet).
- **Seek greater provider input on new rules and regulations.** Federal regulators need to become more acquainted with real world hospital operating environments so that practical implementation issues can be minimized before a regulation goes into place. Agencies should conduct outreach efforts to obtain early input from the health care field, including publishing notices of intent; making relevant databases, cost estimates, assumptions, and methodologies publicly available early on; holding field hearings; and conducting site visits.
- **Enhance the communication of regulatory requirements to health care providers.** Providers are finding it difficult to monitor, identify, absorb and comply with Medicare requirements because of the complexity of the program, the pace of change in requirements, and the numerous ways that HCFA issues policy and administrative requirements. HCFA should more actively communicate these changes and use contemporary technologies to provide free and easy access to a well-organized database of all requirements issued through any means.

- **Enact the Regulatory Fair Warning Act.** Introduced and approved by the House Judiciary Subcommittee on Commercial and Administrative Law in 2000 by Rep. George Gekas (R-PA), the measure would ensure that federal rules are issued and available in a timely manner, and in terms understandable to both the regulated entities and the regulators. Most importantly, it would prevent federal agencies from penalizing businesses or entities for alleged violations if the rule was not published in a public document, the agency did not give fair warning that a type of conduct was prohibited or required, or the agency already had given specific guidance that contradicted an inspector's claim that the regulation had been violated.
- **Restrict use of interim final rules.** HHS has increasingly issued new rules as interim final rules; that is, issued and implemented before the agency takes public comment. To reduce the disadvantages of this approach – which negates the public comment process – HHS should be required to issue final rules within a year after the interim final rules so that public comments are taken into account on a timely basis.

Provide relief from specific regulations:

- **Revise the HIPAA privacy regulation and offer grants to help hospitals with the huge costs of complying with the HIPAA rules.** These rules are so complex and prescriptive that they are unworkable and excessively costly, creating serious financial and administrative burdens.
- **Streamline the Medicare cost report.** The Secretary should evaluate and overhaul the cost report, reducing its size and complexity to reflect Medicare payment based on prospectively set rates, not cost-based reimbursement, and modifying or eliminating the arcane Medicare-specific cost accounting principles.
- **Prohibit the denial of payment by fiscal intermediaries for emergency services provided to Medicare beneficiaries that are required under the Emergency Treatment and Active Labor Act (EMTALA).** Fiscal intermediaries often deny emergency department services, applying local medical review policies based on diagnoses determined after screening (including tests) and

stabilization. First, Medicare coverage decisions regarding emergency services should consider a beneficiary's presenting condition, based on the prudent layperson standard. Second, hospitals cannot deny or delay treatment to assess or resolve any financial or coverage issues and cannot bill a beneficiary, even if use of the emergency room was inappropriate. It's simple—if hospitals must provide services to beneficiaries, then Medicare should pay.

- **Limit the collection and reporting of post-acute patient assessment data to useful information.** HHS requires the use of several patient assessment tools – OASIS for home health services and MDS for skilled nursing facilities – and is planning to adopt other instruments for other settings. Recognizing the need for greater consistency and standardization, Congress last year asked the Secretary to study the development of a common patient assessment instrument and report back in five years. In the meantime, though, providers need immediate relief from the excessive burdens and often irrelevant information requirements imposed by these assessment tools, and HHS needs to follow a rigorous process for changing or adopting new requirements.
- **Improve Medicare fiscal intermediary (FI) and carrier customer service performance.** Communication and interaction between FIs/carriers and providers/practitioners is critical to a successfully administered program. Give FIs and carriers specific customer service performance objectives, and allow providers and practitioners to participate in performance evaluations. Enhance accountability by making FI and carrier performance evaluations public.
- **Revise the Medicare Secondary Payer Provision.** Stop the burdensome requirement that hospitals complete a 30-item questionnaire for each inpatient and outpatient visit, just to ensure that an employed beneficiary doesn't have employer-sponsored coverage that should be the primary payer. Collecting this information once every 60 days would suffice.

Appendix: PricewaterhouseCoopers Methodology and Results

Background

PricewaterhouseCoopers (PwC) was commissioned by the AHA to ask some of America's hospitals about their patient care and paperwork experience. The survey methodology and results are summarized in the following pages.

Survey Methodology

The goal was to determine from hospitals the amount of time spent on patient care and paperwork for a typical episode of care. The study had four phases:

1) Outline a Typical Episode of Care

PwC developed a "typical" patient encounter to illustrate both the care delivered and paperwork directly associated with a complete episode of care (see box on opposite page describing the hypothetical patient, "Ida Smith"). A summary of key clinical events (patient care) and corresponding administrative activities (paperwork) associated with the encounter was developed (see pages 22 to 29). The hypothetical, yet typical, episode of care included Ida Smith accessing many health care services: emergency department care, surgery and acute inpatient care, skilled nursing care and home health care.

There was no attempt to capture a variety of other administrative and paperwork activities not directly involved in an episode of care. Hospital staff often spend time on administrative and paperwork activities, such as those associated with implementing new regulations or regulatory requirements (e.g. preparation of compliance reports, working with surveyors, responding to data requests, etc.).

IDA SMITH'S EPISODE OF CARE

Ida Smith is an 80-year old Medicare beneficiary with chronic obstructive pulmonary disease. She has been steadfast in living alone since the death of her husband two years ago. While visiting her daughter, Ida tripped and fell at the bottom of the stairs, experienced searing pain and was rushed by her family to the Emergency Department at Community Medical Center (CMC).

The nurses and doctors in the Emergency Department quickly tended to Ida's intense pain and diagnosed the cause: a right hip fracture. But this was just the start of the care that would be provided by the clinicians and staff of CMC. Ida was then immediately admitted as an Acute Care inpatient in preparation for hip reconstruction surgery the following morning. After her surgery, Ida received three days of specialized post-operative acute care in the hospital's Orthopedic Unit. As her condition stabilized and improved, Ida's attending physician was able to transfer her care to CMC's Skilled Nursing Care Unit for two weeks of monitoring, further recovery and rehabilitation. Ida was happy that her doctor then discharged her back to her own home in the care of her family. Given her pulmonary condition and the lingering effects of her hip injury, Ida needed continuing professional care that her family could not provide. Once again, Ida's medical care needs were served, for the next 60 days, by nurses and other clinical specialists from CMC's Home Care Division. She is now fully recovered and busy enjoying time with friends and family.

2) Create a Survey Instrument

PwC, with the collaboration of AHA and three hospitals, developed the detailed survey instrument. Contributors included physicians, nurses and other clinicians, and health care personnel with administrative and operational experience in areas such as: medical records, coding, compliance and patient financial services (billing, collections, registration) as well as in all settings of "Ida Smith's" care. The illustrative care episode developed resulted in a 31-page questionnaire, detailing each patient care activity, as well as each paperwork activity. This was necessary to clearly and completely identify the key elements directly associated with this episode of care. The questionnaire was segmented into the four settings of "Ida Smith's" care: emergency department care, surgery and acute inpatient care, skilled nursing care and home health care. Pages 22 through 29 summarize the patient care and paperwork associated with "Ida Smith's" episode of care.

Survey Hospitals

Twenty-five hospitals, representing large healthcare systems, rural hospitals, urban hospitals and academic medical centers, were asked to complete the detailed questionnaire. Of these 25 facilities, 19 responded. This provided a cross-section of hospitals; it is not a statistically valid sample.

Each organization received the questionnaire and instructions. In general, the organizations selected an individual responsible for obtaining sound responses to the survey representing what actually happens given the typical episode of care presented. Hospitals were asked to obtain and provide their best estimates of minutes required for each defined patient care and paperwork task by obtaining the input of the hospital's knowledgeable clinicians and administrators.

The AHA and PwC would like to thank the following hospitals that volunteered to share their experiences and generously spend the time required to complete the survey.

Charles Cole Memorial (Pennsylvania)

East Liverpool City Hospital (Ohio)

Eastern Health System—Medical Center East (Alabama)

HCA Healthcare Co.—Hendersonville Medical Center (Tennessee)

Huron Valley-Sinai Hospital (Michigan)

Mayo Foundation—Saint Mary's Hospital (Minnesota)

Mayo Regional Hospital (Maine)

Methodist Hospitals (Indiana)

Montclair Baptist Medical Center—Baptist Health System (Alabama)

Wake Forest University—Baptist Medical Center (North Carolina)

Northwestern Memorial Hospital (Illinois)

Scottsdale Healthcare Shea (Arizona)

Shands HealthCare (Florida)

St. Cloud Hospital (Minnesota)

St. John's Mercy Health Care (Missouri)

St. John's Medical Center, Inc. (Oklahoma)

St. Luke's Regional Medical Center (Idaho)

Sunnyside Community Hospital (Washington)

University of Pittsburgh Medical Center (Pennsylvania)

3) Tabulate Results

Below is a summary of the number of organizations that were able to complete surveys and submit the results to PwC for tabulation:

Survey Section

Care Setting	# of respondents
Emergency Department Care	19
Surgery and Acute Inpatient Care	19
Skilled Nursing Care	15
Home Health Care	14

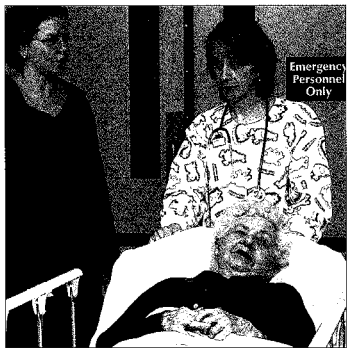
Results

The summary of the number of patient care and paperwork minutes reported by the hospitals for each setting within "Ida Smith's" episode of care were converted to ratios and averaged for all respondents. The resulting ratios, shown below, present the proportion of paperwork time for each unit (e.g. hour) of patient care time.

Care Setting	Ratio of Patient Care to Paperwork Time
Emergency Department Care	1 to 1
Surgery and Acute Inpatient Care	1 to 0.6
Skilled Nursing Care	1 to 0.5
Home Health Care	1 to 0.8

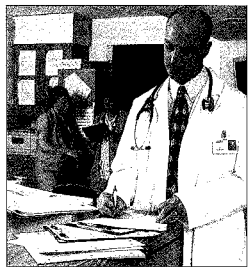
Emergency Department Care

- When Ida arrived at the Emergency Department (ED), she was greeted by a Triage Nurse who assessed her injury, evaluated her pain level and checked her blood pressure and pulse.
- After Ida's intake evaluation by the Triage Nurse, she was placed on a stretcher and taken to the treatment area of the ED where she was evaluated for an emergency condition by the ED Resident Physician.
- Nurses constantly monitored Ida's vital signs and gave her pain medication as needed, while she waited to be evaluated by the ED Physician.
- The ED Physician performed a medical evaluation, ordered blood tests and X-rays.
- The tests were completed and the results were sent to the ED Physician, who diagnosed her hip fracture and determined further examination by an Orthopedic Surgeon was necessary. The Orthopedic Surgeon on-call for the ED was consulted by the ED Physician to evaluate and assess Ida's condition.
- The Orthopedic Surgeon evaluated Ida, reviewed her test results, confirmed the diagnosis of her condition and determined that she needed surgery to repair her hip fracture.
- After the Orthopedic Surgeon discussed the diagnosis with Ida and her family members, she was admitted to Community Medical Center's (CMC) Medical/Surgical Orthopedic Unit for surgery.
- Ida was taken from the ED to her assigned inpatient bed by a hospital Transporter.



Paperwork Generated from Emergency Department Care

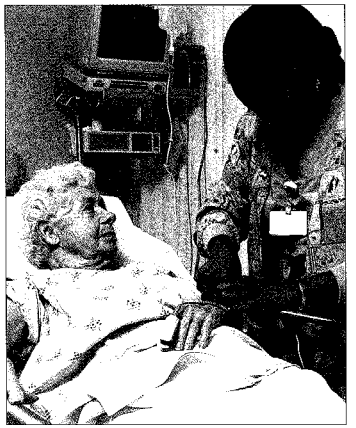
- The Triage Nurse who performed initial care activities documented Ida's medical history, vital signs, the appearance of her injury, and mode of transportation to the ED in the Hospital's triage log.
- Following the Nurse's initial assessment, the ED Resident Physician then documented within the medical record the clinical judgement that Ida's injury should be considered an emergency condition, as required to comply with government regulations.
- After confirmation of the emergency condition, the Registration Clerk entered Ida's demographic information into the hospital's central log, as required by government regulation. The Clerk then documented Ida's insurance information, obtained the necessary waivers and created paperwork to track Ida's care. Ida signed several government-required forms including: conditions of admission, consent to treatment and Medicare Secondary Payer. The Clerk then explained the policies on patient rights, the hospital's privacy policy, and grievance procedures: all as required by government regulations. The Clerk also entered Ida's personal and insurance information into the hospital information system.



- The ED Nurses documented every detail of the care they provided, including periodic pain assessments, vital signs and treatments performed.
- The ED Physician and Orthopedic Surgeon documented in the medical record all of their clinical judgements and decision making according to the government's Evaluation and Management coding guidelines in order to justify to the government that the care was really needed, and to prove they were actually physically present when providing the care to Ida.
- The orders written by the Physicians were entered into the ordering system by the Clerk and routed to the appropriate testing departments. The departments prepared government-required paperwork to verify the tests were performed as ordered and were medically necessary. They then entered information into the billing system.
- The ED Physician documented that the ED "on-call specialty list" was used, and that the Orthopedic Surgeon responded in a timely manner, in order to demonstrate compliance with government regulations.
- The Orthopedic Surgeon prepared documentation to justify the decision to admit Ida for surgery.
- Ida met with a Case Manager who reviewed the government's Medicare requirements for hospitalization and what would, and would not be covered by Medicare.
- The Clerk entered the orders to admit Ida into the hospital's information system and updated the growing file of medical records for this episode of care.

Surgery and Acute Inpatient Care

- When Ida arrived at the Orthopedic Unit, an Orthopedic Care Nurse admitted her to a medical-surgical bed. The Nurse gave Ida her prescribed pain medication, checked her blood pressure and other vital signs and prepared her for surgery.
- During her first day in the Orthopedic Unit, Ida's Primary Care Physician (PCP) evaluated and managed her medical problems. Her Orthopedic Surgeon performed a history and physical examination and ordered additional tests prior to the surgery. Her Anesthesiologist explained the medications that would be administered during surgery and their side affects.
- Ida was taken to an Operating Room, prepared for surgery and the surgery began. The Anesthesiologist administered anesthesia, and the Orthopedic Surgeon, an Assistant Surgeon, and a team of Surgery Nurses and Operating Room Technicians performed the hip reconstruction. During surgery, Ida experienced some blood loss and received a blood transfusion.
- After the surgery was completed, the Anesthesiologist brought Ida into the recovery room for constant observation by the Recovery Room Nurses.
- Once Ida was awake and her vital signs stable, the Transporter brought her back to her patient room for continuation of care. Once back on the Orthopedic Care Unit, the Nurse checked Ida's vital signs, cared for her surgical area, administered medication ordered by the Surgeon and provided Ida with other care that she needed for the duration of her three-day stay in the acute care unit.
- During Ida's post-operative care, her PCP and Orthopedic Surgeon visited Ida daily to evaluate her progress, monitor her recovery and assess additional medication needs.
- After three days, the Orthopedic Surgeon and the PCP determined that Ida did not need such a high level of nursing care. Therefore, the PCP wrote an order to discharge her to a Skilled Nursing Facility (SNF) for an additional two weeks of monitoring and rehabilitation. CMC's SNF was selected by Ida and her family.
- A Discharge Team, which consisted of a Nurse, Case Manager, Physical Therapist (PT) and Occupational Therapist (OT), planned Ida's discharge to the SNF and developed a plan for her continued care needs at the facility.
- The Nurse prepared Ida for discharge by performing the required tests (such as TB) and reviewing the discharge instructions with Ida and her family. The Transporter then moved her to the SNF wing of the Hospital.



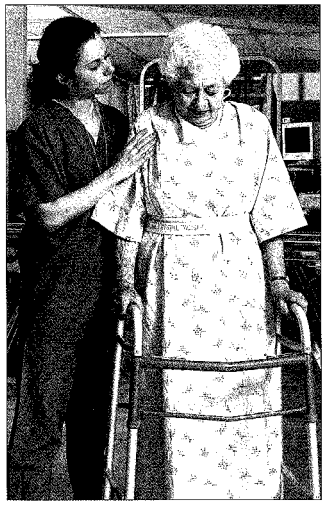
Paperwork Generated from Surgery and Acute Inpatient Care

- On Ida's admission to the Orthopedic Unit, the Hospital's Admitting Specialist explained the grievance, admitting and discharge processes to her and her family. The Unit Clerk entered the admission orders and demographic information into her medical record.
- The PCP and Orthopedic Surgeon documented the medical and surgical orders and their medical decision-making and clinical judgments in the medical record to justify the care provided.
- The Orthopedic Nurse documented Ida's vital signs and pain level, and completed required pre-operative paperwork. A Nutritionist documented Ida's dietary evaluation.
- The Laboratory processed the blood-work and completed the necessary documentation of the tests. The lab results were sent to the Orthopedic Surgeon and a copy of the results placed in her medical record.
- After Ida arrived in the pre-operative area, the Surgical Nurse checked the pre-operative paperwork, validated that Ida signed the surgical consent form, and verified that all of the consent forms and Ida's history and physical were present in the medical record. The Operating Room staff documented the instrument sterilization procedures, instrument count and supplies available for surgery.
- Extensive documentation of the operative procedures performed was completed by all of the caregivers, including blood administration paperwork. The Orthopedic Surgeon wrote a report about the surgery and documented post-operative orders for Ida. The Surgical Nurse inventoried and verified the surgical instruments and supplies used. The Anesthesiologist documented the anesthesia and medications that were administered, as well as Ida's response to the medications. The Recovery Nurse documented Ida's recovery progress. A Clerk in the Surgery Department gathered all of the documentation and entered the information into the Hospital's information system.
- During daily follow-up visits, the Orthopedic Surgeon and PCP documented their clinical judgments and decisions in the progress notes.
- The PCP, Orthopedic Surgeon and the Hospital's Discharge Team documented their discharge plans.
- Once the PCP wrote the SNF admission order, the Case Manager discussed SNF options with Ida and her daughter, and a selection was made. The Case Manager completed a required Medicare eligibility form to verify that Ida qualified for skilled care and arranged for transportation to the SNF.

- Charge tickets were prepared by the Hospital's Staff and Physicians to support all the care provided, and resources consumed, in Ida's acute care and surgery. These were entered into the Hospital's billing system by a Clerk. Ida's medical records were sent to the Health Information Management Department for "coding," a complex system as required by the government. Due to the complexity of this system, and the resulting potential for inadvertent errors and government charges of non-compliance, multiple layers of supervisory review were required. The bills were generated and reviewed for accuracy, completeness and compliance with relevant Medicare rules, then submitted to the government's Fiscal Intermediaries for payment. Routine follow-up to collect the bill was performed by the Patient Accounting Staff.

Skilled Nursing Facility Care

- Accompanied by her daughter, Ida arrived at the special Skilled Nursing Facility unit at CMC and was transferred from the transport stretcher to a bed in her assigned room.
- When Ida was situated in her room, a Nurse evaluated her, obtaining her vital signs, height and weight, checking her skin for signs of irritation, and determining whether Ida could be at risk to fall if she was left unattended.
- A Dietician then met with Ida to develop a meal plan and a Social Worker discussed resources Ida may need after discharge from the SNF. Later that day, the PT and OT performed their initial evaluations to determine the necessary therapy. The Nurse, Social Worker, and Therapists worked together with Ida to develop a plan of care and set goals for Ida during her stay in the SNF.
- Ida's PCP visited her within the first three days of her arrival into the SNF, and then as needed, to evaluate her condition and determine if any changes in her medical care were necessary. The Orthopedic Surgeon also checked Ida's surgical incision and removed her stitches before her release from the SNF. Ida's Physicians wrote orders for her care and made notes in the medical record to document their on-going review of her care.
- The Nurses visited Ida multiple times per day, checking her incision, changing her surgical dressing, monitoring her vital signs, and assisting her with activities of daily living such as bathing and grooming.
- The Therapists worked with Ida daily to enable her to be more independent. The PT trained Ida to get in and out of bed and chairs, and how to use a walker. The PT also initiated an exercise program. The OT worked with Ida on how to dress and bathe herself given her limitations.
- The Nurse, Social Worker, Therapists, Physician, Ida and her family discussed Ida's progress. The clinicians evaluated whether Ida had met her goals and should be sent home.
- Ida's caregivers determined that she was ready to be sent home after a two-week SNF stay, but required continued professional care that her family could not provide.
- The PCP made a judgment to discharge Ida to her home in the care of her family, supported by professional home health care services. The Social Worker assisted Ida and her family with the selection of a Home Health Agency.
- After Ida's discharge, her family picked her up from the SNF and took her home.



Paperwork Generated from Skilled Nursing Facility Care

- Once Ida's was referred to the SNF, the SNF Intake Coordinator completed the necessary pre-admission forms, obtained copies of Ida's hospital medical record, checked for bed availability, and verified Ida's insurance benefits and eligibility for skilled nursing care in accordance with Medicare rules. The Intake Coordinator registered Ida, collected additional information and created her SNF medical record.
- The SNF Staff discussed, with Ida and her daughter, the policies mandated by government regulators, including privacy, patient's rights, the grievance process, resuscitation status and advanced directives. Ida signed the conditions of admission and authorization for treatment, as required by government regulations, and the Clerk arranged a visit by her PCP.
- The plans of care developed by the Nurse, Social Worker, and Therapists (the Care Team) were collected and combined into one plan of care which guided Ida's care and established goals and projected outcomes.
- The Minimum Data Set (MDS) coordinator completed the MDS form (a government requirement) and the Resident Assessment Protocols form (another government requirement) in conjunction with the Care Team, verified its accuracy, and transmitted the documents to the State Department of Health and HCFA, as required by government rules. Based on the MDS "scores," Ida was designated with a Resource Utilization Groups (RUG) assignment (a complex system mandated by the government) which determines the amount Medicare pays for Ida's care.
- The PCP completed the government-required Medicare certification forms to document the clinical judgments and to justify, for purposes of regulatory compliance, Ida's need for daily skilled care. He followed government-prescribed documentation guidelines to validate the nature and extent of their medical decision-making.
- The Nursing Staff regularly completed the Activities of Daily Living forms required by the government, and wrote notes in the medical record that detailed Ida's on-going care and progress to her goals. The Therapists documented each treatment and her tolerance of the treatments.
- The Nursing Staff monitored Ida for a significant change in condition that would require the completion of an additional MDS, which may result in a different RUG assignment, as specified in government regulations.

- The Unit Clerk validated that the amount of therapy time provided to Ida to ensure regulatory compliance, and sent that information to the billing department.
- On the 14th day of Ida's SNF stay, the Care Team documented that Ida met the goals of her plan of care and was ready to be discharged to her home with the support of professional home health care.
- Ida's PCP wrote a discharge plan regarding the judgments for discharge and documented in the medical record Ida's need for home care.
- The clinical care team documented the discharge plan they had developed. Then, the Social Worker, Ida and her family reviewed Home Health Agency (HHA) options. Ida chose an agency best suited for her needs—one that was affiliated with CMC.

Home Health Care

- Soon after Ida returned home, the HHA Nurse visited Ida to evaluate her safety and health care needs. The Nurse completed a physical assessment, reviewed Ida's ability to care for herself, and began working with Ida on her activities for daily living. After the visit, the HHA Nurse contacted Ida's PCP to obtain medical orders to implement Ida's care plan.
- The HHA Nurse regularly visited Ida, evaluated Ida's vital signs and healing of her wound, and changed her dressings. Ida was doing well, so the nurse turned over the care management to a PT.
- The PT initiated Ida's home exercise program and taught her how to get in and out of bed and properly use her walker.
- During a PT visit, Ida had a flair-up of an old lung problem. This recurrence made it necessary for the HHA Nurse to reassess Ida's condition. The HHA Nurse notified the PCP who decided to change Ida's medications and begin home oxygen therapy.
- The Nurse arranged for the home oxygen equipment delivery from a Medical Equipment provider. The Medical Equipment provider trained Ida on how to use the oxygen equipment, and visited her several times over the course of her home health care.
- The OT also met with Ida several times to teach her how to dress herself, use a shower chair and complete household chores while using her walker.
- The Social Worker visited Ida and her daughter to educate them on the available community resources, including meal-on-wheels, financial assistance and transportation for doctors' appointments.
- The HHA Aide visited Ida several times a week to assist her with bathing, as well as follow up on her physical and occupational therapy exercise programs, until this was no longer necessary.
- After 60 days of home health care, the HHA Nurse, Ida and her daughter agreed that Ida had met the goals of her plan of care and was ready to be on her own. The Nurse contacted the Care Team and the PCP to discuss discharging Ida. The PCP agreed that it was appropriate to discontinue home care and each Care Team member developed discharge instructions for Ida and her daughter.
- The PCP reviewed the plan of care, which was developed by the Care Team and wrote notes and medical orders in the medical record that justified Ida's continued need for home health care, as required by the government.
- Ida was now able to resume her normal lifestyle, enjoying good health and time with her friends and family.

Paperwork Generated from Home Health Care

- Prior to Ida's first home health visit, the HHA Intake Clerk collected Ida's clinical information from the SNF, and entered her personal and medical information into the HHA's computer system. The Clerk then verified Ida's Medicare eligibility, in accordance with government regulations, and as required by government regulations, checked the "HIQH database" (Health Information Query for Home Health) in the Medicare Common Working file to verify that only one agency was providing HHA services.
- During the care planning stage, the HHA Nurse validated Ida's eligibility for home care based on Medicare regulations and verified the physician's orders.

- On the first home health visit, the Nurse reviewed with Ida a host of government-mandated forms and regulations, including advanced directives, Medicare Secondary Payer criteria, patient's rights and responsibilities and privacy rights. The Nurse then obtained her signature on the "consent to treat" and other authorization forms. The Nurse documented Ida's physical evaluation in the medical record, completed the HCFA 485 care plan form and completed the Outcome Assessment Instrument Set (OASIS) — all additional tasks and forms mandated by the government.
- A Clerk entered and electronically transmitted the OASIS to the State Department of Health (SDH), as required by government regulations. The Clerk received from SDH a Health Insurance Prospective Payment System code, a Home Health Resource Group classification, and a Matching Key which is used for Prospective Payment System billing — systems mandated by the government.
- The Billing Clerk was then able to file a Request for Anticipated Payment with the government's Medicare Carrier, the organization that pays claims.
- The Nurse obtained verbal orders from the PCP to implement the care plan and a Clerk sent Ida's written care plan and orders to the PCP for review and signature.
- The PCP signed and returned the care plan and the Clerk filed it in the medical record. To ensure regulatory compliance, the Clerk also notified the billing office that a signed care plan and medical orders were on file.
- Each time the Nurse, Therapists, Social Worker or Home Health Aide visited Ida, they documented their interventions in the medical record and coordinated Ida's care with each other, as mandated by the government.
- When Ida's lung problem recurred, the nurse completed another OASIS as required by government. The form was entered and electronically transmitted by the Clerk to the appropriate government authority.
- After 60 days of home health care, the Nurse, Therapists and PCP documented their judgments about Ida's discharge, and wrote discharge instructions and a discharge summary of the care they provided to Ida. The Nurse completed a discharge OASIS, as required by the government, and received verbal discharge orders from the PCP.
- The HHA Clerk transmitted the final OASIS to the SDH and obtained the PCP's signature for the discharge order, then filed it in Ida's medical record.
- The billing clerk filed the final claim with the government's Medicare carrier and tracked the collection of the bill.

STATEMENT OF THE

AMERICAN DENTAL ASSOCIATION

TO THE

SMALL BUSINESS COMMITTEE

UNITED STATES

HOUSE OF REPRESENTATIVES

ON

HEALTH CARE FINANCING ADMINISTRATION PAPERWORK BURDENS: THE PAPERWORK REDUCTION ACT AS A PRESCRIPTION FOR BETTER MEDICINE

SUBMITTED

BY

ROBERT M. ANDERTON, D.D.S., J.D., LL.M.

May 9, 2001

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On behalf of the approximately 144,000 members of the American Dental Association (ADA), I would like to thank you, Mr. Chairman, and other members of the committee for the opportunity to testify on the paperwork, and other administrative and regulatory burdens that are imposed upon dentists by the Health Care Financing Administration (HCFA) and other entities.

The morass of rules and regulations governed by HCFA has surpassed thousands of pages of complicated and confusing text that, quite frankly, can overwhelm many dental offices. Most private sector dentists are solo practitioners with fewer than four employees. Very few offices employ more than one administrative staff person, who often also serves as the receptionist. This structure is sufficient to handle patient and private insurer paperwork and should be adequate to process *reasonable* paperwork demands of public programs. However, the staff resources necessary to address the enhanced administrative burdens caused by excessive paperwork and other mandates can easily outstrip the dental office administrative staff's capabilities.

HCFA and Private Sector Paperwork Requirements

Excessive paperwork requirements seem to be an endemic problem at HCFA, especially in the Medicare and Medicaid programs.

Claims Submission for "Non-covered" Medicare Services

Any dentist who treats a Medicare beneficiary can be required to comply with the program's quagmire of rules, even if the services provided by the dentist are "non-covered" and considered "categorically excluded" from the Medicare program (thereby not subject to Medicare's regulations[1]). This can and has, in fact, already occurred because a HCFA rule, which has been interpreted by the agency as giving the beneficiary a right to file a Medicare claim for virtually any dental service, has taken precedent over the Medicare statute excluding the vast majority of dental services. Beneficiaries request that claims be submitted generally either because they believe the service is covered by Medicare or because they need a denial to submit to their supplemental dental benefit coverage plans.

If a Medicare beneficiary receives non-covered, categorically excluded dental services and requests that the dentist file a Medicare claim, despite the fact that Medicare does not cover the services provided[2], the dentist must comply. The dentist must honor this request[3] and all parties affected (the patient and HCFA, as well as the dentist) must absorb the financial burden of filing an unnecessary claim.

There are additional costs for dentists related to the filing of a Medicare claim solely at the request of a beneficiary. Because the program does not reimburse for most dental services, the majority of dentists are not Medicare providers. In order to file a Medicare claim, dentists must enroll in Medicare and obtain a provider number. Provider

[1] Medicare Carriers Manual, section 3044.19.
[2] 2000 Guide To Health Insurance for People with Medicare, page 8.

enrollment is an administratively complex process that can take numerous hours for the paperwork requirements alone.

However, dentists, unlike many other providers, are unable to decline or withdraw participation in Medicare. Section 1802 of the Social Security Act, as amended by Section 4507 of the Balanced Budget Act of 1997, permits a physician or practitioner to enter into private contracts and effectively withdraw their Medicare participation with Medicare beneficiaries, if specific requirements are met. Dentists are not covered by this law.

Providers who choose to enter into private contracts with Medicare Part B beneficiaries are not permitted to participate in the program for a two-year period and are effectively not recognized by HCFA. Therefore, providers who have "opted-out" of Medicare do not have to abide by Medicare's regulations and do not have to submit unnecessary claims.

The ADA believes HCFA should bring its regulation into conformance with the Medicare statute and make it clear to regional plan administrators, dentists, and Medicare beneficiaries that there is no obligation to submit a claim for categorically excluded dental services. The Association also believes it is necessary to include dentists in the private contracting law. This is important not only because it is fundamentally fair to allow any practitioner the ability to decide whether the practitioner wants to participate in a federal program, but also because opting out eliminates unnecessary paperwork

[3] Medicare Carriers Manual, section 3043.

affecting all of those associated with the Medicare system. The Association would be willing to work with the Committee to provide language to accomplish this change.

Improved Oversight of the Medicaid Program

HCFA also needs to do a great deal more to clear up confusion surrounding its rules and regulations concerning the Medicaid program. Misunderstandings about federal agency rules hamper needed changes by the states that could eliminate many barriers to access for the underserved populations, including excessive paperwork requirements.

Dental services are a mandatory Medicaid benefit for children under the EPSDT program; however, only one in five children nationally receives any mandated preventive dental services. State compliance with complex Medicaid administrative requirements is part of this problem. In addition, excessive paperwork, whether required by HCFA rules or state regulations, serve as a disincentive to participation in the program. These problems can be ameliorated with active HCFA involvement.

Secretary Thompson is working to improve communication between HCFA and the states. Consistent with this effort, the ADA has encouraged the Secretary to support the January 18, 2001, HCFA compliance letter sent to state Medicaid directors that provides guidance on how the agency will assess state compliance with achieving children's access to dental services under Medicaid. This letter speaks to the need for new administrative strategies to enhance provider participation, among other things. Included in the suggestions are simplification of provider enrollment procedures, rapid confirmation of

eligibility, using the ADA Dental Claim Form and *Dental Code*, facilitating electronic transmissions of claims, and mirroring commercial prepayment plans administrative processes to the extent possible.

Simplifying and shorting the existing Medicaid provider applications (some of which are 50 pages in length) will save the practitioner and affected agency valuable resources. Rapid confirmation of eligibility will help ensure that Medicaid patients are provided care promptly and that dentists are paid for their services. Use of the ADA Dental Claim Form and *Dental Code* by state Medicaid programs will reduce provider overhead because these items are commonly accepted in the private sector market. All of these changes will make participation in the Medicaid program more attractive to the dentists.

Unfortunately, at the present time misinformation remains about HCFA rules and regulations. Because of this confusion, states will often blame HCFA for the paperwork requirements. HCFA officials for their part, will assert that they have no such requirements. HCFA needs to clarify for the states exactly what their requirements are and to encourage the states to simplify those requirements that are at the states' discretion.

The ADA requests that the committee notify HCFA in a letter that the procedures listed below are important to implement in order to reduce the paperwork and general administrative burden facing dentists participating in the Medicaid program.

- Simplifying and shortening provider applications to require only essential identifying information and proof of a valid license to practice dentistry in the jurisdiction in which the services are to be provided. (Existing applications are often excessive in length, some over 50 pages.)
- Utilizing the ADA Dental Claim Form and the current ADA Code on Dental Procedures and Nomenclature as the standard for claims submissions.
- Establishing systems to ensure rapid confirmation of children's eligibility under Medicaid or the state children's health insurance program (SCHIP), at the point of service.
- Clarifying for the states (perhaps in a "Q&A" format) exactly what are federal requirements under the Medicaid program and where decisions are left to the states' discretion.

The above named strategies would reduce costs to dental providers, therefore, providing an incentive to accept Medicaid patients. The strategies would also save the payers (state and federal governments) a considerable amount of funds on administrative matters that can be better spent on services. Such strategies would have the broad effect of increasing access to dental services.

Facilitate Compliance with the DHHS Final Rule on Electronic Transactions and Code Sets

Paperwork costs can be decreased as the health care industry, both private and public, move toward electronic transmissions. It is vitally important that HCFA facilitate the movement of the Medicare, Medicaid and SCHIP systems into compliance with the DHHS final rule on electronic transactions and code sets, for example. But there is much more HCFA can and should be doing to reduce the excessive paperwork burden on dentists.

Pursuant to the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), DHHS published a final rule identifying required standard electronic transactions and code sets to be implemented by October 16, 2002. The regulations affect all health plans, health care clearinghouses, and any health care provider who chooses to transmit health information in an electronic transaction.

More than eighty percent of dentists have computers in their offices and most practice management systems permit dentists to use electronic transactions, but only 25% of dental claims are transmitted electronically. Clearinghouses charge approximately $.50 for processing an electronic claim, which is comparable to postage and mailing costs.

The real benefit to dentists is not only in the claim transmission. It is the almost instant response that can be obtained for confirming eligibility, the patient's financial responsibility, and notice of the electronic transfer of funds to the dentist's account. The ADA's Department of Dental Informatics has developed a spreadsheet that allows a cost comparison of paper and electronic transactions in the private sector. This spreadsheet allows the dentist to customize the information with individual practice statistics and time estimates and calculates the weekly costs for eligibility verification, claims preparation, account posting, status checking, and the cost of accounts receivable.

The significant benefits of "going electronic" are in the time saved. Ten minutes on the phone to check eligibility compared to six seconds electronically adds up. An electronic remittance advice can be posted in a fifth of the time required for manual posting. The Association estimates that replacing paper and phone transactions with electronic transactions could save a dentist $200 per week.

E-Commerce Benefits	Paper/Phone Transactions	Electronic Transactions
Practice Statistics		
Visits Per Week	80	80
Percent with Insurance	60%	60%
Eligibility Verification	10%	10%
Staff Cost per Hour	$15.00	$15.00
Average Claim	$95.00	$95.00
Average Co-payment	$20.00	$20.00
Uncollected Co-payments	40%	20%
30 Day Payments	30%	80%
60 Day Payments	30%	10%
90 Day Payments	30%	10%
Cost of Capital	10%	10%

Time Estimates (in minutes)		
Eligibility Determination	10	0.1
Claim Preparation	5	0.5
Account Posting	3	0.5
Status Checking	10	0.1
Weekly Cost Estimates		
Eligibility Verification	$12.00	$0.12
Claims Preparation	$60.00	$6.00
Account Posting	$36.00	$6.00
Status Checking	$84.00	$0.24
Mailing or Clearinghouse	$25.44	$24.00
Investment in AR	$41.76	$10.92
Weekly Total	$259.20	$47.28

On August 18, 1999, the ADA and HCFA entered into a License Agreement in connection with use of the ADA's Code on Dental Procedures and Nomenclature as published in *Current Dental Terminology - Third Edition* (CDT-3). Use of a single code set will expedite the processing of claims and save resources in both the dental office and among the payers, both private and public sector.

HCFA should be actively involved in disseminating information to the states to ensure that they understand their obligations to update Medicaid and SCHIP systems to be in compliance with the transactions and code set final rule. HCFA also must adequately inform Medicare's regional administrators concerning how that program's claims processing procedures will be affected by the final rule.

Additional Administrative Burdens Placed on Small Employers Who Provide Health Care Services

Privacy Regulations

While the ADA generally supported many of the provisions of the proposed privacy rule, the final privacy rule contains many new features that were added without proper discussion or consultation with the healthcare industry. The resultant final rule generates more questions about compliance than it answers and creates unnecessary paperwork.

Key provisions of the final rule of concern to the Association which were not present in the proposed rule include:

- *Oral* communications by covered entities, such as dentists and dental personnel, are covered by the final rule.
- Written consent for release of health information must be obtained prior to routine use or disclosure for treatment, payment, or health care operations.

Dental offices are designed to be "patient friendly" with most having open operatories, a receptionist located in the waiting room area and limited accommodations for confidential discussions. Public health clinics, health fairs and dental schools facilities are also generally open for maximum efficiency.

By expanding coverage to include oral communications, the final rule adversely affects the effective and efficient provision of dental services because it:

- has the unintended consequence of negatively affecting the doctor - patient relationship by limiting doctor - patient discussions where they are most needed, at chair-side;
- limits the activities of a receptionist at the front desk who makes follow-up phone calls to patients after extensive procedures, or calls patients to remind them of their appointments, or discusses payment with patients.

Compliance with the final rule could cost a dental office thousands of dollars, including potential sound proofing costs if the oral communications requirement is maintained.

- Much if not all of these costs will have to be passed along to the American public and employers through increased fees and premium payments for dental coverage.
- This will make it more expensive for the average person to access needed oral health care services where already fifty percent of these services are paid for out-of-pocket, and therefore would also undermine efforts to expand access to underserved populations, as already low Medicaid fees will fall further behind the fees charged by most dentists.

By including the requirement for written consent for release of health information prior to routine use or disclosure for purposes of treatment, payment, or health care operations,

the final rule creates unnecessary paperwork. In addition, given the requirement of securing written authorizations from each patient, the prior written consent also adversely affects the effective and efficient provision of dental services because it could have the unintended effect of making it difficult and time consuming to sell dental practices.

The Association is concerned that the final rule, especially with respect to these new key provisions, is so vague, dentists may be uncertain how to comply, and may go to great and inordinately costly lengths to avoid potential criminal penalties. Further, the ADA believes that dentists should not be subject to criminal sanctions for violations until the rule is modified.

Office of Civil Rights Guidance

Last August, the Office of Civil Rights (OCR) within the DHHS issued guidance that requires many health care professionals (HCP) to furnish translation services for patients with limited English proficiency (LEP). HCPs who are determined to be recipients of "federal financial assistance", including those (according to OCR) who provide services to Medicaid and some Medicare beneficiaries, must provide this service and do so at their own expense.

This requirement, if applied to privately practicing dentists, would significantly increase the cost of providing care to Medicaid and Medicare beneficiaries, who are already underserved. For example, the American Medical Association is aware of a physician who treated a LEP patient that requested translation services. The cost for the translation

services was over $200, yet the Medicaid reimbursement for that visit amounted to less than $40. When this unfunded mandate is coupled with current Medicaid reimbursement, which often fails to cover the cost of providing services, the LEP cost will serve as another disincentive for dentists, physicians and others to participate as Medicaid providers.

The difficulty of finding and funding translators is evidenced by the fact that HCFA publicly stated that it has only hired three interpreters to provide language assistance to Medicare and Medicaid beneficiaries due to budget constraints. If an agency the size of HCFA has difficulty complying with the requirements of this guidance, how can dentists, physicians and other small healthcare practices afford to comply?

The Association is encouraged that DHHS Secretary Tommy Thompson has announced his intention to help HCFA become more user friendly. The ADA believes the agency must do a great deal more to ensure that the costs to beneficiaries, providers, HCFA and, in some cases, the states are properly weighed when making decisions about needed paperwork and other regulatory mandates.

Mr. Chairman and members of the committee, thank you again for providing the ADA with this opportunity to discuss our concerns about HCFA's regulatory and administrative burdens that are imposed upon dentists. The Association looks forward to working with you on this issue, which is so fundamentally important to dentists and other health professionals.

Supporting Quality Health Care Services at Home

United States House of Representatives

Committee on Small Businesses

Hearing
on

Health Care Financing Administration Paperwork Burdens

Testimony of Craig Jeffries
President and CEO
HEALTHSPAN Services, Inc.

On Behalf of the
The American Association for Homecare

May 9, 2001

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Mr. Chairman, my name is Craig Jeffries, President and CEO of HEALTHSPAN Services, Inc. I am pleased today to present testimony on behalf of the American Association for Homecare. AAHomecare is the only national association representing Homecare providers in every industry segment, including not for profit, proprietary, facility-based, and freestanding, home health agencies and home medical equipment providers.

HEALTHSPAN is an independent, for profit regional provider of home health care that services patients in eastern Tennessee, southwestern Virginia and western North Carolina. The company was founded in 1936 in Johnson City, Tennessee, and today provides a full range of home care including home health nursing and therapy services, home infusion pharmacy services, home medical equipment, and respiratory and specialized rehabilitation equipment. Approximately 35% of our total home care business is with Medicare, 25% is with TennCare (the Tennessee Medicaid program) and the remaining 40% of our business is primarily with private insurance. We provide needed home care to over 3,000 patients per month through more than 200 employees, and our annual payroll exceeds $5 million.

HEALTHSPAN services are built upon a strong clinical foundation (including consulting pharmacists, nurses, therapists, and respiratory therapists) and are designed to achieve optimal patient outcomes with a sophisticated financial business support system to assure a cost effective outcome for patients, employers and physicians. HEALTHSPAN employs leading edge information and communications technology to achieve clinical productivity and improve the accuracy and timeliness of communication with health peers including physicians, case managers, and consumers.

The members of AAHomecare would like to express their gratitude to the Committee for initiating an in-depth review and analysis of the regulatory requirements imposed by the Health Care Financing Administration (HCFA) in administration of the Medicare program. This is an important first step toward addressing inefficiencies existent within the current structure and prescribing concrete solutions to promulgate more effective policy.

We have identified three areas where improvements are needed to reduce the information collection burdens on home care providers and patients and to increase the efficiency and effectiveness of the Medicare program in accordance with the requirements of the Paperwork Reduction Act. (44 U.S.C. § 3501(1) and § 3506(b))

1. Eliminate Unfair Burdens In Documenting Medical Necessity

One regulatory burden that has caused particular consternation among home medical equipment (HME) providers is the determination of medical necessity. It highlights the need to evaluate the multiple requirements that HCFA has developed and mandated. The CMN is a form to document the medical necessity of certain items of medical equipment. It is required by statute, and was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act. The CMN collects information necessary to determine whether the beneficiary meets Medicare coverage criteria for the

item of medical equipment. In order to receive payment for a covered item of medical equipment, a provider's claim (HCFA - Form 1500) must be accompanied by a CMN signed by a treating physician. The original CMN must be maintained by the supplier and must be produced upon the request of the carrier, HCFA, or the Office of the Inspector General.

A supplier that submits a properly executed CMN has satisfied its legal obligation to document the medical necessity for an item of medical equipment. HCFA should be prohibited from requesting medical equipment suppliers to provide documentation in support of medical necessity beyond the scope of a properly executed CMN.

HCFA and the carriers ignore the original intent of Congress to designate the CMN as a tool to determine medical necessity. The carriers routinely require medical equipment suppliers to submit documentation of medical necessity *in addition* to the CMN. The requests for additional documentation are unpredictable and often require information that fails to be specified in current medical policy for the item. Additionally, Medicare auditors often request additional documentation for hundreds of claims simultaneously, creating an unreasonable administrative burden for suppliers. The carriers also request documentation supporting medical necessity from hospital and physician progress notes, although suppliers do not have access to a patient's confidential medical records. Further, medical equipment suppliers can be assessed overpayments when they fail to produce portions of these records.

Equally, medical equipment suppliers are subject to overpayment demands when they have obtained the appropriate medical documentation but the physician's notes contained therein are deemed inadequate for corroboration even though the physician, by acting as signatory, expressly certifies that the information on the CMN is "true, accurate and complete" and acknowledges that any "falsification, omission, or concealment of material fact" may subject him (the physician) to civil or criminal liability. Medicare auditors also assess overpayments for technical errors on CMNs even though these technical errors have no bearing on the documentation of medical necessity for the item.

The Medicare paperwork requirements are far in excess of the requirements by private insurance for comparable equipment. An additional FTE is required for every 80 new Medicare patients per month because of the CMN documentation requirements. For example, after we receive the initial order information for medical equipment, we need to call back the prescribing physician to get additional CMN information approximately 70% of the time for a Medicare patient compared to only approximately 50% of the time with respect to private orders. Additionally, it takes more time and labor to obtain the signed CMN back from a physician compared to getting a signed order for private care. Approximately, 95% of the signed orders for private insurance come back from the physician's office correct and ready to support a claim for payment. By contrast, approximately 70% of the signed CMNs for Medicare patients come back correct.

In short, the physician's office assumes a difficult burden in completing the required paperwork for Medicare correctly, and of course our company carries a similar burden in

having to hire more staff to manage that Medicare paperwork in addition to the financial burden of carrying the accounts receivable for more days for Medicare than for private payors.

The Association recommends that HCFA use the CMN for its original intent as a tool to document medical necessity and eliminate the additional requirements for documentation.

2. Remove Non-Medicare and Non-Medicaid Patients from Participation in OASIS

A second example of where information collection requirements need to be simplified under the criteria of the Paperwork Reduction Act is the Outcomes and Assessment Information Set for home health services (commonly known as "OASIS"). HCFA requires home health agencies to collect extensive sensitive personal information on an 80 question OASIS survey form from every patient, regardless of whether they seek Medicare or Medicaid coverage, on admission, every 60 days, after any hospital discharge, whenever there is a significant change in condition, and on discharge from the home health agency. The OASIS assessment form requires elderly and disabled patients who are suffering from an illness or injury to disclose such information as whether they live alone, whether they go shopping alone or with someone else, whether they own their own residence, and whether they are sad or depressed.

AAHomecare understands that approximately 19 of the 80 OASIS survey questions are needed to implement the prospective payment system that went into effect on October 1, 2000.

We do not believe that it is necessary to collect the extensive data required by OASIS from non-Medicare and non-Medicaid patients who do not seek coverage or payment under those government insurance programs. In addition, it would seem that much of the data required to be collected from Medicare and Medicaid patients under OASIS is not necessary to administer Medicare and Medicaid benefits.

The OASIS data collection requirements have imposed a crippling administrative burden on home health agencies and the patients they serve. According to estimates from HCFA, home health agencies spend approximately 800,000 hours per year collecting OASIS data at a cost of approximately $30 million. 64 Fed. Reg. at 3783 (January 25, 1999). This is on top of approximately 850,000 hours and $17 million required to comply with the data collection requirements under the other Medicare conditions of participation. See supporting information for HCFA's request under the Paperwork Reduction Act to extend the data collection requirements of the Medicare conditions of participation. 66 Fed. Reg. 14157 (March 9, 2001). Accordingly, the data collection burdens on home health agencies for just OASIS and the other Medicare conditions of participation consume at least 1.7 million hours and nearly $50 million annually. As the Department of Labor noted recently in its analysis of the impact of the ergonomics standards, the home health industry has the lowest profit margin of nearly any industry (3.2% in 1996). Thus, the cost of data collection under Medicare can only be offset by reducing services to patients or reducing wages for employees.

The length and overuse of the OASIS assessment tool has, in fact, served as a key factor in the marked reduction of nurses interested in entering the field of home health. Additionally, many nurses already working in the industry are choosing to leave as a result of the procedural burden being placed on them due to increased OASIS requirements. Nurses leaving the field routinely state that they have become too removed from direct patient care and resent being required to spend excessive amounts of their time complying with data collection requirements.

Furthermore, many patients object to home health workers entering their homes and obtaining detailed personal data about them without their consent which is then reported, in fully identifiable form, to a federal and state data bank. Patients particularly object when the care they are seeking has no connection to the Medicare or Medicaid programs. This practice would appear to be inconsistent with the intent of the privacy rights set forth in the health information privacy regulations which became effective on April 14 of this year. 65 Fed. Reg. 82462 (December 28, 2000). This would also seem inconsistent with the requirement under the Paperwork Reduction Act that collection of information be consistent with "laws relating to privacy and confidentiality." 44 U.S.C. § 3501(8).

The impact of Medicare paperwork requirements for OASIS are burdensome compared to HEALTHSPAN's experience with private insurance. An additional FTE is required for the data entry and administrative support necessary to manage the OASIS paperwork. In addition, a field nurse has to almost double the amount of time he or she spends with a new Medicare admission compared to a private insurance admission because of the 80 OASIS questions. Obviously, with the current nurse shortage, this is time taken away from direct patient care. Additionally, during the initial months when OASIS became a new Medicare requirement, approximately 70% of the initial OASIS paperwork needed correction from the visiting nurse, impacting his or her their patient time again. I'm pleased that only about 30% of that Medicare paperwork requires correction by the nurse today, but that is still 30% more than required by private insurance. The expansion of the OASIS requirements to private insurance is very difficult for us because we have a large pediatric business and a special focus on developmentally disabled adults. The OASIS data collection form simply is not designed for these populations.

The Association recommends that the application of OASIS be limited to Medicare and Medicaid beneficiaries and the amount of OASIS data collected on Medicare and Medicaid patients be reduced to that which is essential to implement the prospective payment system.

3. Clarify Use of the Home Health Advanced Beneficiary Notices

The Home Health Advance Beneficiary Notice (HHABN) is given to Medicare patients when a home health agency believes that services prescribed by a patient's physician will not qualify for coverage under the Medicare home health benefit (65 *Fed. Reg.* 24217). AAHomecare supports the use of these standardized notices as a mechanism to accurately inform patients of their Medicare rights. However, the Association has significant reservations concerning the applicability of the Home Health Advanced Beneficiary

Notice (HHABN) as it relates to determining coverage under the Medicare and Medicaid programs. In certain states, Medicaid agencies have embarked on a Medicare maximization policy under which they retroactively deny millions of dollars of Medicaid claims until a home health provider can prove that the claims were not payable under Medicare. Some states have required that the providers produce a signed advance beneficiary notice for each patient.

Thus, in order to be paid for home health services provided to dually eligible individuals, a home health agency must submit patient paperwork *twice*, once to Medicare and again to Medicaid, before being eligible for Medicaid reimbursement. In many instances, agencies have been forced to hire a full-time staff person just to address these Medicaid resubmission requests.

Additionally, some states require home health agencies to appeal coverage denials by Medicare before being allowed to submit a claim to Medicaid. In these instances, home health agencies incur a huge burden of providing additional documentation to support a coverage decision on behalf of a patient.

We believe the HHABN can be helpful in informing the patients of their rights. However, we do not believe that an advance beneficiary notice or an appeal of a Medicare denial should be required in order to file a claim for reimbursement with Medicaid.

Conclusion

Finally, we note that several home health agencies are reporting efforts by intermediaries to get providers to complete forms that have not been approved for use as required under the Paperwork Reduction Act. We suggest that the Paperwork Reduction Act be amended to provide for fines for government contractors that fail to comply with its provisions.

We also commend the Committee for seeking information comparing the paperwork requirements of private insurers to the paperwork burdens imposed by Medicare. We believe that there should be a permanent requirement under the Paperwork Reduction Act for federal agencies to determine whether data is collected for a comparable purpose in the private sector, and if so, to provide an explanation if similar processes are not adopted.

AAHomecare appreciates the interest of this Committee to explore and address the significant administrative and paperwork burdens that the Medicare program places on providers. We look forward to working with members of Congress and HCFA officials to simplify administrative policy for the Medicare home health and durable medical equipment beneficiary provisions while preserving the overall integrity of the Medicare program.

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May 30, 2001

The Honorable Felix J. Grucci, Jr.
Vice Chairman
Small Business Committee
United States House of Representatives
Washington, DC 20515

Dear Representative Grucci:

The American Dental Association (ADA) and the American Association of Oral and Maxillofacial Surgeons (AAOMS) are pleased to respond to your request for additional information regarding dentists' paperwork burdens that are imposed by the Health Care Financing Administration (HCFA). While our responses focus primarily on Medicare policies, dentists traditionally have more extensive dealings with state Medicaid programs, so we have also identified some general Medicaid improvements that could be implemented by HCFA.

Q. Please identify the top three-recordkeeping or reporting requirements that should be streamlined. Please provide rationale for each recordkeeping or reporting requirement so identified.

A.

Medicare Specific Burdens

- One significant burden is imposed by the requirement to utilize Advanced Beneficiary Notices (ABN). ABNs must be completed when services are performed that may not be readily identified as medically necessary or non-covered. This often applies to many services rendered in the oral and maxillofacial surgery office.

  When a Medicare beneficiary seeks evaluation of a mandibular intra-osseous lesion upon referral from their general dentist, the oral and maxillofacial surgeon performs a clinical examination as well as a diagnostic radiograph. Although the

Medicare program generally does not cover "dental" services, it does cover medically necessary dental care. In this scenario, the etiology of the lesion is unknown and a consultation of this type should not be automatically considered "dental" in nature and not medically necessary. Therefore, a Medicare claim needs to be submitted, however only after the patient signs the required ABN.

The ABN is required because Medicare will typically deny the payment, based on the fact that these services being performed are generalized as "dental" in nature. If it is determined that a biopsy is needed, the patient returns for surgery and the dental practice must again submit a Medicare claim. This claim must contain the appropriate modifier indicating that there is an ABN on file (separate form required for each visit).

If the surgery is approved and paid by Medicare, the dentist may then resend the original claim form with the appropriate ICD-9 code along with a letter describing that the radiograph was not "dental" in nature. The dentist must further explain that the radiograph was used as a diagnostic tool to determine the need for surgery. Therefore, the evaluation and management service as well as radiograph should be paid accordingly.

As mentioned in our response to question two below, the solution to the above burden is to allow the patient to sign one ABN form, not a new form for each visit.

- Another burdensome requirement for dentists is the mandatory claims submission-reporting requirements. Case in point, when a Medicare beneficiary receives dental services provided by any dentist, it is explained that Medicare does not cover dental services[1]. Even so, some beneficiaries request that claims be submitted either because they continue to believe that Medicare covers the services or because they need a denial to submit to their supplemental dental benefit coverage plans.

  Mandatory claims submission requirements imposed by HCFA require that if a Medicare beneficiary receives non-covered, categorically excluded dental services and requests that the dentist file a Medicare claim, despite the fact that Medicare does not cover the services provided the dentist must comply. The dentist must honor this request[2] and all parties affected (the patient and HCFA, as well as the dentist) must absorb the financial burden of filing an unnecessary claim.

  When the patient asks the dentist to submit the claim "to get a denial" for secondary insurance determination, the dentist bears the burden of notifying the patient that the services may not be covered. In addition, services must be reported appropriately on a HCFA 1500 form using applicable CPT procedure codes and modifiers (GX), etc. It is often not clear to the dentists and the

[1] 2000 Guide To Health Insurance for People with Medicare, page 8.
[2] Medicare Carriers Manual, section 3043.

beneficiaries as to what dental services are allowed and when they may be provided.

Required use of the HCFA 1500 form (the only claim form utilized by Medicare for payment of services) creates an additional hardship on the general dentist. This is a Medicare medical claim form. Therefore, most dental practices often lack of familiarity with this document and Medicare rules in general due to being categorically excluded from coverage. Furthermore, the penalties resulting from inaccurate completion of the form are severe.

HCFA should not expect a general dentist to submit a claim on a medical form for dental services rendered. Dental claims, submitted to Medicare on a HCFA 1500 form at the beneficiary's insistence, are often edited and returned to the dentist as "unprocessable." However, HCFA does not tell the dentist what information is missing or incomplete. Because no initial determination has been made, HCFA does not allow the claim to be reviewed or appealed and the beneficiary is notified that the claim was submitted and is not acceptable. The administrative burden is again placed on the dentist to know the complexities of completing the HCFA 1500 form, which as stated before is not commonly used in a dental office.

- Lastly, the current provider enrollment form being used does not accurately reflect the current practices within Dentistry and the recognized specialties. Currently, dentists enrolling as a provider with Medicare would select provider category 19 (Dentist – Oral Surgeon) and an oral and maxillofacial surgeon should be entitled to select provider category 85 (Maxillofacial). However, general dentists and other specialists often do not want to select category 19 because of the oral surgery designation.

  Oral and maxillofacial surgeons have a unique dilemma and this scenario varies from state to state. Many oral and maxillofacial surgeons often select category 19 and are then denied benefits because services are not "payable when performed by this provider" For example, surgical correction of a fractured mandible. When a surgeon attempts to change the category code from 19 to 85 he/she is often denied because the fiscal intermediary does not know how to implement the change. Again, this is an administrative burden placed on the provider who must now prove that he/she is licensed and credentialed to perform the services.

Medicaid Specific Burdens

- Lengthy Medicaid provider applications present a needless barrier and often serve as a disincentive to participation in these programs. (Some existing Medicaid applications are over 50 pages.) HCFA should provide incentives for states to simplify and shorten their provider applications so that they only require essential identifying information and proof of a valid license to practice dentistry in the jurisdiction in which the services are to be provided.

- State Medicaid programs often require usage of non-standardized claim forms that are different from those commonly used in the private sector dental market. Because dental offices often have limited administrative resources, required use of the ADA Dental Claim Form and *Dental Code* by state Medicaid programs will reduce provider overhead and encourage participation.

- Finally, difficulties in confirming beneficiary eligibility creates unnecessary administrative burdens and decreases the time available for patient care. HCFA should facilitate the establishment of systems to ensure rapid confirmation of children's eligibility under Medicaid or the state children's health insurance program (SCHIP), at the point of service.

Q. What three reporting and recordkeeping requirements, if implemented or modified, would make it easier for you to provide care to your patients? Please explain how these changes would improve your ability to provide care to your patients.

A.

Medicare Changes

- Advanced Beneficiary Notice -- eliminate the need to have the patient sign a new form for each dental service provided. One form, completed annually by the beneficiary and provider explaining that Medicare does not generally cover dental services, would be more reasonable.

- Explanation of Benefits (EOB) – The current Medicare EOB is almost impossible to interpret and makes communication with the patient difficult and escalates the possibility of unintentional fraud. The Medicare Adjudication Codes are difficult to interpret and often are not in "line" with the service. The explanations provided are often ambiguous and difficult to interpret. The EOB should be written in plain English and an easily understandable framework.

- Dental services, as described in the rules, are usually not covered under Medicare, except for medically necessary dental care. Therefore, to decrease the administrative burden imposed on the dental provider, dentists should be given the option of opting out of the Medicare system. This would provide the greatest administrative simplification and would decrease the rising administrative costs associated with submitting and appealing benefit claims.

Medicaid Changes

As stated in our response to the previous question, HCFA could ease dental offices burdens and improve the delivery of care to Medicaid patients by providing incentives to states for:

- Simplifying and shortening the existing Medicaid provider applications;
- Encouraging usage of the ADA Dental Claim Form and *Dental Code*; and
- Developing a rapid confirmation of eligibility system that will help ensure that Medicaid patients are provided care promptly and that dentists are paid for their services.

The above named program improvements would reduce costs to dental providers, therefore, providing an incentive to accept Medicaid patients. The improvements would also save the payers (state and federal governments) a considerable amount of funds on administrative matters that can be better spent on services. As such, these improvements would have the broad effect of increasing access to dental services.

Q. Please rank in descending order of importance the need to streamline HCFA procedures related: a) HCFA's internal processes; b) forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers, and c) recordkeeping requirements associated with HCFA regulations.

A. a) HCFA's internal processes

b) Forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers

c) Recordkeeping requirements associated with HCFA regulations

Q. Do you agree that a universal set of reporting requirements that would be collected by HCFA and then transmitted to fiscal intermediaries under Medicare Part A, carriers under Medicare Part B, health maintenance organizations under Medicare Part C and states under Title XIX of the Social Security Act of 1935 (Medicaid program) would be an improvement over the current reporting and recordkeeping regime?

A. Yes, we believe that a set of universal reporting requirements for the Medicaid program would increase efficiency. For example, states should be required to utilize the ADA claim form. In addition, states should be required to report data regarding access to dental care and services.

Q. If the answer to question number five is affirmative, what potential problems can you envision related to patient privacy? What benefits to patients do you see accruing from some form of universal reporting and dissemination?

A. The Association is strongly supportive of patient privacy efforts. However, any regulations and standards must be written in a manner that is not burdensome to the doctor-patient relationship.

Q. What information would you require from a new patient and would that information be different for a Medicare patient? Would you like to have the information readily available? What information do you believe that HCFA should be provided for new Medicare patients?

A. New patients are asked to provide their name, address, telephone number, social security number and third party benefit details (copy of insurance card, policy number, mailing address, etc). This information is the same for Medicare beneficiaries.

We thank you again for allowing us the opportunity to express our viewpoints on these issues of fundamental importance to dentistry. If you have any further questions or need additional information, please contact Michael Graham, at (202) 789-5167, in the ADA's Washington Office.

Sincerely,

Dorothy J. Moss
Associate Executive Director
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June 5, 2001

The Honorable Donald A. Manzullo
Chairman
House Committee on Small Business
2361 Rayburn House Office Building
Washington, D.C. 20515-6315

Dear Chairman Manzullo:

I am writing in response to your letter dated May 14, 2001, in which you request that I provide answers to questions posed by Vice Chairman Grucci. It is my pleasure to provide you with this information. Please find below my responses:

Question 1. Please identify the top three record-keeping or reporting requirements that should be streamlined. Please provide a rationale for each record-keeping or reporting requirement so identified.

Response: The top three requirements that I believe should be streamlined include the Medicare cost report; post-acute patient assessment data including the Home Health Outcome and Assessment Information Set "OASIS" form; and, the Medicare Secondary Payor form.

First, as I mentioned in my testimony, my small rural 25-bed federally certified Critical Access Hospital spends approximately $100,000 a year to comply with the Health Care Financing Administration's cost report requirements. Yet, some of the information collected goes unused. The present Medicare cost report has outlived its usefulness and should be redesigned and simplified. The cost report itself, as well as the cost reporting process, is extremely burdensome to providers. It is worth noting that Blue Hill's recent cost report was roughly 9 inches high. Not only must I provide a complete cost report in order for my institution to be paid, I must personally attest to the fact that every item contained in the report is accurate and complete. I do this under threat of investigation and prosecution under the False Claims Act. In addition, as I mentioned to the Committee, rather than process and settle the cost report in a timely manner, some fiscal intermediaries may not settle a cost report for two or more years. Blue Hill Memorial Hospital is owed more than $2.5 million on a combined basis from the Medicare and Medicaid programs, going back over three cost reports. We have had to borrow money to meet our payroll, pay our vendors and other current operating obligations.

Second, reporting requirements for post-acute care services are characterized by collection of far more data than needed or used by HCFA. HCFA has devised three separate instruments, the OASIS form, the Minimum Data Set (MDS) for skilled nursing facilities and the MDS-PAC for rehabilitation hospitals, which collect much extraneous information, lack statistical reliability, and are extremely burdensome to hospitals. These reporting requirements need to be streamlined to reduce provider burdens, focus data collection improvement efforts on relevant data elements, and enable sharing and integration of data across providers. For example, the MDS contains approximately 400 questions. The OASIS form has close to 100 questions, of which only 22 are used for payment purposes. Because home health care providers are required to fill out the OASIS forms prior to providing patient care services, many health care providers have complained that the paperwork interferes with establishing a caring and personal relationship with their patients. Given these paperwork burdens, it's little wonder that hospitals are facing a worker shortage. Streamlining of these tools would enable providers to channel more of their resources where they are most needed: to direct patient care activities that address the real problems of real people.

Third, the paperwork placed on beneficiaries and providers by the Medicare Secondary Payer (MSP) form needs to be reduced. Beneficiaries are annoyed at being asked the same questions each time they return for services. For example, a patient taking the anti-coagulant drug Coumadin (warfarin) may require weekly or daily monitoring due to internal bleeding risks. The hospital must ask the same 25 questions each and every time. Hospitals should not have to collect MSP information more than once every 90 days for patients that require recurring services, and hospitals should not be responsible for MSP information for non-patients.

Question 2. Please identify the three record-keeping or reporting requirements that are essential to the provision of care to your patients. Please explain why these record keeping or reporting requirements are critical to providing care to your patients.

Response: The three record-keeping requirements critical to providing care to patients include the medical record, the physicians' and nursing notes contained in the medical record, and vital health statistics required by public health laws such as the reporting of all cases of tuberculosis. The first two items contain the essential information necessary to provide accurate and complete information in order for the patient to receive appropriate medical care. The last item contains information that must be reported to the government for public health purposes and ensures the health of the community at-large.

Question 3. What three reporting and record-keeping requirements, if implemented or modified, would make it easier for you to provide care to your patients? Please explain how these changes would improve your ability to provide care to your patients?

Response: In response to your first question, I have suggested three items that, if changed, would make it easier to provide care to patients. We have also submitted, for the record, a copy of the American Hospital Association's (AHA) recently commissioned

PricewaterhouseCoopers study which demonstrates the paperwork burden in various clinical settings. The report shows that the paperwork burden on health care providers is diverting critical resources such as time and money away from being able to provide patient care. Above, I mentioned that it costs my small hospital $100,000 a year to prepare, audit, and file the Medicare cost report. This money could be used to replace outdated equipment, start new programs to better serve our community, or improve our ability to recruit and retain scarce health care personnel.

Question 4. Please rank in descending order of importance the need to streamline HCFA procedures related to: a) HCFA's internal processes; b) forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers; and c) record-keeping requirements associated with HCFA regulations.

Response: This is a difficult question to answer since all of these issues related to streamlining HCFA procedures are important ones. Perhaps, the single most effective reform or reforms Congress could enact would be to allow hospitals to challenge HCFA's use of the regulatory process in court. As you may know, under the holding in Shalala v. Illinois Long-Term Care Council, hospitals have a very limited ability to actually challenge regulations and exercise due process. Unlike other federal agencies, Medicare program policy decisions made by the Secretary of Health and Human Services (HHS) are insulated from judicial review. Health care providers are required to exhaust all administrative processes and remedies before they file suit against HHS. There is no such process, however, to exhaust on policy questions as to whether the Secretary has exceeded his authority or failed to meet his duty. This effectively means that providers can bring suit only if they violate Medicare requirements so significantly that they are thrown out of the Medicare program. HHS policy decisions should be subject to the same level of judicial review as other federal regulatory agencies.

Two other changes, both administrative in nature, would go a long way toward streamlining both HCFA's processes and forms. The first is to establish a central clearinghouse at HHS – perhaps within the Secretary's Office – that would: a) verify and attest to the need for a particular regulation and/or form before its implementation; b) assure that it is not duplicative or even in conflict with other existing policies, processes, or forms (both within as well as external to HHS); and, c) evaluate – and where appropriate, modify -- the proposed process and/or form to maximize readability/"user-friendliness" and minimize extraneous or intrusive data gathering requirements.

Second, we propose that HHS in general – and HCFA in particular – be required to consult with and to actively involve "front line" healthcare workers from real world settings – hospitals, doctors, home health nurses – in the actual design of processes and forms. As you know, hospitals are not opposed to regulation per se but rather to the combined problems of sheer volume coupled with lack of coherence/coordination among – and even within the same – federal agencies. Put differently, we have a shared interest and a compelling willingness to help HCFA get the data they need in the best and most efficient manner possible. Reacting to proposed rulemaking is far less efficient and

productive – and is more likely to result in unintended, burdensome consequences – than if providers and regulators were collaborating in the design of mutually acceptable processes and forms.

On a regional basis revising the forms and requirements issued by the Fiscal Intermediaries (FIs) and carriers would be most helpful and efforts have begun to make changes in this area. For example, the AHA has suggested that a good first step would be to make the FIs subject to evaluation by the hospitals. Maintaining satisfactory customer relations with and timely response to outstanding issues from providers should be a key determinant in whether the FIs keep their contracts with HCFA. An excellent precedent already exists with Professional Review Organizations (PROs) which undergo periodic competitive review by HCFA. Reforming the record keeping requirements associated with HCFA regulations, many examples of which are included in this letter, could have an even more profound effect on hospitals across the nation.

Question 5, 6, 7. Do you agree that a universal set of reporting requirements that would be collected by HCFA and then transmitted to fiscal intermediaries under Medicare Part A, carriers under Medicare Part B, health maintenance organizations under Medicare Part C, and states under Title XIX of the Social Security Act of 1935 (the Medicaid program) would be an improvement over the current reporting and record keeping regime?

If the answer to question number 5 is affirmative, what potential problems can you envision relate to patient privacy? What benefits to patients do you see accruing from some form of universal reporting and dissemination?

What information would you require from a new patient and would that information be different for a Medicaid patient? Would you like to have information readily available? What information do you believe that HCFA should be provided for new Medicare patients?

Response: The questions address two separate issues: Universal reporting requirements and centralized collection and distribution. We think it would be helpful to pull the two apart. It is important to understand that most individual data required to be reported is billing data submitted as part of claims processing. Funneling thru a central point would likely create more problems than it would solve – slower payment, major problems if the central hub broke down (quite likely given HCFA's antiquated computer systems) and greater opportunity for breaching patient privacy. Any consideration of a centralized collection of information by the government would need to resolve privacy and security of data issues first.

AHA believes that the real key here is greater standardization of billing transactions by all insurers, both governmental (Medicare, Medicaid, CHAMPUS) and private. HIPPA has provided a major start with its administrative simplicity requirements regarding transactions standards and privacy. While there are issues especially with respect to the privacy standards, we need to address the problems and get these transaction standards in

place. The next major need is greater standardization in collection of patient specific clinical data used for calculating patient system adjustments (e.g., patient assessment instruments such as OASIS, MDS) and data collected for utilization review and quality review. Plan by plan, insurer by insurer variations in data required to be submitted -- including definitions and coding -- are a major source of information system complexity and, hence, burden. In addition, much of the data required is often not utilized or is, simply, not "sound" enough to support the use to which it is put. In summary, we believe centralization is not the answer – rather, the answer is standardization so that there are fewer variations. We believe that reporting requirements from all sources need to be trimmed back to useful and useable data.

Thank you again for giving the American Hospital Association the opportunity to testify before your committee. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Bruce Cummings

Bruce Cummings MBST
CEO
Blue Hill Memorial Hospital

Supporting Quality Health Care Services at Home

United States House of Representatives
Committee on Small Business
Additional Questions for the Record of the
Hearing on the Health Care Financing Administration Paperwork Burdens
Testimony of Craig Jeffries
on behalf of
The American Association for Homecare

1. **Question:** Please identify the top three recordkeeping or reporting requirements that should be streamlined. Please provide a rationale for each recordkeeping or reporting requirement so identified.

   Answer:
   a. OASIS: As part of the Medicare Conditions of Participation, each home health agency is required to keep an Outcome and Assessment Information Set (OASIS) for each patient. This OASIS set was originally conceived as a quality assessment tool but has since been jerry-rigged into a billing determinant. Each patient set contains 80 questions which takes a home health nurse considerable time to complete. Many of those questions are not clinically based and irrelevant as an assessment tool. In addition, only 19 of those 80 questions are necessary for reimbursement. The Health Care Financing Administration is now considering further increasing this recordkeeping burden by expanding the OASIS requirements to non-Medicaid and non-Medicare patients. HCFA should be prohibited from extending these requirements and OASIS should be streamlined to those questions necessary to determine reimbursement and outcomes assessment.

   b. CMNs: Currently the Health Care Financing Administration (HCFA) requires suppliers to obtain a Certificate of Medical Necessity (CMN) for 14 types of products in addition to the physician order. Statutory restrictions prohibit the supplier from completing the majority of the CMN. Because the physician must therefore complete specific parts of the CMN, obtaining a properly completed CMN can often take much back and forth between the supplier and the physician. In fact, a recent survey of physicians documented that 39% of CMNs are returned to them *at least* once for completion or correction. Notwithstanding that the supplier is prohibited from completing the sections of the CMN related to medical necessity and the physician attests

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to the CMN, suppliers are regularly asked by the DMERCs to provide back-up paperwork from patient files to prove medical necessity. This practice is inconsistent with Congressional intent and HCFA's representation of the CMN. The CMN should be honored as the sole documentation of medical necessity. As with OASIS above, HCFA should be prohibited from extending these requirements for Medicare Risk HMO or Medicare Plus products that are intended to be private sector alternatives to the fee for service Medicare benefit.

c. HIPAA – Although not yet fully effective, the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations will cause a significant disruption in patient care. Under HIPAA, a supplier will be required to obtain consent for "treatment, payment or healthcare operations" prior to providing any care. Suppliers of home medical equipment, however, have to obtain information from the patient before the delivery of the equipment and the initial contact with the beneficiary. In addition, home health nurses often need access to patient information to develop a plan of care to discuss at the initial meeting with the patient.

2. **Question:** Please identify the three recordkeeping or reporting requirements that are essential to the provision of care to your patients. Please explain why these recordkeeping or reporting requirements are critical to providing care your patients.

   Answer:
   Health Care Financing Administration 1500; UB9; National Supplier Clearinghouse Supplier Agreement; Medicare Conditions of Participation. The HCFA 1500 and UB-9 are the billing forms for home medical equipment and home health respectively. The NSC Supplier Agreement and the Medicare COPs are the accreditation components of durable medical equipment and home health care. These standards should be stringent enough to suffice as the sole criteria for Medicare reimbursement.

3. **Question**: What three reporting and recordkeeping requirements, if implemented or modified, would make it easier for you to provide care for your patients? Please explain how these changes would improve your ability to provide care to your patients.

   Answer:
   a. ABNs – Advanced Beneficiary Notices (ABNs) are given to beneficiaries when a provider or supplier believes the service or supply will likely not be covered by Medicare. The ABN notifies the beneficiary of their liability if Medicare does not cover the supply or service. Currently, a provider or supplier is prohibited from using an ABN routinely, thus limiting a providers options if Medicare will likely not pay for a supply or service. A modified ABN for use in more instances could increase beneficiary access to items and services in instances where Medicare will likely not pay for them.

   b. OASIS – The 80 OASIS questions should be limited to the 19 essential questions necessary to determine payment. As mentioned above, home health agencies are required to keep an Outcome and Assessment Information Set (OASIS) for each patient consisting

of 80 questions. A streamlined OASIS set to the minimum necessary questions would allow home health providers to focus more time on the care of the patient.

c. Eliminate a paper Certificates of Medical Necessity (CMNs) and use electronic CMNs and 484's. Eliminate the requirement that the physician fill in the CMN – their signature attesting to the accuracy of information is sufficient burden for the physician. This would alleviate the significant amount of time spent by both the supplier and the physician allowing both to spend more time on patient care.

4. Question: Please rank in descending order of importance the need to streamline HCFA procedures related: a) HCFA's internal processes; b) forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers; and c) recordkeeping requirements associated with HCFA regulations.

Answer: In order of priority:

i. A – HCFA's internal processes are often arbitrary and capricious. Policies are instituted or changed without any provider input or notice and comment period. HCFA and its contractors -- Fiscal Intermediaries, Durable Medical Equipment Regional Carriers and the National Supplier Clearinghouse -- should be prohibited from instituting changes without notice and comment or sufficient time to implement the new policy, with an exception for emergencies. In addition HCFA and its carriers should be required to do a comparison with the private sector to justify need.

ii. C – Recordkeeping requirements are onerous and often unnecessary as mentioned above in the cases of OASIS and CMNs.

iii. B – Forms issued by HCFA or carriers are often complicated and directions are unclear. For instance, for the home health ABN HCFA has issued instructions and two rounds of clarifications to those instructions. In the case of the CMN, reimbursement to the *supplier* is dependent on the *physician* promptly and accurately completing the form.

5. **Question**: Do you agree that a universal set of reporting requirements that would be collected by HCFA and then transmitted to fiscal intermediaries under Medicare Part A, carriers under Medicare Part B, health maintenance organizations under Medicare Part C, and states under Title XIX of the Social Security Act of 1935 (the Medicaid Program) would be an improvement over the current reporting and recordkeeping regime?

Answer: In general, no. Standardization of HCPCS and electronic processes are essential and if HCFA keeps up with needed changes, very helpful. HMOs should be given maximum freedom from all HCFA rules. Coverage and payment policies need to recognize unique characteristics of each program component and where possible provide standard processes, not policy.

6. **Question:** If the answer to question number 5 is affirmative, what potential problems can you envision related to patient privacy? What benefits to patients do you see accruing from some form of universal reporting and dissemination?

Answer: According to the HIPAA privacy regulations, a "covered entity" is required to collect only the "minimum necessary" information for the task for which the information is being collected. Therefore, providers and the government could potentially be in violation of the standards for collecting extraneous information. This would be inconsistent with the letter and intent of HIPAA.

7. **Question:** What information would you require from a new patient and would that information be different for a Medicare patient? Would you like to have that information readily available? What information do you believe that HCFA should be provided for new Medicare patients?

Answer: Only such information that is necessary to provide optimal care should be provided for new Medicare patients. This information would vary according to the product or service. For instance, for a hospital bed, a prescription and a CMN is necessary for Medicare, but a physician's prescription alone is sufficient is necessary for private pay patients.

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Below are responses to questions requested by Representative Felix J. Grucci, Jr. (R-NY), Vice Chairman of the Committee on Small Business, U.S. House of Representatives, following the testimony of Dr. Alan Morris before the Committee on May 9, 2001.

1. **Please identify the top three recordkeeping or reporting requirements that should be streamlined. Please provide a rationale for each recordkeeping or reporting requirement identified.**

First, there should be uniformity of all forms, recordkeeping and reporting requirements required by the Medicare Carriers. Carriers operate with a great deal of discretion and many policies and specific forms generated from Carriers are not required to comply with federal government review. Many physician practices, including many small practices, see patients who are part of different Carriers and therefore are required to comply with the requirements of more than one Carrier. All recordkeeping and reporting requirements should be scrutinized more carefully by HCFA and standardized across all Carriers.

Second, the Medicare enrollment process for seeking and maintaining Medicare provider numbers should be shortened and require less paperwork, especially for those physicians who already practice in the system and are just changing their practice in some way---moving to a new group practices, moving to a new location to practice, etc.---such that they are required to apply for a new provider number.

Finally, the documentation required under the Medicare Evaluation and Management (E&M) requirements should be modified to take into account the variability in the examination environment of a specialty practice. This would reduce paperwork and the time required by the physician to provide quantitative information, often through a basic "check-off" reporting process, rather than providing any documented evidence of quality patient care.

2. **Please identify the three recordkeeping or reporting requirements that are essential to the provision of care to your patients. Please explain why these recordkeeping or reporting requirements are critical to providing care to your patient.**

Appropriate documentation on the patient's medical condition and specific health care rendered should dominate the time physicians spend on paperwork. The E&M documentation requirements referenced in #1 are very problematic, as they require a single-system approach to documentation that lacks emphasis on the patient's specialty condition--- the reason the patient was referred to the specialty physician---and yet they are among that most onerous of paperwork burdens in the Medicare program. While reporting requirements on patient care rendered should be standardized, the recordkeeping and reporting rules should recognize variability in what portions of these reports get completed by various types of physicians and other medical staff, depending on the specialty condition of the patient. The various portions of standardized reports should be completed by staff with the requisite expertise

3. **What three reporting and recordkeeping requirements, if implemented or modified would make it easier for you to provide care to your patient? Please explain how these changes would improve your ability to provide care to your patients.**

Modification of E&M guidelines to place emphasis on patient information relevant to the specialty condition presented to the physician will shift the physician's attention appropriately to the specialty condition and allow more time for the specialty examination and counseling. Also, the fear of post payment audits in the Medicare program have prompted physicians to implement may "check points' to ensure they have initialed every page of all patient records – this has slowed the process – and compounds the review and paperwork burden of administrative staff as well. Eliminating the lack of physician initials as a basis on which to conduct an audit will ease the review burden on physicians and their staff.

4. **Please rank in descending order of importance the need to streamline HCFA procedures related: a) HCFA's internal processes; b) forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers; and c) recordkeeping requirements associated with HCFA regulations.**

b. c. a. : First and foremost, forms issued by HCFA or issued pursuant to contractual authority should be scrutinized and streamlined, followed by the recordkeeping requirements associated with HCFA regulations. HCFA's internal processes certainly should also be examined and no doubt contribute to the paperwork problem, but these will take some time to resolve and the need by providers is immediate.

5. **Do you agree that a universal set of reporting requirements that would be collected by HCFA and then transmitted to fiscal intermediaries under Medicare Part A, carriers under Medicare part B, health maintenance organizations under Medicare part C, and states under Title XIX of the Social Security Act of 1935 (the Medicaid program) would be an improvement over the current reporting and recordkeeping regime?**

6. **If the answer to question number 5 is an affirmative, what potential problems can you envision related to patient privacy? What benefits to patients do you see accruing from some form of universal reporting and dissemination?**

Most certainly. Streamlining the processes and rules for reporting and documentation can assist all staff---physicians, other medical staff and administrative staff---in understanding and accurately reporting what is required. This, in turn, reduces the time necessary to study the various approaches, provides more clarity, not only on reporting requirements, but can also assist further determining and clarifying patient needs and improving patient outcomes. The more data is standardized and available in a uniform format, the easier it will be for physician practices and policymakers to assess the quality of care in the aggregate. Finally, streamlining the type of information reported of the patient and consolidating the transmission of patient information can greatly assist physicians and their staff in maintaining patient privacy.

7. **What information would you require from a new patient and would that information be different for a Medicare patient. Would you like to have that information readily available? What information do you believe that HCFA should be provided for new Medicare patients?**

The type of information required for a new patient should not vary depending on the source of funding for that patient's care. Regardless of the payer source, the provider needs to know the medical history of the patient to the extent necessary to appropriately treat that patient. Across all health care payers, private and public, patient information that is shared should be carefully scrutinized and only what is absolutely necessary, under carefully constructed and thoughtful guidelines, to permit the payer to determine payment obligations, should be made available. In this area, policies should be encouraged that require payers to rely on the judgment of the trained medical professionals who are treating the patient.

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May 30, 2001

Mr. Donald A. Manzullo
Chairman
Committee on Small Business
United States House of Representatives
2361 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Manzullo:

Thank you for your inquiry, on behalf of Vice Chairman Grucci, concerning my testimony before your Committee on May 9, 2001. The American Medical Association (AMA) appreciates your efforts and leadership on this issue, and we are pleased to provide you with additional information regarding the health care burden imposed by Medicare on physician practices.

Our answers to the specific questions you have asked are indicated below:

QUESTION

(1) Please identify the top three recordkeeping or reporting requirements that should be streamlined. Please provide a rationale for each recordkeeping or reporting required so identified.

(3) What three reporting and recordkeeping requirements, if implemented or modified, would make it easier for you to provide care to your patients? Please explain how these changes would improve your ability to provide care to your patients.

Questions (1) and (3) elicit similar information. That is, the top three recordkeeping and reporting requirements that we believe should be streamlined (under question (1)) are the same requirements that would make it easier to provide care to patients (under question (3)).

Each of these top priorities impact quality of care and patient access to care, and any streamlining process with respect to these issues would have the overall effect of allowing physicians to spend less time on paperwork and more time on patient care.

These top priorities are as follows:

Evaluation and Management Documentation Guidelines

The unnecessarily burdensome requirements of the evaluation and management documentation guidelines must be resolved. We urge the Committee to review the paperwork burden imposed by these evaluation and management (E&M) guidelines and explore whether "pilot" projects, designed to test the clinical relevance of E&M guidelines through peer-review, are a more appropriate response to ensuring clinically relevant documentation standards.

As we discussed at the Committee's May 9 hearing, these requirements cause physicians to create documentation in their patients' charts often not for the benefit of the patients' care, but purely to meet the government's demands. These regulatory requirements have resulted in voluminous charts filled with layers and layers of extraneous information, that can actually hurt patients since care is unnecessarily delayed while physicians are forced to search through pages and pages of documentation to identify the truly relevant information.

Further, even though physicians identify the E&M guidelines as the most serious Medicare paperwork problem and Medicare relies on them as an important tool for ensuring compliance, none of the guidelines currently in effect have ever gone through any type of Office of Management and Budget (OMB) clearance process.

Accordingly, we urge that these guidelines be identified as a top priority in the streamlining process.

HCFA Form 855 Enrollment Process

Medicare's enrollment process for physicians through Form 855 is seriously flawed.

In April of this year, we submitted comments to HCFA concerning important changes that would assist in streamlining Form 855. We would be happy to provide you with a copy of those comments upon your request.

As we discussed at the hearing, a physician cannot get paid for treating Medicare patients until the physician has a provider number, which is issued by the program upon completion of the Form 855 enrollment process. Yet, physicians often wait months for carriers to process their 855 applications. This is an extremely difficult situation for physicians who are just beginning to establish themselves in a community, and especially in rural communities that may have difficulty recruiting new physicians. Physicians should receive temporary provider numbers during the enrollment application period.

Further, carriers often wait until the end of the 45-day Form 855 processing deadline to return the application to the physician with a request for minor information that is missing. Clearly, carriers should contact the applicant as soon as possible, preferably by telephone, to request any missing information, without restarting the approval process timeline.

Finally, HCFA is attempting to expand the scope of its enrollment efforts by requiring all physicians to enroll in the program through the Form 855 process, and to re-validate their application information every three years. This would place an enormous additional burden on physicians across the country with respect to costs and time needed to complete the forms. Moreover, it is not clear that carriers are ready to assume the responsibility for this expansion effort, or that it would not disrupt the delivery of care to Medicare patients.

Certificates of Medical Necessity

Physicians, especially those in rural areas, have identified certificates of medical necessity (CMNs) for durable medical equipment as posing one of the greatest problems under Medicare. Often, physicians have between 10 and 25 percent of their CMN forms returned by the carrier with a request for more information.

HCFA recently agreed that problems caused by the CMN process would be a top priority for the agency, and we believe that problems with CMNs need to be resolved in consultation with the medical community, including reduction in the use of CMNs and streamlining the different forms used by each of the carriers.

QUESTION

(2) Please identify the three recordkeeping or reporting requirements that are essential to the provision of care to your patients. Please explain why these recordkeeping or reporting requirements are critical to providing care to your patients.

The recordkeeping mechanism that is most essential to patient care is maintenance of an accurate and concise medical record that is thorough, yet not clouded with extraneous and unnecessary patient information. Further, it is extremely important to have recordkeeping systems for physicians and health care providers to report public health concerns, particularly with respect to communicable diseases.

Any other recordkeeping or reporting requirements are not essential to patient care, and often simply shift physicians' time away from patient care to unnecessary paperwork that do not benefit patients.

QUESTION

(4) Please rank in descending order of importance the need to streamline HCFA procedures related to: (a) HCFA's internal processes; (b) forms issued by HCFA or issued pursuant to contractual authority by fiscal intermediaries and carriers; and (c) recordkeeping requirements associated with HCFA regulations.

The AMA would rank choices (b) and (c) as most important in streamlining HCFA procedures. We believe that (b) and (c) substantially overlap, and cannot be considered mutually exclusive choices. For instance, one could argue that CMNs fall into choice (b) since a CMN form is issued by HCFA. Yet, it also falls into choice (c) since physicians must complete or sign these forms and maintain a record of them for each patient. Almost all forms issued by HCFA or its fiscal intermediaries and carriers impose a recordkeeping requirement on the physician or health care provider.

Accordingly, any streamlining process for HCFA must focus equally on both choices (b) and (c), and secondary to that, such process should focus on choice (a), HCFA's internal processes.

QUESTION

(5) Do you agree that a universal set of reporting requirements that would be collected by HCFA and then transmitted to fiscal intermediaries under Medicare Part A, carriers under Medicare Part B, health maintenance organizations under Medicare Part C, and states under Title XIX of the Social Security Act of 1935 (the Medicaid program) would be an improvement over the current reporting and recordkeeping regime?

The AMA strongly supports the objectives of the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA), which seek to standardize the data content and flow of information from physicians, hospitals, and other providers to insurance companies and health plans. These HIPAA standards will be required for public and private payers and for all providers.

We would not be supportive of another set of new universal reporting requirements that would conflict with HIPAA. Nor would we support a blanket set of reporting requirements that contain reporting elements that are not relevant to various types of health care delivery. We would support, however, a consistent set of reporting requirements where the same reporting elements are relevant to various providers. Moreover, we would support eliminating requests for information that is captured elsewhere by the payer.

QUESTION

(6) If the answer to question number 5 is affirmative, what potential problems can you envision related to patient privacy? What benefits to patients do you see accruing from some form of universal reporting and dissemination?

The administrative simplification provisions of HIPAA will vastly facilitate the flow of patient care information between and amongst physicians, other providers, and insurance companies/health plans. Nevertheless, this increased flow of information, despite the provisions of the privacy regulations, will increase the risk that sensitive patient information may be received by those who should not have access to that information. The same risk would apply to any electronic reporting requirement without strengthening the privacy regulation.

In contrast, a primary benefit of some form of universal reporting and dissemination is that physicians would have more time to spend on patient care if less time were required to prepare and submit insurance claims and to meet other paperwork requirements. In addition, access to more timely patient information may allow physicians to avoid ordering redundant diagnostic tests and provide for more accurate diagnosis and treatment.

QUESTION

(7) What information would you require from a new patient and would that information be different for a Medicare patient? Would you like to have that information readily available? What information do you believe that HCFA should be provided for new Medicare patients?

During a physician's examination of a patient, the physician is required to ask Medicare patients very specific questions necessary to meet the requirements of Medicare's evaluation and management documentation guidelines. As we discussed under questions (1) and (3), as well as at the Committee recent hearing, these requirements are extremely burdensome, and cause physicians to create documentation in their patient charts often not for the benefit of the patient care, but purely to meet the government's demands. These regulatory requirements have resulted in voluminous charts filled with layers and layers of extraneous information that can actually hurt patients by delaying care.

When a patient enters a physician's office and is asked to complete an initial administrative form detailing the patient's personal identification information, including such information as the patient's name, address, telephone number, and primary and secondary insurers, this form is usually the same whether or not the patient is a Medicare beneficiary.

Physicians, however, ought to be permitted to request information about their Medicare patients' enrollment status. Physicians need to know whether a patient is enrolled in a Medicare+Choice (M+C) plan, and, if so, which M+C plan the patient has selected. Each plan has different rules and drug formularies, and physicians cannot be expected to comply with those rules unless they know in which plan a patient is enrolled.

Ironically, hospitals have access to enrollment data that enables them to determine whether patients are enrolled in traditional Medicare or a particular M+C plan. Physicians, however, do not. It is our understanding that access to enrollment data is governed by Social Security Administration privacy rules that generally prohibit the release of such information. An exception is made for hospitals, however, since they sign participation agreements with the government. Physicians have a tacit participation agreement with Medicare and thus should also have access to enrollment data. At the very least, those who have signed participating physician agreements should be privy to the same information as hospitals.

We hope the above information is helpful and responsive to your concerns, and, again we thank you for your leadership on this matter. We look forward to working with you and your Committee to further streamline burdensome requirements imposed on the medical community by HCFA and the Medicare program.

Respectfully,

William H. Mahood, MD

STATEMENT of the American Academy of Family Physicians

Submitted to the

House Small Business Committee

Concerning

Health Care Financing Administration (HCFA)
Paperwork Burdens: The Paperwork Reduction Act as a
Prescription for Better Medicine

May 9, 2000

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Introduction

The American Academy of Family Physicians represents more than 93,100 practicing family physicians, family practice residents, medical students, and other individuals with an interest in family medicine. We are very pleased to offer this written statement for the record of the Small Business Committee's May 9th hearing regarding "Health Care Financing Administration (HCFA) Paperwork Burdens."

The Academy appreciates the Small Business Committee's review of paperwork burdens associated with HCFA. We agree that the effective enforcement of the Paperwork Reduction Act and the Regulatory Flexibility Act may aid the many physician offices that operate as small businesses. In fact, according to "Facts about Family Practice" published by the Academy, four out of ten family physicians operate a solo practice, two-person practices, or multi-specialty groups. For the most part, family physicians are small businessmen and women. For them, examples of unnecessary paperwork burdens are easy to find in the current Medicare program.

According to the Academy's most recent practice profile, 89.7 percent of AAFP members participate in the Medicare program, and 80.1 percent accept new Medicare patients in their practices. Thus, more than four-fifths of practicing family physicians provide health care services to Medicare beneficiaries, making family physicians a significant source of health care for our nation's elderly and disabled citizens.

Compliance with Medicare rules, therefore, is an important feature of many family physicians' daily practice. The following are examples of paperwork burdens that HCFA regulations have created.

Advance Beneficiary Notices (ABNs)

HCFA requires an Advance Beneficiary Notice each time that services are recommended that might not be covered under Medicare. This requirement impacts busy family physicians' practices on a daily basis. Through this requirement, HCFA shifts the onus for knowing and understanding the scope of Medicare coverage from the beneficiary to the physician. Yet, it should be the beneficiary who is presumed to have the most interest in and knowledge of this matter.

The Academy has previously recommended to HCFA a one-time "blanket" ABN that would alert beneficiaries that they are responsible for services Medicare denies on the basis of its own coverage criteria. This recommendation should not affect quality patient care, since physicians will continue to recommend and provide what they believe to be the most appropriate care for their patients, regardless of the need for an ABN. Further, we note that many private insurers effect many of the same restrictions without the additional paperwork required for Medicare's ABN.

Certificates of Medical Necessity (CMNs)

The need to complete and sign CMNs for durable medical equipment (DME), including home oxygen, is a frequent hassle that the Academy believes deserves priority attention. Historically, HCFA allowed DME suppliers to complete the CMN and then forward it to the physician for review and signature. However, in recent years, HCFA has increased the burden on physicians who order DME by requiring that they, rather than suppliers, complete most of the CMN. As with the home health plan of care, completion of the CMN makes the physician responsible for doing someone else's paperwork.

Also, we question why it is necessary for the physician to actually fill out the CMN, given that he or she must review and sign it. The physician signature is enough to hold the physician responsible for the contents of the CMN without requiring the physician to actually fill out the contents.

The criteria for coverage of DME are overly restrictive and would benefit from HCFA review and modification. For example, as a condition of coverage, the physician may be asked to recertify the need for a particular piece of DME every few months even though the physician certified initially that the patient will require the DME on a lifetime basis. A similar example applies to diabetic glucose supplies. Given that there is no known cure for diabetes, an annual certification would seem sufficient. Such seemingly unnecessary recertification increases the physician's workload without any apparent benefit to the patient. We urge the committee to require that HCFA review and modify its coverage criteria for DME, especially as these criteria relate to recertification of equipment and supplies needed on a lifetime basis, and the duties of the physician with respect to the CMN.

Requirements for Establishing and Maintaining Medicare Billing Privileges

HCFA requires that physicians participating in the Medicare program file a Medicare Federal Health Care Programs Provider/Supplier Enrollment Application (Form HCFA-855). In February 2001, HCFA published in the Federal Register a proposed revision of that form, as well as additional requirements on physicians to keep a file of detailed information about their practice up to date with HCFA staff. The Academy has registered strong objections to the proposed form with HCFA staff.

According to the supporting statement for the proposed revision, the major goal of the provider/supplier enrollment application revision is to "simplify and clarify" the enrollment process. We find this impossible to believe. The form for individual health care practitioners, which must be completed by all physicians who render medical services to Medicare beneficiaries and to which our comments are directed, is 31 pages, including 15 pages of instructions. Indeed, the pages of instructions outnumber the pages of information that the physician must actually complete. Further, physicians who plan to provide services as part of an organization must also complete a form to reassign their Medicare benefits. That form is 9 pages, including instructions.

The Academy does not consider this "simple" or "clear." Most health plans have physician enrollment forms that are one or two pages long. We do not believe HCFA needs an application of 31 pages to achieve the same result. Any form that has more pages of instruction than it does pages of information to be completed is probably too long, too complicated, and anything but "clear." The Academy has offered detailed suggestions in its regulatory comment letter on how HCFA might shorten the form.

Further, the form is unnecessarily intrusive. For example, it asks questions about the applicant's age, gender, and national origin, all of which are classes protected from discrimination under federal law. It also asks where patient records are stored, which has nothing to do with the applicant's qualifications for providing quality care to Medicare beneficiaries. HCFA seems to think that a physician's request for a Medicare provider number gives the agency "carte blanche" to learn everything it ever wanted to know about the applicant. We believe that such presumptuousness is unjustified.

Finally, we do not believe that the Medicare carriers will be able to undertake the substantial expansion of responsibility to process, store and verify the material requested within the enrollment form. In town hall meetings with HCFA staff on this subject, we have heard numerous reports of new physicians waiting months to have carriers issue them Medicare provider numbers. During this period, new physicians are unable to bill for services rendered to Medicare patients. We believe that HCFA should get its carriers to meet their obligations under the current enrollment process, rather than beginning a new database of the proprietary business information of physicians who see Medicare patients.

Conclusion

In closing, the American Academy of Family Physicians appreciates the work of the Small Business Committee to try to bring rationality into the regulatory process that oversees the administration of Medicare.

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Statement for the Record

"HCFA Paperwork Burdens"

May 9, 2001
Committee on Small Business

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The American Academy of Ophthalmology (Academy) is pleased to comment on the impact of paperwork requirements on health care providers in the Medicare program. The Academy is the voice for ophthalmologists and their patients in Washington D.C., and is the world's largest organization of eye physicians and surgeons, with more than 27,000 members. Since many eye diseases present themselves later in life, the overwhelming majority of ophthalmologists' patients are Medicare beneficiaries.

For many years, we have tried to work with the Health Care Financing Administration (HCFA) to streamline physician billing requirements, and we also have spent millions of dollars to offer our physician members and their staffs educational programs to handle the growth of paperwork requirements. Over the years, physicians have been required to submit and/or comply with mounting regulations. We hope that this committee, along with all of the committees with jurisdiction over the Medicare program, can work with the health community to develop reasonable requirements that achieve a balance between responsible health care administration and beneficial patient care.

We agree that the Medicare program needs some reforms. The Department of Health and Human Services would be well served to begin with streamlining the existing program's administrative burdens to health care providers before attempting completely new approaches. We highlight only a few areas for improvement in this statement, but believe they are 1) critically important; and 2) well within HCFA's capabilities based on existing resources. In most of the cases we will point out, improvements can be made administratively, with congressional oversight to insure that they are executed.

Universal Provider Identification Number (UPIN)

The Health Insurance Purchasing and Portability Act (HIPAA) calls for the establishment of one identifier for all physicians/providers in the Medicare program. This Universal Provider Identification Number (UPIN), not currently being implemented, would make it possible for physicians to move to new practices and new states without having to apply for new Medicare provider ID numbers. Currently, physicians who have been active in the Medicare program are forced to re-apply for an identification number any time they move practices. This is a needless step that delays patient care when the only pertinent piece of information that Medicare may need is an address change. The National Center for Vital Health Statistics held discussions on establishing a UPIN in 1997. To date, no further action has been taken.

Application to Become a Medicare Provider

HCFA's enrollment application for physicians is a 31-page document intended to establish a provider ID number for the individual physician. If that physician participates in a group practice, additional documentation is required in a separate application. Oftentimes, there are significant delays in HCFA's response to assigning the numbers, which affect a practice's ability to care for patients in a timely manner. In addition, the greatest delay comes when new physicians begin practicing medicine, but cannot bill for the care they provide despite having already been hired by a practice. Not only does this affect patient care, it delays a new physician's ability to begin re-paying student loans let alone earn a living. This delay follows a resident's introduction to the Medicare program via HCFA's 100-page document "What Every Resident Needs to Know About the Medicare Program." Please keep in mind that the document

does not address specific billing issues or compliance, merely what the Medicare program is, what it provides to beneficiaries, how claims are filed, etc.

Compliance

Complying with Medicare regulations is perhaps the single most costly burden on physicians. On a rolling basis, HCFA publishes new payment policies, documentation requirements for billing and legal responsibilities for physicians. In many cases, these requirements are confusing, sometimes retroactive, sometimes delayed for a year, sometimes effective immediately and often without warning. The greatest paperwork burden that comes to mind over the years is the confusion created by the interim final rule on Physician Self-Referral and Ownership, also known as Stark II. In this case, physicians had significant expenses over several years altering their practice set-ups in light of the interim final rule. Six years later, the final rule was published and many requirements in the interim rule were removed. In fact, ophthalmic devices such as intraocular lenses, and post-cataract eyeglasses and contact lenses were exempted. The burdens that were lifted in the final rule are a great benefit to the physicians and patients, yet physicians spent millions of dollars to comply with a law that was not in effect, but still was required by HCFA.

HCFA makes updates to Medicare payment policies throughout the year via program memoranda and program transmittals. These changes are released without advance notification, and many regional carriers do not inform the providers in their plan of the changes until after a bill has been submitted. These types of breakdowns in communication only delay payment and require additional Medicare administrative work for the physicians to correct their claims submissions. HCFA could very easily remedy some of the confusion and costs by establishing a

calendar for releasing payment changes. A quarterly or monthly update would allow providers to know when to look for revisions, keeping all sides of the Medicare playing field on even ground.

Growing complexity and volume of regulations require not just additional staff, but higher skilled staffing. Too often, physicians cannot afford to hire a compliance officer for their practice -- a staff person responsible for watching for all changes in Medicare regulations and payment policies and implementing those updates accordingly. Instead, physicians may have a member of their administrative or clinical staffs keep an eye out for changes. We strive to assist our members in remaining compliant by alerting them to changes as soon as possible to help cut down their costs. Compliance is critical to making sure that a practice follows all of the Medicare rules to avoid audits, and the simple step of providing updates on a consistent basis would greatly assist in streamlining administrative responsibilities in physician practices.

Auditing Fairness

Regional Medicare carriers could greatly reduce paperwork burdens by establishing a working partnership with physicians to cut down on improperly submitted claims. Currently, physicians may receive notification that a claim cannot be processed without additional documentation, or that the claim is downcoded to a lower payment level. Physicians do not receive notification as to the cause of concern in the claim they originally submitted. Failing to inform a medical practice about the cause for the initial denial of payment does not aid a practice in improving its claims submissions.

Sustainable Growth Rate

In 1997, Congress recognized that physicians face significant paperwork burdens and mandated that the calculation of the Sustainable Growth Rate (SGR) -- a component of the formula that.HCFA uses update the annual Medicare conversion factor -- include a factor for administrative costs related to Medicare compliance. To date, HCFA has not accurately reflected the cost in the SGR leaving physicians to incur significant costs to the practice based on federally mandated requirements. We hope that in respect to the many physicians who run small practices, responsible for employing an adequate number of talented administrative and clinical staff in order to provide timely patient care, this committee will work to have the administrative inputs in the SGR calculations included in determining the conversion factor for 2002. Administrative burdens are rising and fewer Medicare beneficiaries than expected are enrolling in Medicare+Choice – another aspect of the SGR calculation which should lead to continuing increases in the conversion factor. A recent announcement by HCFA which raised concern on the part of the Medicare Payment Advisory Committee indicates that the physician payment update for 2002 could actually be negative – a cut in payment only serves to continue to threaten access.

"Medicare Education and Regulatory Fairness Act"

Congress is considering two bills, H.R. 868 and S. 452, both titled the "Medicare Education and Regulatory Fairness Act" (MERFA), which includes some of the remedies we have addressed. We urge this committee to work with Representatives Patrick Toomey (R-PA) and Shelly Berkley (D-NV), the House bill's lead sponsors, to advance this legislation and achieve some of the administrative relief that the Medicare system desperately needs. MERFA

would require fair auditing practices, a consistent schedule for the release of program memoranda and transmittals, and a reflection of administrative costs in the Sustainable Growth Rate, as is already required by law. In addition, the bill would provide for educational programs for physicians and their administrators to improve billing practices and compliance. The educational programs would be paid from existing HCFA funds already designated for this purpose and would be offered in tandem with the medical specialty societies. Ultimately, this type of training would reduce the paperwork burdens faced by Medicare claims processors and physicians due to incorrect claim submissions.

Congressional Budget Office Study

The Academy encourages this committee to seek a study by the Congressional Budget Office (CBO) to review HCFA's current administrative costs to manage Medicare Part B payments. The study should include the potential savings that would be incurred by:

- shifting to a UPIN
- establishing a schedule for program update releases
- streamlining audit practices to provide full information to physicians, thereby resulting in long term reduction of incorrect claims submissions
- providing education to practices to improve claims submissions and,
- improving the Medicare provider enrollment process to cut down on paperwork and time.

Conclusion

In the interest of Medicare's beneficiaries and the health of the Medicare program, Congress is advised to take a two-pronged approach to reducing paperwork burdens. First, we recommend

that issues such as the UPIN and the SGR, which have been mandated in previous legislation, be implemented by HCFA, with congressional oversight. Second, action must be taken to achieve passage of MERFA and any other legislative vehicles that would streamline changes in the program, improve communication between carriers and providers, and would establish educational opportunities to improve billing and compliance. We appreciate this committee's dedication and interest in the paperwork burdens Medicare providers encounter and would be pleased to work with you to alleviate some of these obstacles.

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& Exposition of the
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Statement for the Record

of the

American Physical Therapy Association

to the

Subcommittee on Regulatory Reform and Oversight of the House Small Business Committee

regarding

Medicare Regulatory Requirements and the Health Care Financing Administration

May 9, 2001

Mr. Chairman and members of the Subcommittee on Regulatory Reform and Oversight, the American Physical Therapy Association (APTA) is pleased to provide written comment for your consideration regarding the important task of reforming the Medicare program. APTA sincerely appreciates your efforts this Congress to explore this issue in greater detail and hold necessary hearings to ensure all views are heard on the matter.

Tommy Thompson, the newly appointed Secretary of Health and Human Services, summarized the feelings of the physical therapy community in a speech given to the American Association of Health Plans on February 26, 2001. The former governor of Wisconsin stated, "Patients and providers alike are fed up with excessive and complex paperwork. Rules are constantly changing. Complexity is overloading the system, criminalizing honest mistakes and driving doctors, nurses and other health care professionals out of the program."

There are a number of regulations that are unnecessary and take away vital time and resources from patient care. These regulations impact physical therapists working in a variety of settings, which include: hospitals, skilled nursing, facilities, home health agencies, comprehensive outpatient rehabilitation facilities, rehabilitation agencies, and physical therapy private practice offices. If necessary deregulation can take place, physical therapists will be able to provide care to Medicare patients in these settings in a more timely manner, which will speed recovery.

The following are problematic regulations and policies under the Medicare program that impact physical therapy. APTA has notified HCFA that these regulations and policies need to be eliminated, revised, or clarified. In most cases, we are still awaiting action.

Certification/ Recertification

Section 1861 (p) of the Social Security Act requires that outpatient physical therapy, occupational therapy, or speech-language pathology services be furnished only to an individual who is under the care of a physician. According to Medicare regulations, for outpatient physical therapy services furnished in rehabilitation agencies, physical therapist private practice offices, outpatient hospital departments, and skilled nursing facilities (Part B), there must be evidence in the patient's clinical record that he or she has been seen by the physician every 30 days. In addition, the clinical record must show that the physician reviewed the plan of care and recertified the need for that care every 30 days. For home health agencies and comprehensive outpatient rehabilitation facilities, the physician is required to review the plan of care and recertify the need for care every 62 days.

The need for a physician visit every 30 days is problematic. In many instances, it takes a week or two before the patient goes to receive his or her outpatient physical therapy treatment. After receiving two weeks of treatment, the 30 days expires, and the patient then needs to see the physician again in order to continue treatment. Returning to the physician's office in this time frame is an inconvenience to the patient and the physician.

It is particularly problematic in rural areas, where the patient may have to travel a long distance to get to a physician's office.

Physician signature on plan of treatment

Medicare requires that the physician recertify the need for therapy services every 30 days. Because this policy is not written clearly in HCFA's manuals, there is considerable confusion with respect to when the 30-day time frame begins and at what point the physician signature has to be on the plan of care. It is not clear whether the 30-day time frame begins after the physical therapist conducts an evaluation, after the initial physician visit, or when the physical therapy treatment actually begins. It is also not clear whether the physician signature has to be on the plan of treatment before therapy begins, before the claim is submitted to Medicare, or shortly after therapy begins.

APTA has tried unsuccessfully to obtain clarification from HCFA on these issues. Because there has been no clarification, carriers and fiscal intermediaries throughout the country are interpreting this provision differently. APTA's recommends that the 30-day time frame begin when the therapist sees the patient, and that the physician signature be on the plan before the claim is submitted to Medicare. Because it can often be difficult to obtain physician signatures, requiring the signature before treatment begins would result in delays in needed patient care.

"In Room" Supervision Requirement of Physical Therapist Assistants in Physical Therapist Private Practice Offices

HCFA's final rule, published in the November 2, 1998 Federal Register, HCFA required that a licensed physical therapist in private practice (PTPP) must personally supervise the physical therapist assistants and physical therapy aides. HCFA defines personal supervision to mean the physical therapist must be in the room during the performance of the service. Prior to that date, the standard for supervision was "direct supervision." In our view, the "in the room" supervision requirement is too strict and unnecessary. PTAs are state regulated practitioners, who can safely and effectively furnish therapy services under a less stringent supervision standard. The personal supervision requirement imposes a level of supervision higher than that required for PTAs furnishing services in other Medicare settings.

APTA has provided written opposition to the "in-the-room" requirement in its comments on the Medicare physician fee schedule for the last 2 years, and in numerous other correspondences. APTA has also had several meetings with HCFA on this issue. Most recently, HCFA stated in the final physician fee schedule rule that they are carefully examining the issue. We are still awaiting action.

Correct Coding Initiative Edits

On January 1, 1996, the Health Care Financing Administration (HCFA) implemented a national Medicare policy involving more than 80,000 coding edits that restricted certain coding combinations. AdminaStar Federal developed these code edits under a contract with HCFA. These code pair edits are combinations of two CPT codes that cannot be billed together because either the code pair represents services that are considered mutually exclusive or one code in the pair is considered a component of a more comprehensive procedure code. The CCI edits are applied to services furnished in physical therapist private practice offices and in outpatient hospitals.

APTA recognizes the need for HCFA to create edits in their systems to detect inappropriate billing. However, HCFA has created a number of edits that do not make clinical sense, and therefore are inappropriate. APTA has requested that HCFA delete the problematic code pair edits, but is still awaiting such deletion.

Clarification of Use and Documentation of Timed Codes

In March of 2000, HCFA issued program memorandum AB-00-14, "Questions and Answers Regarding the Prospective Payment System (PPS) for Outpatient Rehabilitation Services and Physical Medicine Current Procedural Terminology (CPT) Coding Guidance." This program memorandum answers questions related to Medicare outpatient therapy policies and provides guidance regarding coding therapy services. Because most physical medicine and rehabilitation codes are 15 minute timed codes, the memorandum defines how to bill for a 15 minute unit and how to determine what services count as time. Specifically, in AB-00-14, HCFA states that when billing units of therapy, one unit is equal to or greater than 8 minutes but less than 23 minutes of care. Two units are equal to or greater than 3 minutes but less than 38 minutes, and so on. Providers are instructed not to bill for anything less than 8 minutes of care. HCFA also states "pre-and post- delivery services are not to be counted in determining the treatment service time.

The language regarding counting minutes of therapy has caused considerable confusion. APTA, along with other rehabilitation organizations, met with HCFA in June 2000, to discuss the policy and clarify any confusion associated with it. At that meeting, HCFA agreed to develop a question and answer program memorandum that would further clarify how to determine what time counts as a 15-minute unit and how to bill for units of service. In this program memorandum, HCFA would respond to questions developed by the organizations. The questions were submitted to HCFA on July 21, 2000, and APTA is still waiting for HCFA to issue this program memorandum.

Stark II law

HCFA published an interim final rule (66 *Fed. Reg.* 856) on January 4, 2001, which incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act. This law, referred to as the "Stark II" law, prohibits

physicians from referring Medicare and Medicaid patients for designated health services" to health care entities in which they have a financial relationship, unless an exception applies. According to the law, physical therapy is a "designated health service."

APTA was pleased to see that HCFA published a final rule and supports the intent of the Stark II regulations. Physical therapists and patients needing physical therapy services are adversely impacted by physicians that obtain financial gain by referring patients to their own clinic for physical therapy services.

Although we are pleased to see that these issues are being addressed in HCFA's regulations, we are seriously concerned that some of the provisions in the interim final rule weaken the Stark II law and open the door for physician abuses in the provision of physical therapy services.

HIPAA: Final Rule on Privacy of Individually Identifiable Health Information

The Department of Health and Human Services released the long awaited final privacy regulations on December 20. The Final rule implements the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) and sets forth complex limitations on the use of individually identifiable health information by most health care providers (including physical therapists), health plans, and clearinghouses.

While APTA supports the protection of individually identifiable health information, the regulation that was issued is extremely cumbersome for our membership. For example, providers have to ensure the compliance of their business associates and have a new duty to mitigate known privacy violations by third party contractors. Many of our members are small business providers and the cost for implementing the requirements of the privacy regulations will be too onerous.

Reimbursement for Physical Therapy Students

There is considerable confusion regarding HCFA's policy on supervision and reimbursement for therapy student services under Medicare in the outpatient therapy setting. The American Physical Therapy Association (APTA), American Speech Language Hearing Association (ASHA), and American Occupational Therapy Association (AOTA) met with HCFA to discuss this problem in March 2001. After this meeting, HCFA began working on a program memorandum regarding reimbursement of services for students under Medicare Part B. The therapy associations are still awaiting issuance of this program memorandum. We are hoping that the issuance can be expedited. It is our hope that HCFA's policies will ensure that students can continue to obtain the clinical training they need to better serve Medicare beneficiaries in the future.

Provider Education

Many physical therapists have difficulty finding the "right" answer to questions regarding Medicare requirements. Carriers and intermediaries often give incorrect information to providers. There appears to be a lack of communication of information between HCFA national and the carriers and fiscal intermediaries.

In addition to receiving incorrect information from carriers and fiscal intermediaries, providers find that carriers and fiscal intermediaries are interpreting HCFA regulations and policies differently throughout the country. As a result, providers in different regions are subject to different standards for Medicare coverage and reimbursement. There is a need for uniformity. Physical therapists are trying to provide good patient care while complying with Medicare regulations, but because of the confusing and conflicting information they are provided, this has become more difficult.

There is a need for HCFA national to provide clear, concise guidance on its Medicare policies to its fiscal intermediaries and carriers, to national associations, and to providers. This guidance would ensure providers receive accurate and timely information to assist them in complying with Medicare requirements.

HCFA recently contracted with DynCorps to examine inconsistencies throughout the country with respect to Medicare coverage and reimbursement of occupational therapy, physical therapy, and speech-language pathology services. It is our hope that DynCorps and HCFA can remedy this problem through their work on this project.

Alternative Payment Methodology

The Balanced Budget Act of 1997 mandated an alternative payment policy be implemented for outpatient therapy services. Originally, a $1500 limit was placed on outpatient therapy services until an alternative payment policy was developed and implemented. This arbitrary limitation on services proved to have an adverse impact on patients, and in 1999, Congress placed a 2-year moratorium on the $1,500 limit. HCFA is still required to develop the alternative payment policy for outpatient therapy services and report to Congress on an alternative by January 1, 2001.

Due to a provision in the BBA of 1997, beginning January 1, 1999 all outpatient therapy providers, are reimbursed according to the physician fee schedule instead of a cost-based system. Therefore, APTA does not believe its necessary to develop an alternative payment methodology because the needed savings are achieved under the physician fee schedule.

Practice Expense Methodology

In determining payment under the physician fee schedule, there are three relative values: 1) relative value (RVU) for clinical work, 2) RVU for practice expense, and 3) RVU for malpractice expense. In January 1999, the practice expense RVU was revised to be

resource based rather than charge based. In the November 1998 Medicare Fee Schedule rule, HCFA discussed its methodology for developing these resource based practice expenses. We believe that the methodology used to determine the physical therapy practice expenses is flawed.

APTA believes that the administrative payroll, office, and other practice expenses per hour used by HCFA in computing the practice expense component of RBRVS under the Medicare Physician Fee Schedule is not sufficient to reflect expenses of physical therapists in private practice. APTA urges HCFA to adopt data from a survey conducted by the APTA during 2000. In the alternative, APTA believes that the "all physician" category more accurately reflects practice expense costs for physical therapists in private practice.

Medical Review and Audits

There are many problems with the current medical review and audit process. In many instances, the auditors do not understand the regulations that apply to physical therapy providers, and thus inappropriately seek overpayments. In addition, providers find that they are not given a reason for the overpayment determination, and carriers and intermediaries are unwilling to answer provider questions about the overpayment determination. Therefore, providers are forced to devote considerable time and resources to defend themselves.

In a number of cases, carriers and fiscal intermediaries seek overpayments based on a "technicality". For example, the physical therapy service was provided, was medically necessary, there is documentation in the file to support the medical necessity of the service provided, and a physician signed the order for services. Despite proof of medical necessity in the clinical record, the auditor still seeks the overpayment because the physician did not date the order. Thus, the provider is required to pay the money back to the Medicare program, because of this missing information.

APTA recommends that HCFA educate its auditors about its policies and regulations pertaining to physical therapy services, and ensure that providers are given sufficient rationale for the overpayment determinations.

Appeals

Approximately, 85% of the appeals that come before the Administrative Law Judges are overturned. When Medicare determines that there is an overpayment, the provider often must pay the overpayment before the appeal is heard. Many physical therapy providers who have received overpayment determinations are small business owners. To require the return of the overpayment when the provider believes the determination was made in error is extremely costly and a violation of due process. Therefore, APTA recommends that HCFA prohibit recovery of alleged overpayments until appeals have been exhausted.

Additionally, APTA believes that HCFA should permit physical therapists to appeal an alleged overpayment without waiving their administrative appeal rights. In many instances, a therapist will receive a consent letter informing them of an overpayment determination. The letter provides three choices: pay back the money and forego any appeal rights; provide additional documentation and forego any appeal rights; or appeal the overpayment determination but subject the company to a full blown investigation. APTA believes that these choices are unfair and deny providers due process.

Conclusion

We appreciate your serious consideration of APTA's concerns and recommendations. We recognize that HCFA has numerous regulations that need to be implemented as a result of the Balanced Budget Act of 1997, the Balanced Budget Refinement Act (BBRA), and BIPA. Because of the major impact of these regulations on the provision of critical rehabilitation services to Medicare beneficiaries, it is our hope that HCFA addresses these issues expeditiously.

We frequently hear from physical therapists that they can no longer provide services to Medicare patients because of the onerous regulations and unfair review processes. The purpose of the Medicare program is to provide access to quality health care services for senior citizens. Unfortunately, due to the number and complexity of Medicare regulations, beneficiaries may have difficult getting access to the rehabilitation services that they need.

The APTA looks forward to working with you and the rest of the Committee members to address these concerns on behalf of the physical therapy community and the patients they serve. For more information, please contact Patrick Cooney at (703) 769-0020. Thank you for your consideration of these comments.

APTA represents more than 68,000 physical therapists, physical therapist assistants, and students of physical therapy. The goal of APTA is to foster physical therapy practice, education, and research.

Statement
of the
American Society of Clinical Pathologists
to the
House Small Business Committee

Hearing on Health Care Financing Administration Paperwork Burdens: The Paperwork Reduction Act as a Prescription for Better Medicine
May 9, 2001

Thank you for holding this hearing on Health Care Financing Administration paperwork burdens. We 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. We hope the information provided below may be of assistance.

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

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.

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 the American Society of Clinical Pathologists.

Power Mobility Coalition

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United States House of Representatives
Committee on Small Business

Hearing to Explore the Reporting and Recordkeeping Requirements Imposed on Health Care Providers by the Health Care Financing Administration

Submitted by:

The Power Mobility Coalition

May 9, 2001

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The following statement is respectfully submitted to the House of Representatives Committee on Small Business on behalf of the Power Mobility Coalition ("PMC"). The PMC is a coalition of power mobility suppliers who provide motorized wheelchairs and scooters to disabled individuals nationwide including paraplegics and quadraplegics, and patients suffering from neurological and cardiopulmonary disorders. Our members are located in all regions of the country and currently represent roughly half of the nation's power mobility market. The members of the PMC commend the House Committee on Small Business for conducting a hearing regarding the reporting and recordkeeping requirements imposed on health care providers by the Health Care Financing Administration ("HCFA").

Congress Enacted Procedural Safeguards in the Paperwork Reduction Act

Congress enacted the Paperwork Reduction Act ("PRA") in part to "minimize the paperwork burden for individuals [and] small businesses" "resulting from the collection of information by or for the Federal Government." In addition, Congress sought to "improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in Government and society."

In enacting the PRA, Congress established procedural requirements (e.g., 60-day public comment period) that must be adhered to when a government agency develops a paperwork "collection of information" request from the public. The PRA defines a "collection of information" as "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions, by or for an agency, regardless of form or format calling for...answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons."

The Certificate of Medical Necessity Form Was Approved In Accordance With the PRA

The Medicare Part B program requires in written policy that claims submitted for power mobility equipment include a Certificate of Medical Necessity ("CMN") form that is completed and signed by the beneficiary's treating physician. A CMN is defined by Congress in the Medicare law ("Social Security Act") as "a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member."

The current CMNs were developed by the Health Care Financing Administration ("HCFA") with the input of the Medicare Part B carriers and groups such as the American Medical Association and the Practicing Physicians Advisory Council. The physician signs and completes the CMN form with the express understanding that any falsification, omission, or

concealment of material fact with regard to the medical necessity information in Section B may result in civil or criminal liability.

HCFA submitted the current CMNs to the Office of Management and Budget ("OMB") for approval pursuant to the PRA. In their PRA submission, HCFA declared that a CMN is a standardized form "used by carriers to determine the medical necessity of an item or service covered by the Medicare program and being used for the treatment of the Medicare beneficiaries condition." The current CMN forms were originally approved by the OMB in 1996.

The Medicare Program Has Imposed Several Additional Paperwork Burdens That Run Contrary to the PRA

Despite the explicit guidance from Congress, HCFA and the OMB concerning the medical necessity and legal significance of the CMN, the Medicare Part B carriers have often treated this form as if it was merely a piece of paper to be included in the file. This has led to the following results:

- Medicare policies that require beneficiaries, suppliers and physicians to submit additional documentation for claims even though the Medicare documentation requirements require only the submission of a CMN. Examples include randomly developed beneficiary and supplier questionnaires as well as a requirement that suppliers submit newly created paperwork for each Power Operated Vehicle ("POV") claim. One questionnaire sent to beneficiaries throughout the Northeast read as follows:

  > Dear Beneficiary:
  >
  > We have received your claim for the services listed below. In order to fully process the claim, it is necessary that you answer the questions below and return this letter in the enclosed envelope. You may want to call the beneficiary number listed at the top of this page if you need help completing this form. ***Failure to respond to this letter within 30 days may result in a partial or complete denial of the claim*** (emphasis added).

  These questionnaires, which never underwent the PRA process, impose an unfair burden on Medicare beneficiaries who may not be able to competently complete such paperwork based on their existing condition.

- Pre-payment and post-payment reviews on a class of suppliers that establish arbitrary and confusing medical necessity requirements. For example, a Medicare Part B carrier representing the entire Western Part of the United States is regularly requiring suppliers to submit additional paperwork for power mobility claims, and subsequently denying payment based on arbitrary criteria, after payment has been made to such suppliers. This is in effect a general investigation of an entire industry which may create a chilling effect on

companies attempting to enter the Region's market. General investigations are subject to the procedural requirements set forth in the PRA.

- One Part B carrier established a new policy requiring suppliers to collect additional documentation in addition to the OMB approved CMN on all power wheelchair claims. The carrier was instructed to halt this practice based on such practice being in violation of the PRA. Unfortunately, suppliers are still receiving similar paperwork requests today.

Conclusion

The above highlighted Medicare paperwork requirements represent "collections of information" that were developed without undergoing any formal process as set forth by Congress in the PRA. In each instance, the Medicare program has developed new paperwork submissions that go beyond what is expressly required by the program in written policy. These requests for additional documentation place an unfair burden on physicians, beneficiaries and suppliers that participate in the Medicare program.

Violations of the Paperwork Reduction Act by HCFA have a significant impact. Suppliers may be unfairly denied or delayed payment based on arbitrary and confusing paperwork requirements. In one case, a company received identical requests from a Part B carrier for additional documentation on every claim that it had submitted to the Medicare program. If not for OMB intervention prohibiting the practice of the Part B carrier based on noncompliance with the PRA, this company would have had to significantly cut its workforce and perhaps close its operations. Other companies have faced similar issues and have been forced to lay off workers and in some instances go out of business. Ultimately, Medicare beneficiaries are denied legitimate services and medically necessary products.

The PMC applauds the Committee for reviewing these issues and respectfully requests that Congress contemplate the development of an enforcement mechanism to ensure that the Medicare program complies with the procedural requirements established by Congress in the PRA.

Once again, we appreciate the opportunity to submit written testimony. Please feel free to contact Stephen Azia with any questions or comments concerning the issues raised in this statement.

PMC

THE POWER MOBILITY COALITION

The Power Mobility Coalition ("PMC") commends the House Committee on Small Business for holding today's hearing regarding the reporting and record keeping requirements imposed on health care providers by the Health Care Financing Administration ("HCFA"). The PMC is a coalition of power mobility suppliers who provide motorized wheelchairs and scooters to disabled individuals. Our members are located in all regions of the country and currently represent roughly half of the nation's power mobility market.

As HCFA violates the Paperwork Reduction Act ("PRA"), small businesses are shut down. HCFA has allowed its regional carriers to blatantly violate the PRA causing dozens if not hundreds of small businesses to go out of business, lay off workers, and as a result, thousands of Medicare beneficiaries are denied legitimate services and medically necessary products.

HCFA submitted the current Certificates of Medical Necessity ("CMN") to the Office of Management and Budget ("OMB") for approval pursuant to the PRA. In their PRA submission, HCFA declared that a CMN is a standardized form "used by carriers to determine the medical necessity of an item or service covered by the Medicare program and being used for the treatment of the Medicare beneficiaries condition." The OMB approved the current CMN forms in 1996. The following are our concerns with respect to the PRA.

1. The regional carriers originally attempted to require sweeping paperwork burdens across the board, in which all suppliers were forced to submit to the requests.
Example: The Region B DMERC confirmed in their December 1998 Supplier Bulletin they were requiring suppliers to collect additional documentation in addition to the approved CMN on all power wheelchair claims. (See Attachment A1) The carrier was told to stop the questionnaires in a letter from Tim Hill, Deputy Director of Program Integrity at HCFA dated sometime after the spring of 1999. (See Attachment A2) Suppliers are still receiving these requests today.
Example: The Region D DMERC in their June 1997 DMERC Dialogue required that significant paperwork, in addition to the CMN, be submitted with each POV claim. (See Attachment A3) After repeated questions from the supplier community, the Fall 1999 DMERC Dialogue reinforced the requests for additional documentation. (See Attachment A4) The DMERC has never been instructed to withdraw this request.

2. General investigations are not exempt from the PRA. The DMERCs are claiming code specific audits trying to not comply with the PRA. What is being created is an audit that affects an entire industry; therefore, it is a general investigation of the entire industry and must comply with the PRA. These investigations require random industry wide audits of voluminous amounts of paperwork, which should be prohibited by the PRA. Attached is a notification of a review that states, "CIGNA Medicare routinely performs post-payment reviews...". (See Attachment B1)

3. The suppliers that represent this industry who collect and submit the OMB form, the CMN, often find themselves being accused of fraud by the DMERCs and HCFA. (See Attachment C1 and C2)

The PMC applauds the Committee for reviewing these issues and hopes that appropriate controls can be put in place to ensure that the Medicare program complies with the procedural requirements established by Congress in the PRA.

Sincerely,

Tim Zipp
President, The Power Mobility Coalition

1667 K Street, NW Suite 700 Washington, D.C. 20006-1608 830.608.0672
www.pmcoalition.com

December 1998

This code is effective for claims with dates of service on or after January 1, 1999.

A custom fabricated prosthesis is one which is individually made for a specific patient starting with basic materials. A molded-to-patient-model breast prosthesis is a particular type of custom fabricated prosthesis in which an impression is made of the chest wall and this impression is then used to make a positive model of the chest wall. The prosthesis is then molded on this positive model.

Compared to a prefabricated silicone breast prosthesis (L8030), the additional features of a custom fabricated prosthesis are not medically necessary. Therefore if an L8035 breast prosthesis is provided to a patient who has had a mastectomy, payment will be based on the allowance for the least costly medically appropriate alternative, L8030.

Power Wheelchairs - K0011

For the past several months, the Region B DMERC has been conducting an intensified pre-payment medical review of K0011 power wheelchairs. We have developed claims, requesting information from the patient's medical record which documents the medical necessity of the item. Prepayment review will continue until further notice. If they are not already doing so, in addition to the CMN, suppliers should begin submitting the following information with the initial claim for a K0011 wheelchair: the manufacturer and model name/ number of the wheelchair, a copy of a detailed evaluation describing the patient's functional capabilities and limitations and explaining the medical necessity for the power wheelchair and any separately billed options/accessories. This evaluation must be completed, signed and dated by a qualified professional (e.g., physical therapist, occupational therapist, physician). Assigned claims submitted on or after 2/1/99 that do not include this information will be denied as not medically necessary. If the claim is denied and the supplier subsequently obtains the information, the claim must be sent for review to the Appeals unit; it should not be sent as a resubmission.

Some suppliers have asked for guidance concerning the type of information that we are seeking We do not have any specific form that must be completed. However, the following are examples of commonly reported elements of detailed wheelchair evaluations that we receive: condition necessitating use of a power wheelchair, date of onset of the condition, progression of the condition and prognosis, semi-quantitative assessment of strength in the extremities, quantitation of limitations to passive range of motion in the extremities, the presence or absence of increased muscle tone or spasms, trunk stability and sitting posture, quantitation of the patient's ability to ambulate and what assistance (e.g., cane, walker, other person, etc.) is needed for this (if applicable), ability to transfer from bed/chair to wheelchair (including the ability to stand and pivot), endurance, cognitive abilities, visual impairments, description of current wheelchair (if applicable) , age of equipment, and why it is being replaced.

Attachment A-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

TO: Allison Eydt
Office of Management and Budget

SUBJECT: Power Wheelchairs and the Paperwork Reduction Act (PRA)

FROM: Deputy Director
Program Integrity Group

We are writing this letter in response to the letter that your office has received from regarding the collection of information for power wheelchair claims initiated by the Durable Medical Equipment Regional Carrier (DMERC) for Region B.

In his February 19, 1999 letter, raised a concern that DMERC B has violated the Paperwork Reduction Act (PRA) by publishing a December, 1998 bulletin article requiring that all claims for power wheelchairs must be submitted with additional medical necessity information. Although, the purpose of the article was to educate suppliers on the types of information that would assist the DMERC in making medical necessity determinations on power wheelchair claims, we believe that this article does represent a violation of the PRA. We have instructed DMERC B to retract the December 1998 bulletin article. Claims will not be denied for not providing documents in response to the bulletin article.

We hope that this answers any questions you have and addresses your concerns.

Tim Hill

Attachment A-3

Region D DMERC DIALOGUE
A Medicare Newsletter for Region D DMEPOS Suppliers
A Service of CIGNA HealthCare Medicare Administration

DMERC
General R

June 1997

POV Documentation Requirements

Robert Zone, M.D.

In 1996, there were increasing national Medicare allowed charges for Power Operated Vehicles (POVs)--$4.4 million in the 1st quarter to $6.6 million in the 4th quarter. This carrier has evaluated clinical records and interviewed beneficiaries associated with Certificates of Medical Necessity (CMNs) submitted for prior approval and/or payment of POVs. In the vast majority of cases, there were inconsistencies between the CMNs and the record/interview findings. Many beneficiaries are able to ambulate and/or do not use the POVs in their homes. As a result of these findings, effective for dates of service on or after September 1, 1997, additional documentation must be submitted with all POV prior authorizations and POV claims without prior authorization. The documentation required is a copy of the clinical evaluation performed by the ordering physician (as found in the physician's records) that resulted in the prescribing of the POV. Separate Astatements@ outside of the medical records will generally not be adequate for these purposes. The clinical evaluation must clearly identify the patient, must be date specific, and must be signed by the physician. The clinical evaluation notes will be reviewed to verify statements on the CMN pertaining to the patient's medical and physical condition and to insure that all coverage criteria are met. This requirement will remain in place until such time as it is clear that the vast majority of POVs are supported by the beneficiaries' clinical condition.

Attachment A-4

Region DMERC DIALOGUE
A Medicare Newsletter for Region B DMEPOS Suppliers
A Service of CIGNA HealthCare Medicare Administration

GR 99-3, Fall 1999, Page 6 through 7.

Power Operated Vehicles (POV) Documentation Revisited

In recent years, the Medicare program has seen an increase in the prescription of powered mobility devices such as power wheelchairs and power-operated vehicles (POVs). In July 1997, an article was published in the *DMERC Dialogue* outlining the documentation requirements for POVs. This article detailed the basic requirements for completion of the certificate of medical necessity (CMN) and prior authorization requests.

For any item to be reimbursed by Medicare, it must be "reasonable and necessary." Speaking specifically to the case of POVs, it is expected that:

- the beneficiary be unable to operate a manual wheelchair,
- the beneficiary would otherwise be bed or chair confined without the use of the POV,
- the beneficiary can safely operate the equipment, and
- the equipment is appropriate for use in the home.

Since the publication of the POV article in 1997, a number of questions have been raised with respect to documentation requirements for POVs, mainly related to the clinical evaluation (sometimes called a functional assessment) requirement. What constitutes a clinical evaluation?

According to Medicare national policy, a clinical evaluation must be performed and documented by a physician specializing in the practice of physiatry, neurology, rheumatology, or orthopedics. The documentation must be detailed enough to determine that the conditions of "reasonable and necessary" described above are met. Therefore, elements of the clinical evaluation should detail (not all-inclusive):

- Current limitations of ambulation.
- Lower and upper extremity body strength.
- Other medical conditions that potentially impact operation of a manual wheelchair or POV such as sensory deficits, cardiopulmonary limitations, or rheumatologic diseases.
- Intended use and expected benefit of the POV.

A list of diagnoses alone does not prove medical necessity. Vague, subjective statements such as

"weak upper extremity strength" or "cannot walk very far" should be avoided. Instead, physical limitations should be objective and quantitative such as "in-home ambulation is limited to ____ feet," "grip strength in right hand is 3/5" or "the patient is non-ambulatory and can only stand for transfers."

The evaluation must clearly identify the beneficiary and the date of the evaluation, and the physician must sign and date the evaluation. Clinical evaluations performed by a physical therapist, while acceptable for power wheelchairs (if co-signed by the prescribing physician), are not acceptable as sole documentation for POVs. According to Medicare national policy there must be a clinical evaluation performed by a physician specializing in one of the four approved specialties.

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Rec 6-2-00
By B.Cuevas

Attachment B-1

Sheila Tallent
Medical Policy Analyst
DMERC Region D

CIGNA HealthCare
Medicare Administration

May 30, 2000

Supplier Number:

Dear Sirs:

By contractual obligation to the Federal Government, CIGNA Medicare routinely performs post-payment reviews of services rendered by you.

The standard - weight frame motorized/power wheelchair with programmable control parameters for speed adjustment, tremor dampening, acceleration control and braking (K0011NU) you billed for Medicare beneficiaries (list enclosed) has been identified for review.

Please send copies of medical records including doctor's/nurses progress notes, physical/ occupational therapy notes, and any other documentation, which supports the medical necessity. The medical records should clearly indicate ambulatory status, why a power wheelchair is needed as compared to a regular wheelchair and medical justification for each accessory billed. Also include a Certificate of Medical Necessity (CMN), physician's written order, and invoice including manufacturer name and model number.

All records for jhe ten beneficiaries listed should be submitted within 30 calendar days of the date of this letter and sent to CIGNA-Medicare, ATTN: Sheila Tallent - Medical Review, PO Box 22057, Nashville, TN 37202.

Please attach a copy of this letter with the requested information. If you have any questions concerning this request please contact me at (615) 244-5600 EXT. 28810. Your cooperation is appreciated.

Sincerely,

Sheila Tallent

Sheila Tallent
Medical Policy Analyst

Connecticut General Life Insurance Company
Part B & DME Contracted Carrier for
Health Care Financing Administration

Attachment C-1

Bernadette Doig, RN
Medical Policy Analyst
DMERC, Medical Review

CIGNA HealthCare
Medicare Administration

July 13, 2000

Supplier Number:

Dear Supplier:

As the Medicare carrier for the 17 states and territories designated as Region D, we conduct periodic post payment reviews of claims processed. Reviews of this type are required because Medicare coverage is not only based on the reasonable charges for services rendered, but also on medical necessity. We must also be aware of any over-utilization, which might be prevalent by either the suppliers or the patients. You were chosen for review because our data shows you have a high utilization of motorized/power wheelchairs (K0011NU) in Region D as compared to your peers.

Also on review of the claims submitted, we were unable to determine the medical necessity for the power wheelchairs, as there were no medical records provided. The functional capabilities of the patients could not be determined based on the documentation provided, nor was there a clear definition of the limitations of the patients as it relates to the need for a power wheelchair.

We also noticed the same wheelchair accessories being provided to all beneficiaries without any medical documentation to support the medical necessity for these items.

A motorized/power wheelchair, standard weight frame (K0011NU) is covered when, 1) the patient's condition is such that without the use of a wheelchair, he/she would otherwise be bed or chair confined (an individual may qualify for a wheelchair and still be considered bed confined), 2) the patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually, and, 3) the patient is capable of safely operating the controls of a power wheelchair.

A patient who requires a motorized/power wheelchair usually is totally nonambulatory and has severe weakness of the upper extremities due to a neurologic or muscular disease/condition. Options that are beneficial primarily in allowing the patient to perform leisure or recreational activities are not medically necessary. A motorized/power wheelchair is covered only if the patient's condition is such that a motorized/power wheelchair is required long term (at least 6 months). (See DMERC Region D Supplier Manual Chapter IX pages 51-52).

It is also important to assure that you are using the correct code for the items you rent or sell. You can verify correct coding by contacting the Statistical Analysis DME Regional Carrier (SADMERC) - Palmetto Government Benefits Administrators.

Limitations of future claims:

The following coverage limitations have been imposed against your initial motorized/power wheelchairs (purchase) (K0011NU) because this code appears to be excessive (over-utilization).

For all initial claims for motorized wheelchairs (K0011NU for dates of service on or after August 13, 2000), the claim must be accompanied by additional documentation including, 1) Certificate of Medical Necessity, 2) Clinical records documenting the medical necessity for a motorized/power wheelchair; if used in the home and/or community, and the ambulatory status of the patient. Documentation should also address the reason for weak upper extremities and why the patient cannot propel a standard wheelchair (K0001). 3) Name, model number and description of the wheelchair together with a catalogue picture indicating the type of wheelchair provided. 4) For each wheelchair option a separate medical necessity statement should be addressed, 5) dated delivery and/or pick up slips for the items provided.

Claims should be submitted in paper form and sent to the attention of Sheila Tallent, Medical Review at the above address. If we determine the claims billed for this item are in compliance with Medicare policy, the requirement for additional documentation will be discontinued.

You should review your billing and business practices to insure that all Medicare policy and coding requirements are met. If there are extenuating circumstances, which you believe will justify the practice aberrance described above, please forward this information to me so that we can update our files. If, however, you identify any problems as a result of your review, these should be corrected as soon as possible. Medicare regulations stipulate that we continue to review the practice of any provider who has required corrective action. Therefore, prepayment screens and/or other corrective actions could be applicable in the future.

We wish to take this opportunity to advise you of the importance of adequately documenting a patient's records. If questions are ever raised as to the validity of the items billed, Medicare can only pay for those items, which are actually documented. Therefore, in cases of controversy, thorough documentation may be the supplier's only incontestable source of proof of services. Billing for items for which there is no supportive documentation can be construed as possible fraud.

If you have any questions about the issues discussed herein, please write to me at the address above or you may call me at (615) 782-4500, extension 28805.

Sincerely,

Bernadette Doig, RN
Medicare Policy Analyst

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

Attachment C-2

APR 2 6 2001

Dear Ms.

This is in response to your recent letter concerning medical review and documentation issues raised at our March 20 meeting.

We have discussed prepayment review status with CIGNA, the Region D Durable Medical Equipment Regional Carrier (DMERC). CIGNA has informed us that they placed your company on pre-payment review because you did not supply medical records as CIGNA requested during their performance of a Focused Medical Review (FMR). To this point, you have continued to supply only the claim and CMN despite repeated requests by CIGNA for you to provide additional supporting documentation.

I want to clarify several points about medical record documentation. Many claims submitted with a properly completed and accurate CMN are paid. DMERCs may perform more complex medical review of claims either before or after making payment. During this review, the DMERC can request medical records to support that an item is reasonable and necessary. If the DMERC does not receive the records it requests, they may view the service as not medically necessary and can deny the claim.

CIGNA found the ten claims in the FMR sample to be not medically necessary because you failed to provide the medical records. The subsequent denial of those claims constituted adequate basis for initiating prepayment review of future claims. While CMNs provide information needed to determine the medical necessity of an item, they do not constitute the totality of information needed by the DMERC in order to perform more complex review. DMERCs expect to find contemporaneous information in the medical record to support the CMN and the need for the items provided. The DMERC has authority to request to see this additional information in order to verify that the CMN accurately reflects the patient's condition.

The quote you cite: "Billing for items for which there is not supportive documentation can be construed as possible fraud" is not in error but is probably too strongly worded. A pattern of continued billing for which no documentation can be submitted, despite notification of documentation deficiencies and efforts to educate the provider on documentation requirements, could be referred for investigation of potential fraud.

Based on our review, we believe CIGNA correctly initiated prepayment review based on insufficient documentation to support medical necessity in the postpayment review of the ten-claim sample. Requests for additional documentation for ongoing prepayment review are essential to ensure accurate medical review determinations, and I would encourage) to comply with the DMERC's requests.

I hope this information is helpful to you.

Sincerely,

Beth Giebelhaus
Director
Division of Medical Review

cc: Tim Hill
Valerie Eastwood
Mary Rheinecker, RN CIGNA
Dr. Robert D. Hoover, Jr. CIGNA