CMS: NEW NAME OR SAME OLD GAME?

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CMS: NEW NAME, SAME OLD GAME?

THURSDAY, MAY 16, 2002

House of Representatives, Committee on Small Business, *Washington, DC*.

The Committee met, pursuant to call, at 9:45 a.m. in Room 2360, Rayburn House Office Building, Hon. Donald Manzullo [chairman of the Committee] presiding.

Chairman MANZULLO. The Small Business Committee will come to order.

I have been advised by Mr. Pascrell that he has to leave in 20 minutes, so what I am going to do is I am going to postpone my opening statement and fit in so that Members that have to leave right away can get their's in first.

Mr. Pascrell, if you could limit your opening statement to say three or four minutes then we will go to Mrs. Kelly.

Mr. PASCRELL. I will be quicker than that.

Thank you, Mr. Chairman. Thank you for bringing us together. Thank you, Mr. Scully for being here. It was an interesting meeting the last time without you. It will be an interesting meeting with you today.

I am very concerned, and I will go right to the point, the 110,000 pages of Medicare rules, policies and regulations. In a recent AMA survey more than one-third of the 650 responding physicians report spending one hour completing Medicare forms, administrative requirements. And through the Chair, through the Ranking Member, I am asking this committee today, one of our objectives, one of our main goals should be a reduction of that paperwork. The Pythagorean Theorem took 24 words, we have 110,000 pages. We keep adding to those pages. It is absolutely ridiculous. We are going in the wrong direction.

I believe there should be a policy of this Committee to ask of CMS that they reduce the paperwork involved with Medicare 10 percent every year for the next five years. It is not impossible to do. It is something that we should be directed to do.

Number two, you are part of a department that has an F rating in grading in terms of small business contracts. This is unacceptable to this Committee, regardless of which side of the aisle we sit on. I am asking you to give us a floor plan by which you, in your own department, in your own division, is going to increase the opportunity for small businesses throughout this country.

The secretary has to do his homework, but each of the directors of the administration or agencies have to do their's. Mr. Chairman, that is totally unacceptable as well. I welcome Mr. Scully, and I thank you, Mr. Chairman, for giving me that quick opportunity.

Chairman MANZULLO. Thank you, Mr. Pascrell.

Mrs. Kelly.

Mrs. KELLY. Thank you, Mr. Chairman.

I simply want to say that I think this is a very important hearing that we are holding today.

I also want to go on record as saying that I think that most of us in this room understand that there is a great deal of work that needs to be done at CMS.

I also want to thank Mr. Scully for being here today and for the work that he has begun at CMS and that I hope he will continue. My dealing with CMS under Mr. Scully have been such that I feel they are looking at new ways of approaching things that perhaps will come to the benefit of all of us. So I thank you very much, Mr. Scully, for being here today.

Chairman MANZULLO. Dr. Christensen?

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I will be brief, and I hope I will be able to return.

I want to welcome the witnesses, I want to welcome you, Mr. Scully.

I am looking forward also to this hearing being one where we can resolve some of the issues. We are not here to point fingers and cast blame. We know the mammoth bureaucracy that you are working with. But at the end of this day I would like to see a couple of issues resolved.

My first one that I want to reference is a carrier issue, the contractor issue. When you were here for your first hearing you indicated that one of the priorities was going to be contractor reform. It is my understanding that it is not happening. It feels like a broken promise to me. I get the same complaint from my physicians day after day. Based on what I heard at your first hearing I asked them to be patient, to hold off on their request for a change of carrier because the system was going to be reformed.

I have here a record from a physician where, this is just one of many. This is an example of denied claims. It was stated in our calls to CMS that the point of service was incorrect. The point of service is correct, and payments have been delayed for this provider for months. He has not been able to get a response from our carrier. So I need to have some clarification on when—

Chairman MANZULLO. What I would like to do is I would like the affirmation of Mr. Scully that we will have an answer to that letter delivered to your office with a carbon copy to me and Mrs. Velazquez, delivered by personal carrier, signed for in receipt within ten days.

Can I have your assurance on that?

Mr. SCULLY. Sure. Absolutely.

Chairman MANZULLO. If you need more time than that, it has to come from the carrier and we can understand that, but if you can get back within ten days, let us know what timeframe they would need to get back to Mrs. Christensen in.

Mrs. CHRISTENSEN. Actually, we want to sit down and talk to some of the people in your agency because this is just one example. The claims were clean, and yet they were denied, and yet he has been unable to get a response. That response is in progress now, but they still insist the claims were not clean.

The other one is the provider payment issue. You have long held that you do not have the administrative authority to fix that. From all that we have been able to read and research, and several legal opinions that have been given, you do have the authority. Doctors' offices are closing, other provider offices are closing. We are facing a major health care catastrophe because of the cuts to provider payments. Not the first, and from what I understand it is not proposed to be the last. We need to correct it now.

So I am hoping, again, what I would like to see at the end of this hearing is that we reach some resolution on that.

Thank you, Mr. Chairman.

[Mrs. Christensen's statement may be found in the appendix.]

Chairman MANZULLO. Mr. Davis, did you have an opening statement?

Mr. DAVIS. Thank you very much, Mr. Chairman, Mr. Scully and colleagues. I certainly want to appreciate the fact that you are here.

My statement will be actually very brief. Let me just say that I think I understand the role and function of your office and I am not sure that I envy the task that you have. As a matter of fact I recall when this agency was established with the idea that cost containment was absolutely essential and necessary; that there was too much waste and corruption in health care; and somehow or another we had to ferret some of that out.

I have watched over the years the administration of the agency and the work that it has done, and there seems to be some thought that while the agency has carried out its functions well that it might have gone a bit overboard, and that there might be instances where rather than making sure that there is legitimacy of claims and there is the opportunity for people to be reimbursed for the work that they have done, that there is an over-zealousness on the part of some components that have actually boggled things up and have helped to create the crisis that Delegate Christensen was talking about a moment ago.

So I simply want to share that with you. It causes me a tremendous amount of consternation. I represent a district that has 23 hospitals in it, 25 community health centers, the number of nursing homes I cannot even remember, home health agencies and others. I guess about half of our problem case work really deal with businesses indicating that they are on the verge of going out of business, that for some reason or another they simply cannot get reconciliation of difficulty that they are having.

So I thank you very much for being here and look forward to your testimony.

Chairman MANZULLO. Mr. Bartlett, do you have an opening statement?

Mr. BARTLETT. No.

Chairman MANZULLO. Thank you. On July 25th of 2001, Administrator Scully voluntarily appeared before this Committee and stated that he intended to meet the goal of not simply changing the name of HCFA but changing its culture. Nearly a year later the new name has been on HCFA's door but this hearing examines whether it is still the same old game. By that I mean is HCFA still being intransigent and unresponsive to health care providers and to the elected officials that make the laws, the United States Congress? Is HCFA still imposing undue and unnecessarily regulatory burdens on small businesses?

At our last hearing which if Mr. Scully had decided to attend as opposed to not complying with a validly issued congressional subpoena, he would have heard the devastating and heart-wrenching testimony from various providers about the regulatory burdens that are driving physicians out of Medicare.

Dr. Warren Jones, one of the most esteemed African American physicians in this country, an instructor/professor at the University of Mississippi, traveled all the way from Jackson to be here to be at the same dais as Mr. Scully to present to him personally the concerns of the people that he represents in his profession. He is the President of the American Academy of Family Physicians, a guest of Dr. Christensen. He noted that there are physicians who are now funding practices out of their own financial resources. He was also instrumental in demonstrating a chart that he showed to the people here in this Committee room, that if the cuts continue in Medicare that the rural areas of this country will be devastated, especially with the second round, to show that most Americans will not have the availability of health care services.

In such a situation it is going to be impossible for young physicians with substantial debts to provide care to Medicare patients, and that is why at a number of medical schools in this country the enrollment and the people seeking application has actually gone down.

Mr. Scully would have heard from Dr. David Nielsen, the incoming Executive Vice President of the American Academy of Otolaryngology about how reimbursements for Medicare do not take into account the new regulatory burdens such as the availability of translators for patients whose first language is not English; could have answered questions about what discretion Mr. Scully has, and it appears to be substantial, to modify the various components of the physician fee schedule to help physicians.

Today's hearing will present equally wrenching testimony. We will hear about the economic and emotional toll that occurs when health care providers are audited without rational basis. At this table today is my chiropractor who along with his two brothers was terrorized, I mean terrorized, by HCFA when they were presented with a bill for \$250,000 claiming that these three boys were out scamming the system. By the time we finished working with Dr. Hulsebus and HCFA, it was obvious that the people at HCFA had absolutely no practice, no experience, no expertise, no rules, no guidelines, nothing. Helped them in no ways. The fine went from \$250,000 down to a compassionate zero, then up to \$40,000, then back to \$1500, and Dr. Hulsebus took it up on appeal, won the appeal with the Administrative Law Judge excoriating HCFA for the way it treated him, and then with HCFA having the nerve to finalize and try to appeal that \$1500. We wonder where all the money is going. It is going to the bureaucrats in HCFA instead of to the providers in America who have the obligation to provide health care to the American people.

HCFA is an agency charged with protecting the health of the Medicare Trust Fund, but as we will hear today HCFA makes decisions that squander those resources by driving portable X-Ray and electrocardiogram providers out of business. Without this service, residents of skilled nursing facilities must be transported via much more expensive and reimbursable ambulance services to hospitals or to clinics.

We will hear about physicians following the advice of their carriers only to be told by HCFA to complete reimbursement forms in a different manner. We will hear about carriers in one state denying coverage for medical procedures that are covered in bordering state. We will hear from physician providers of durable medical equipment supplies about their need to second-guess Certificates of Medical Necessity that are signed by a physician.

But as a result of the inefficiency of HCFA, health care costs more. The agency itself is the most egregious offender of waste, fraud and abuse, all to the detriment of the American people at large and medical providers in particular. And Mr. Scully, 99 percent of these regulatory decisions were made before your watch.

Given these facts, it is no wonder that physicians and other health care providers are abandoning Medicare patients in record numbers. To them, it is simply not worth wading through the morass of red tape to obtain paltry payments that failed to meet their costs and then have the integrity, second-guessing the guys protecting against waste, fraud and abuse.

The question remains, who will protect the providers from harassment and unnecessary regulatory burdens? Something must be done and it must be done soon.

This Chairman will do all in his power to help these small health care providers and HCFA needs to step up to the plate. First, it must, it must reduce the inconsistency and decisions made by its contractors. If this requires HCFA to proffer more nationally applicable regulations such as national coverage determination, so be it. Second, HCFA must direct its carriers to direct an audit process that is fair and rational as opposed to the star chambers that take place across this nation. Third, HCFA must do more to ensure that its regulations and guidance are properly assessed for their impact on small health care providers. By doing this, HCFA will meet the President's goal that all agencies comply with the Regulatory Flexibility Act. And finally, HCFA must demonstrate that it is responsive not just to the Ways and Means Committee or the Energy and Commerce Committee, but to all committees of Congress including this Committee.

We are willing to work with HCFA, willing to entertain HCFA's name being changed to CMS, but at this point we are going to call it HCFA because the proof is not yet there, but we are open to it. We are willing to work with HCFA to help it improve compliance with the Regulatory Flexibility Act and take other actions to reduce regulatory burdens. That requires Administrator Scully and the rest of HCFA to be responsive to this Chairman, the Ranking Member, and our staffs.

We welcome all of you witnesses here. Mr. Scully, thank you for coming. You are appearing today on your own. I just want to say thank you to all the witnesses that are here. Let me instruct all the witnesses to tell your stories as they have happened to you. You do not have to read them. Mr. Scully is here to listen to your stories, and he has advised us by letter that he is willing to help. So any time an Administrator says he is willing to help, let us take him up on it. Okay?

I have the assurance that he is willing to work with us, that he is willing to help, and that is why we are having this hearing today.

So I would yield to my Ranking Minority Member from the great State of New York, Mrs. Velázquez.

[Chairman Manzullo's statement may be found in the appendix.] Mrs. VELÁZQUEZ. Thank you, Mr. Chairman. Good morning and welcome.

Today is the sixth in a series of hearings we have convened to examine the Center for Medicare and Medicaid Services. I believe that these hearings have made clear that we have a pattern of communication breakdown between the agency and its stakeholders, which I believe CMS needs to keep in mind are not just Medicare and Medicaid recipients, but also health care providers.

There has also been a breakdown between the agency and the congressional committees that have a constitutional duty to ensure that you are properly fulfilling the agency's mission.

Regulatory agencies like CMS must evolve from a command and control mentality where the agency says we will tell you what you are going to do and you will do it; to an atmosphere of partnership and compliance assistance. By creating a partnership your stakeholder becomes invested in your mission. Now we have heard that CMS has engaged in a new customer service practice for Medicare and Medicaid recipients, but this new approach also needs to be expanded to the industries that you oversee in order to be fair and effective. The name may have changed but the game is still the same.

This can be done through outreach and consulting because when agencies invest in this partnership up front it will pay dividends later on. Tools like regulatory negotiations where agencies work with stakeholders yield regulations that have higher compliance rates and operate more efficiently, which means savings for the government and small businesses. They also create a better-informed stakeholder that is less likely to have trouble later on.

This has not been the case with CMS. This agency's record is very inconsistent. Recently it proposed a Medicare drug card program developed behind closed doors that promises only very limited benefits to seniors while destroying a critical part of our health care system, your community pharmacist. CMS still does not seem to grasp the concept that Reg Flex and SBREFA were created for a reason. These laws serve an important purpose. They protect the interests of small businesses to ensure they are not negatively impacted or overly burdened by an agency rule in the pipeline.

CMS has ignored the requirements of Reg Flex and SBREFA. As a result, small businesses suffered from regulatory burdens and complex paperwork. The regulatory compliance process is confusing and time-consuming, but by using the two tools of Reg Flex and SBREFA, agencies can ensure that regulations are fair, balanced and still provide the necessary protection to our health, welfare and environment. CMS must do a better job of working to determine the impact of their regulations on small businesses, explore the regulatory options for reducing that impact and work with their affected stakeholders.

I believe, that given the culture of CMS, this Committee should give serious consideration to not just expanding SBREFA to the IRS but should also include CMS. The arrogant, aloof and distant culture of CMS is so deeply ingrained that I believe we must have a radical shift in how the agency approaches these issues if anything is to change.

It is my hope that today's hearing can serve as a starting point to change this adversarial relationship into one of partnership. There is no disputing the goal of protecting the health and welfare of those who use our Medicare and Medicaid programs. Now there needs to be a reconciliation between CMS and its stakeholders.

We are all in this boat together. We can either row together in one direction or as three separate antagonists and keep going in circles without any improvement to the existing system.

Thank you, Mr. Chairman. I look forward to this hearing.

Chairman MANZULLO. Thank you. We have a journal vote and then there is not going to be a vote until late this afternoon, so we are going to stand in recess for a few minutes, then we will come back, then I will recognize Dr. Weldon for an opening statement at that time.

[Recess]

Chairman MANZULLO. Thank you.

We are going to have an opening statement by an esteemed Member of Congress from Florida and a medical doctor, Dr. David Weldon.

Dr. WELDON. Thank you, Mr. Chairman and Ranking Member Velázquez for the opportunity to sit in on this hearing, not being a member of the Committee. Though I think I am quite interested in the testimony and the issues that we are dealing with.

Let me just say for starters, Mr. Scully, I do not envy the position that you are in. I personally voted against the Balanced Budget Act of 1997 specifically because I thought the Medicare funding levels were grossly inadequate and I continue to hold to that position. I certainly would like to say that I am prepared to work with the Administration on the problems that we face in this area. I think we are really facing some very, very critical problems on a multitude of levels.

Regarding the main issue that the Chairman wanted me to address is my personal experience with portable X-Ray.

I practiced general internal medicine for about 15 years before I was elected to the House of Representatives. The first six years were in the United States Army Medical Corps and the last eight years were in private practice. In private practice I saw about 30 patients a day in my office and carried between five and ten patients in the hospital, and I also was one of the few practitioners who continued to manage his own patients at the nursing homes. This is where my experience comes to play. A lot of my colleagues would not follow their patients at the nursing home, would turn their care over to somebody else. So typically I would get a phone call from a nurse, at a nursing home, in between seeing my patients in the office, and the phone call would be about one of my patients in the nursing home who had a cough and a fever or who had fallen and hurt themselves. The decision to be made was do we load them in an ambulance and bring them to my office? Do we load them in an ambulance and bring them to the emergency room? And fortunately, I have to say, the other choice we had was in many cases to utilize some of the diagnostic studies that we had available to us right there at the nursing home. We could have outside medical labs come in and draw blood if I wanted to see a white blood count. Fortunately, in a multitude of instances we could get a portable X-Ray.

The service that I received, let me just say, was outstanding in that the portable X-Ray people would frequently go to the nursing home and obtain the X-Ray often more quickly than I could get it in the emergency room at the hospital. Then they would develop the film and take it to the radiologist and the radiologist would call me. I would literally say cough and a fever, let us do a chest X-Ray, I need to make a decision about antibiotics in this patient. They are very old, enfeebled, let us try to avoid putting them in the hospital. They are an associated list of hospital complications that you could run into. I would get a phone call from a radiologist telling me that the chest X-Ray is normal, or the chest X-Ray shows an infiltrate in the right lower lobe. With the new antibiotics, I could put these people on oral antibiotics. And the bottom line here, and this is the main point I want to share on this issue, and I know there are a lot of other issues before the Committee that you are wrestling with but this is the main thing that I was asked to comment on today, was that I felt in the vast majority of instances we provided better care at reduced cost by making use of those services. I found the quality of the service that I got in the sense that I got a phone call from a radiologist, unlike the emergency room where I would have to go over to the hospital, find the X-Rays, track down a radiologist to look at the X-Rays with me if I have a question about the X-Ray and did not trust my own interpretation of it, I would be getting a phone call from a radiologist.

In my opinion it served the taxpayers very very well the way we utilized that in that dramatic amounts of funds were saved. To put a patient in an ambulance, send them to the emergency room, you have the emergency room charge, the ambulance charge, you have the emergency room doctor's charge, and then you would have all the associated labs. And frankly, I always felt when they went into the emergency room they did too many studies, and we all know why they do that, because they are afraid of lawsuits from trial attorneys, so they do every single test possible when they roll into the emergency room to keep them out of court. It is often not what is in the best interest of the patients.

So I have been of the opinion that these services are extremely valuable and that CMS should be supportive of the service because it does ultimately in the end keep people from ending up going to the emergency room.

And might I also add, frequently once they are in the emergency room you end up admitting them to the hospital too. And so in some cases I think you are actually talking about possibly thousands and thousands and thousands of dollars in costs that are actually saved simply by having this portable diagnostic service.

We also make use of it in portable EKGs as well. But the portable X-Ray to me was just wonderful.

I thank the gentlelady for the opportunity, and thank the Chairman for the opportunity.

Chairman MANZULLO. Thank you very much, Dr. Weldon.

Mr. Scully, let me give you an option here. I have you number one out of the box without the five minute clock because they have individual disciplines and you, unfortunately, have all of them. But I want to give you the option to lead off or to be cleanup. If you want to go last and have the opportunity to listen to the people and then perhaps comment on that, or if you want to go first. It is your option.

Mr. SCULLY. What do you prefer, Mr. Chairman? Either way is fine. I can go quickly first and then comment at the end.

Chairman MANZULLO. That would be fine.

Mr. Scully, I am going to set a ten minute clock, but again, if you need more time, please, and we look forward to your testimony.

The complete statements and the Members of Congress will be made a part of the record without objection.

STATEMENT OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. SCULLY. Thank you, Mr. Chairman.

First I just want to say, Mr. Chairman and members of the Committee, I apologize for not being here on April 10th. I think we discussed that. I am sorry I was not here. I apologize to the Committee and the Members. I appreciate greatly the Chairman's willingness to be understanding about that and move on to what we are here for.

Chairman MANZULLO. Mr. Scully, your apology is accepted. I agree with you that the main mission here is to provide the best health care to the American people and also the best possible system to the health care providers and it is time to move on.

Mr. SCULLY. Thank you, Mr. Chairman.

Obviously I run a huge agency. Our budget, if you count Medicare and Medicaid, both halves of Medicaid, it is about \$550 billion this year which is sometimes hard to even comprehend. But I came out of the health care sector a year ago and I think we have tried from the first day to be focused on trying to help small businesses and be focused on making this very large, two large, very large programs, easier to deal with.

Medicare in particular is really run, we have 4800 employees at CMS. Most of them are policy people. Medicare as I am sure most of your witnesses will get into this morning, is really run by contractors. We have 50 of those nationwide. Actually as of next week it will be 49. Some of the frustration, obviously I am responsible for all those, but from the beginning one of the things I have tried to do is reform that.

The House, which we are very happy about, passed the reform bill last year I think 410 to 5. The bill is in the Senate. We have made a lot of progress and I have worked a lot with Senator Baucus and Senator Grassley on the Finance Committee and we are very hopeful that we will get contract reform that will at least allow us a little more aggressively to try to fix a very large, very unwieldy system, once we get that bill passed I hope in the Senate, and I am pretty certain it will happen this year.

I read Mr. Sullivan's testimony from the first hearing as well as the other witnesses, and I agree with a lot of it. I agree with most of what I heard this morning. In fact one of your members, Mr. Pascrell, suggested that we have a ten percent a year reduction in paperwork for five years. I think that is certainly Secretary Thompson's goal and certainly mine, that might even be a little modest. I hope I will tell you about some of the things we have already done on that front.

Additionally, Ruben King-Shaw who is my Deputy and the Chief Operating Officer of the agency and a number of my members of staff have met with Mr. Sullivan and his staff a lot in the last couple of weeks and I hope we are making some progress with the FDA both on working more cooperatively with the SBA as well as with the RFA. Also by coincidence I have basically three major subcomponents of the agency. We have not actually announced it yet but I will say, just somewhat by coincidence, but somebody from the Small Business Administration actually starting in a few weeks will be running a third of the agency so that will probably additionally add to the sensitivity of the agency.

Let me add a couple of other points about RFA. We are very concerned about making sure we are responsive to that.

The fact is the agency is so large and with things like portable X-Ray suppliers, portable EKG suppliers, no matter how aggressive we are in doing our RFA sensitivities, the reality is to make the agency and its rules really sensitive to the impact of every small provider we affect is pretty tough because they are just huge programs. Medicare is \$260 billion. The physician payment component of which the portable EKG and X-Ray suppliers for instance come out of is about \$66 billion this year and those two programs alone are probably around \$170 million. So trying to make these huge regulations and huge payment systems sensitive to every provider group is tough to do. We can do RFA impacts and we will do them aggressively, but my view of this and the Secretary's in the beginning has been to try to open up the process at the agency. We have tried to aggressively do that.

One of the things we have done to make it more understandable to the outside world because I do not believe you should have to hire a lawyer at \$500 an hour to interpret what is going on at HCFA/CMS, is to try to make our regulatory scheme more predictable. Last year we came up with a quarterly compendium. If you are an outside provider this is just the beginning of some of our remedies, hopefully. Every regulation that we are going to put out, every major program memorandum is published ahead of time so once a quarter there is a memorandum that is out put in the Federal Register saying what we are going to do once a quarter. So if you are worried about being regulated as a portable EKG supplier or a nursing home, if it is not out at the beginning of the quarter we are not going to do it that quarter.

Additionally, we put out every regulation once a month so that people do not have to read the Federal Register every day. We put out I think more regulations than anyone in the government most likely. Our goal here is to at least be sensitive to the fact that once a month people that are being regulated by us can look in the Federal Register once a month. Hopefully for a lower volume and smaller regulations, but at least it is a little more predictable.

The other thing we have done is I have created 11 what we call open door policy groups which may sound bureaucratic, but you remember that Mrs. Clinton was sued for having policy meetings that did not have open doors, so we call them open door policy groups. Anybody is welcome to be involved. Anybody in the industries that are affected and virtually every sector of health care is one of the 11. I chair three. I chair one on diversity along with Ruben, my Deputy. I chair one on rural health care and one on nursing homes. There is an open door group for physicians, there is an open door group for hospitals, home health, dialysis, virtually every sector of the health care field has one involved.

So far with these 11 groups we have had more than 50 meetings in the last 11 months. We have over 1,000 actual individuals come to CMS either in Washington or Baltimore and meet with me and my staff personally. All of these generally have a 1–800 call-in number. We have had 3700 people on these phone calls. The ones that I chair get together at least once a month, usually it is every three weeks, and for an hour and a half I sit around with the staff, whether it is rural health providers or nursing homes, and for an hour and a half we sit around and answer questions and sometimes they are extremely obscure and extremely technical and they are not, we are not trying to replace what the Washington trade associations do. We are trying to have home health aides in rural Montana, if they have a gripe about the program will have a place to come through and get their issues fixed.

I would note we cannot fix everything. The first long term care open door policy meeting I had last summer was at the National Governors Association. The long term care group is co-chaired with Ray Chapak and I. Ray is the head of the National Governors Association. Because this issue involves Medicaid and the state so much.

The first half of that meeting was with the portable X-Ray providers, and for the first 45 minutes of that meeting we spent time talking, the first meeting I had last summer, talking about portable X-Ray providers. They have a lot of problems obviously which I am sure we are going to discuss today. But from the first we have tried to be sensitive to that and open up the agency to give people access to the policymakers in there.

I personally probably answer 40 to 50 e-mails a night from patients, nurses, patient advocates, hospital administrators, people around the country. I think the volume is growing so at some point I might not be able to do that forever, but at least for now we have tried to be as responsive as we can to people around the country that have problems with the agency and obviously that is a very large number.

As far as RFA compliances, we have tried to be open with the SBA. We have had over 100 CMS staff trained on the RFA compliance with over 600 hours of training. I am not aware that there is any other statute related to the agency where we have spent more time doing staff training. But we are trying to be responsive to that.

Let me briefly run through and I will do it later more in response to the other witnesses, some of the points you have raised about various industries, and you have raised a lot of valid points as have other members this morning.

There is a problem with obviously EKGs in nursing homes. There was a ruling made on that in 1997 by the previous Administration. We had covered transportation for nursing homes for EKGs. That rule was changed in 1997. The agency has not felt that it has statutory authority to overturn that, although we have looked into it extensively.

On portable X-Ray suppliers, we do pay for transportation. It varies by region, by local carrier. It is usually about \$100 for a portable X-Ray supplier to transport an X-Ray to a nursing home. I agree that is a very useful issue. They are feeling a lot of the pressure that other providers are feeling this year and that there was a negative 5.4 percent update in the overall \$66 billion pot that physicians and portable X-Ray suppliers are paid out of.

We work with the AMA and their relative value committee to decide relatively who should take what increases or reductions every year and the recommendation of that group was for an 11 percent total reduction this year so I am not surprised that portable X-Ray suppliers are feeling a lot of heat and more than some of the other people in the industry. But as many of you have mentioned, I hope, that we are working hard with the Commerce and Ways and Means committees to fix the physician update formula which has some significant glitches in it right now before we go out this year, and we are fairly confident that will happen.

You also mentioned the hospital restraint rule and I have talked to you about the Merry Walker and other things. I personally, again, the one hour restraint rule was something that was done a few years ago. There is a lot of patient interest behind that. I do not think we can reverse it without significant public discussion with patients. I happened to have run a hospital association for the last six years before I took this job. I personally believe the restraint rule is unworkable and is an unrealistic burden for a lot of rural hospitals, but I do not think we are going to change it without a significant discussion about the impact on patients because there have been significant problems with patient restraints in the past.

You have mentioned repeatedly the MDS reductions. One of the first things the Secretary and I did was we eliminated the MDS which is the nursing home form for critical access hospitals. They are no longer required to file it. We did that a couple of months ago. I do not want to preempt the Secretary, but I think you are going to see the Secretary give an announcement fairly shortly on some very significant nursing home data reductions on MDS which I think will be a step in the right direction.

I will not go through all the other things, I will wait until your witnesses go through here, but I would be happy to comment on pain management, on chiropractors. Obviously we talked last summer about one of our carriers probably clearly overly harassing chiropractors in your district. I hope we have made some progress on that.

But generally I think the Secretary and I are committed to opening up the agency, talking to the constituencies. We have made a very aggressive effort to do that. I think if you ask the rural hospitals, rural physicians, nursing homes, nurses, home health agencies, I hope you will find that they found the place to be much more open. Everybody always wants more money for Medicare. We cannot always do that but I think hopefully you will find that most of the providers we deal with have found at least some marginal improvement in openness and accessibility of the agency. We have made a big effort to do that.

I have gone around the country already and had 21 town hall meetings all with members of Congress to talk about these issues and most recently in Seattle and last week in central Massachusetts and on Monday in Connecticut. One thing I can assure you is nobody is happy with us but we are doing the best we can to shake up the agency, turn it around, make it more responsive. A lot of these issues are legislative. A lot of them have to do with Medicare payment formulas that are very arcane that have been around for years, that we are going to work with you and the committees to change, and hopefully you will find that at least the rules will be a little more fairly implemented, we will be a little more open to constructive criticism, and we will be a little more responsive.

But it is a big, big ship to turn. I cannot tell you that we can turn it immediately, but we are doing the best we can to try.

Thank you, Mr. Chairman.

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

Chairman MANZULLO. Thank you for your testimony.

Before I go to the next witness I just, I am stunned to hear you say that CMS has 4,800 employees. The agency is so large that it is "tough to consider every provider".

Mr. Scully, those providers are small business people and they have been wounded, grievously wounded by HCFA, and you do consider them. You chop their rates without considering the cost to the American people or what it does to these people whose lives have been wiped out because they are too little to be considered, "tough to consider every provider".

What I want to impress upon you, I want every provider considered or do not lower the rates. And that is exactly what you are doing. You lower the rates and you do not do the analysis. We can continue that as we go through here.

Mr. SCULLY. I think we do consider every provider. My point on that is, just for example, the portable EKG providers and the X-Ray providers, that \$66 billion pot of money, it is all statutory. It is adjusted by statute. The rates are not reduced by us, they are reduced by statute. The formula that they are involved in is basically set up by the AMA.

So I am totally sensitive to it, I just think, my point is that I do not believe the RFA requirements are actually——

Chairman MANZULLO. And that is precisely the point. You see the purpose of the RFA is to protect little people. Those are small business people. They are being rolled over by a steam roller called HCFA. And with 4800 employees, if you do not have the time to consider every medical provider, that is pretty gross mismanagement.

Let us get on to Mr. Sullivan.

I am going to set the clock at five minutes. And again, Mr. Scully, 99 percent of those regulations were set before your watch so I am not blaming you personally, but you are having the opportunity to work on these and we would love to work with you on those.

Mr. Sullivan.

STATEMENT OF THOMAS SULLIVAN, CHIEF COUNSEL FOR ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION

Mr. SULLIVAN. Chairman Manzullo, members of the Committee, good morning and thank you for the opportunity to appear before you this morning to address how government agencies, specifically the Centers for Medicare and Medicaid Services, CMS, can benefit small business by considering the consequences of their mandates on small employers before they regulate.

On April 10th I appeared before you to testify on CMS' compliance with the Regulatory Flexibility Act and whether such compliance could be expected to resuscitate small health care providers. I testified then and I stand by that prior statement now, that it was Advocacy's goal for CMS to consider more fully the consequences of their regulatory actions on small health care providers prior to finalizing their rules as required by the Reg Flex Act.

We have learned at Advocacy that early intervention with administrative agencies prior to the promulgation of their rules does work. It serves to minimize the impact of rule makings on small businesses without compromising the underlying mission or statutory requirements of the agencies.

During my closing remarks in April I indicated a desire and willingness to work with CMS early in its rulemaking process. This I felt was consistent with President Bush's decision on how to protect small business, and Secretary Tommy Thompson's plan to reform the regulatory process within HHS.

I am pleased to announce that since my testimony on April 10th, my commitment to this committee to work with CMS has begun to take shape. On April 22nd I met with representatives from Mr. Scully's front office and from HHS' General Counsel's office, and last week I met with Mr. Scully's Deputy, Mr. Ruben King-Shaw.

These meetings helped start a new dialogue between my office and CMS. The meetings focused on general, small business issues and data gathering mechanisms. The meetings resulted in a commitment between the Office of Advocacy and CMS to work together in a concerted effort to reduce the impacts associated with CMS rulemakings on small health care providers.

It is my hope that this recent contact between our office and CMS is only the beginning. I look forward to maximizing this new relationship that has been developed since I appeared before this Committee in April. This can only result in cost savings for small business and in better communication and action between my office and CMS on the issues that are of concern to all of us this morning.

Thank you.

[Mr. Sullivan's statement may be found in the appendix.] Chairman MANZULLO. Thank you.

The next witness will be Mr. Zachary Evans who is Chairman of the Board of the National Association of Portable X-Ray Providers out of St. Joseph, Missouri.

Mr. Sullivan, I am sorry I did not introduce you as Chief Counsel for Advocacy of the U.S. Small Business Administration.

Mr. Evans, we look forward to your testimony.

STATEMENT OF ZACHARY EVANS, CHAIRMAN OF THE BOARD, NAT'L ASS'N OF PORTABLE X-RAY PROVIDERS

Mr. EVANS. Thank you, Chairman.

I am the Chairman of the Board for the National Association of Portable X-Ray Providers. I am pleased to have this opportunity to testify before you again today. Mr. Chairman, the plight of portable X-Ray providers has been described by CMS as very complex. They inform us that they have no cost data on our industry and therefore cannot perform the regulatory flexibility analysis required by law.

Chairman MANZULLO. Let me interrupt you. That statement that you just made came in a letter that was sent by Mr. Scully to my office within the last couple of days. Is that correct? That they have no cost data upon which to—That is the statement?

Mr. Evans. Yes, sir.

Chairman MANZULLO. Go ahead. I just wanted to verify the source of that.

Mr. Evans. Yes, sir.

Chairman MANZULLO. Go ahead.

Mr. EVANS. They assure us that their policies are appropriate, although they cannot provide any empirical evidence to support their position and discard any data that supports opposing views. They refuse to answer the most basic questions posed by providers or to meet with us when we come to Washington seeking guidance, yet boast of their openness and responsiveness.

I appear before you today to explain simply and accurately and fairly the costs of our services and the cost of the alternative. You will see that in fact this situation is not particularly complex. You will see that a side-by-side comparison of the cost of portable X-Ray services versus the cost of transporting a patient to the hospital provides a clear—

Chairman MANZULLO. Excuse me a second. We need to be able to look at them on this end here. Maybe you could—

Mr. EVANS. These are attached to my testimony also.

Chairman MANZULLO. Okay, thank you. Proceed.

Mr. EVANS. Would you like those turned around—

Chairman MANZULLO. We have it before us, so that is fine.

Mr. EVANS. The charts we have prepared illustrate the cost of providing 3.5 million portable X-Ray procedures which were performed according to CMS in 2000 in a very conservative estimate of the cost of the services had they been performed at a hospital after transport by ambulance. The chart displaying the portable service cost is based upon national averages for the three component costs of portable services transportation, set-up, and the technical component.

Again, using the CMS figure—

Chairman MANZULLO. Mr. Evans, excuse me. Which chart is it that you are referring to?

Mr. EVANS. It should say Portable X-Ray Services Annual Cost to Medicare.

Chairman MANZULLO. Okay, thank you.

Mr. EVANS. That will be the first one. The second chart I will speak of is the one on, "If We're Gone."

Chairman MANZULLO. Go ahead.

Mr. EVANS. The figure of 3.5 million comes from CMS and we find that the average costs of \$284 million in transportation; \$38.5 million in set-up; and \$63 million in the technical component for a total of \$385.5 million.

If we very conservatively estimate the cost of performing these same 3.5 million procedures at a hospital, which will be the outcome if current CMS policies continue, we see the costs in the second chart. The technical component cost remains unchanged at \$63 million. The ambulance transport cost based upon CMS ambulance transport cost data contained in a March 12th CMS letter to you, Chairman Manzullo, is \$1.2 million. The hospital admissions cost is \$945 million. These costs total \$2,810,500,000. This means the result of a collapse of our industry which is going to be an eventuality will result in an increased cost to Medicare of nearly \$2.5 billion annually. Viewed alternatively, the portable X-Ray industry saves Medicare nearly \$2.5 billion annually while providing higher quality patient preferred services than the alternative.

To further illustrate our point we have provided, and this is also attached to my testimony, several examples of actual remittance documents or Medicare benefit bills. In the interest of time I will not take the Committee through these line by line but offer them as examples of the cost of ambulance transport, emergency room treatment, et cetera, as compared with the portable provider costs.

I would be happy to address the specifics of these documents during the question and answer period.

In summation, our industry provides vital, cost effective services that if CMS is allowed to proceed on their current policy course will cease to be available to the public. Not only will this policy failure result in dramatic cost increases, the quality of patient care will suffer significantly.

In this obvious truth my industry is confronted with punitive audits, regressive policy initiatives, unwillingness to respond to basic guidance inquiries, and overall contempt from an agency which spends millions of tax dollars telling America that they support small business and are solving problems through open door policy forums.

Mr. Chairman, I have attached a letter sent on December 13, 2001 to Mr. Scully requesting answers to fundamental guidance questions posed by our industry. CMS has never responded to that letter.

Sadly, this is not the exception but the norm. Speakers are unavailable, correspondence is ignored, and administrators refuse to appear before the Congress and small businesses because they do not like the seating arrangements. This was the behavior of HCFA and this is the behavior of CMS.

We applaud the tireless work of this Committee in the face of such unrelenting bureaucratic opposition to change and we sincerely hope that through the work of this exceptional Committee and a handful of caring, conscientious members of Congress—thank you, Dr. Weldon—we might serve to provide our services to our patients.

Thank you for the opportunity. I would be happy to answer any questions.

And I would like to state that I am in total agreement with you, Chairman Manzullo, that it is not Mr. Scully's fault. A lot of this stuff has come in Administrations before, but we need him now to help us solve these problems.

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

Chairman MANZULLO. He is here today.

Mr. EVANS. Thank you.

Mr. PASCRELL. Mr. Chairman, may I comment on that last comment?

Chairman MANZULLO. Yes. A little bit out of order, but go ahead.

Mr. PASCRELL. It sounds wonderful, now we have heard it twice, to say to Mr. Scully, and I am sure he feels very relieved at that, that the problems that are facing this department and division are the results of what has happened long before he became the Director. That is easy to say, Mr. Chairman. But the fact is that a new Administration has been there for 18 months, and the bureaucracy has not gone the other way, it has gotten worse. We had our problems with the last Administration. I think we crossed across aisles here, were non-partisan in making sure we got our positions well known. But if you are sitting there and telling me that this is an inherited problem, it has been 18 months and we are going backwards, and doctors are leaving the field every day. Every day. And people are not getting serviced every day.

Doctors are stopping to handle, in many areas of this country, Medicare patients. So do not tell me about the last Administration. You have blamed everything but the plague on them and I am sure that is next.

Mr. EVANS. May I comment?

Chairman MANZULLO. I want to proceed with the testimony. We will have a chance to interchange.

Our next witness is Brian Seeley. We welcome your testimony and look forward to it.

STATEMENT OF BRIAN SEELEY, PRESIDENT, SEELEY MEDICAL INC., ON BEHALF OF THE POWER MOBILITY COALITION

Mr. SEELEY. Thank you, Mr. Chairman, esteemed members of the Committee. My name is Brian Seeley and I am the President of Seeley Medical which is a small, family-owned business. We supply medical equipment and services to patients at home in Florida. I have owned the company since 1988. It was founded by my father in 1960 before there was a beast called Medicare.

I would like to thank the Committee for holding this hearing and appreciate the opportunity to present testimony today from the Power Mobility Coalition. While CMS has overall responsibility for the Medicare program, many of the responsibilities have been delegated to the Durable Medical Equipment Regional Carriers we know as the DMERCs.

CMS has allowed the DMERCs to administer policies that are in direct contrast to existing law. One example of this is the inconsistent application of the Certificate of Medical Necessity. The Certificate of Medical Necessity is defined by Congress, developed by CMS, and was formally approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act. The Certificate of Medical Necessity is signed by the patient's treating physician. This is the only medical record required to be submitted by a supplier to demonstrate medical necessity.

Several DMERC inconsistencies are displayed by the chart that is included in your statements and also up here.

Congress defined a Certificate of Medical—

Chairman MANZULLO. Excuse me. We do not know what is up there.

Mr. SEELEY. It is in your handout, Chairman.

Chairman MANZULLO. Could you explain what they are?

Mr. SEELEY. They show the inconsistencies between-----

Chairman MANZULLO. Could you turn those charts so the Members of Congress can take a look at them also. We like to know what he has reference to.

Mr. SEELEY. Congress defined a Certificate of Medical Necessity as a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary. CMS said that when it went through the OMB approval process, and I quote, "The information on the CMN is needed to correctly process claims and ensure that claims are properly paid. This form, the CMN, contains medical information necessary to make an appropriate claims determination." Here is what one of the regional DMERCs said about the CMN. "The mere existence of a signed CMN is not sufficient evidence of medical necessity."

Another example is the DMERC audit process and its inconsistencies with CMS policy. PMC members have been audited and assessed overpayments even though equipment was provided with the properly completed Certificate of Medical Necessity. Suppliers comply with the rules established by the Medicare program and are still penalized by new and arbitrary criteria developed by the DMERC.

Mr. Chairman, in your opening statement of the July 25, 2001 hearing of this Committee you said, and I quote,, "Contractors in interpreting the guidance provided by HCFA may require a durable medical equipment supplier to obtain more information before providing equipment specified in a physician signed Certificate of Medical Necessity. What purpose exists to have a non-physician second-guess the determination of a licensed physician?"

The PMC wants CMS and its DMERCs to conduct audits. The manner of the audit is the problem.

We think, for example, an audit should validate the treating physician who completed the Certificate of Medical Necessity, or as another example, validate that the beneficiary received the equipment ordered on a Certificate of Medical Necessity. The audit should not be an opportunity to second-guess the doctor's orders.

We have witnessed an increasing number of audits and medical reviews being performed in our industry without regard to rules established by Congress and CMS. In fact two DMERCs have recently conducted general investigations of our industry without complying with the PRA, the Paperwork Reduction Act.

While CMS indicated that the DMERCs do not conduct industry audits based on utilization, the facts show a different story. The Region C DMERC recently conducted an audit of the top 30 mobility suppliers based solely on utilization. And every supplier that provided more than six power wheel chairs per month was audited by the Region D DMERC.

We are concerned that general investigations of our industry will continue to hamper our ability as small businesses to provide equipment and services to Medicare beneficiaries.

As a side note, when I gave testimony to this Committee last July, as I gave my testimony an unannounced audit had taken place by CMS OF my coalition's president in his business.

Chairman MANZULLO. Excuse me a second. Would you say that again?

Mr. SEELEY. While I was testifying last July 11th, we found out, actually one of the lead attorneys found out that the President of the coalition I represent, his business was audited by CMS as I was testifying.

Chairman MANZULLO. What is his name?

Mr. SEELEY. That would be The Scooter Store, and his name is Doug Harrison. They walked into his offices as I was—It seems highly coincidental.

In conclusion, the Power Mobility Coalition applauds CMS for issuing a recent program memorandum entitled Cessation of Certain DMERC Activities. The Agency instructed the DMERCs to cease specific activity being imposed on power mobility suppliers. The agency stated that the DMERCs must not require additional information for all power-operated vehicle claims, and must not require additional documentation when a beneficiary progresses to a higher level piece of equipment.

The agency's program memorandum is a positive step in the right direction. We do caution, however, it does not address the inconsistent and arbitrary manner in which the DMERCs conduct audits.

Mr. Chairman and esteemed members of the Committee, thank you again for providing the Power Mobility Coalition with this opportunity to discuss these important regulatory and procedural issues.

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

Chairman MANZULLO. Mr. Seeley, before we proceed, you stated that the last time that you testified, the day before that the President of your society was subject to a snap audit?

Mr. SEELEY. No, the day of the testimony.

Chairman MANZULLO. The day of the testimony.

Mr. Evans, what happened to the President of your society the day that you testified?

Mr. EVANS. He was audited and in fact there is a letter to Ranking Member Velázquez that states that Mr. Cavalier of Cavalier Portable X-Ray was audited in December and that CMS had never audited them when in fact the letter is obviously in error. They were at his office the day of testimony.

Chairman MANZULLO. Interesting.

Mr. Evans. Yes.

Chairman MANZULLO. Two witnesses come before the United States House of Representatives representing two organizations and the Presidents of the organizations are snap audited by HCFA.

I want a full and complete investigation, Mr. Scully. I want a criminal referral if necessary. I want to know the names of every single person involved in that audit. I want that on my desk within 21 days.

Mr. SCULLY. I am happy to do that, but if I can comment on it. Nationwide apparently did an unrelated audit to the gentleman, in Ohio, and Nationwide is no longer our contractor.

Secondly, I have-

Chairman MANZULLO. But they work for you, all right? Mr. SCULLY. I understand, that, Mr. Chairman.

Chairman MANZULLO. They work for HCFA. All I am saying, we are going to move on, we will give you an opportunity to comment later, is the fact that as the Chairman of this Committee I am extremely offended that when I ask witnesses to come here to Washington they pay their own way, they testify here, and the presidents of their respective organizations are snap audited by the very organization that they come here to testify that is not working.

Mr. SCULLY. Mr. Chairman, if that is the case I will be every bit as outraged as-

Chairman MANZULLO. Mr. Scully does not say if that is the case, that is the case.

Mr. EVANS. Excuse me, Mr. Chairman-

Chairman MANZULLO. And that is why we are here.

Mr. EVANS. Mr. Chairman, I have a point that important that I put in here.

Chairman MANZULLO. I understand.

Mr. EVANS. It was not audited—He was audited by Nationwide months before. CMS, his agency, walked in for a snap audit. It was the federal government. It was not the carrier.

Chairman MANZULLO. I want to know the names-

Mr. SCULLY. I will check on that.

Chairman MANZULLO. More than checking on it. Who here in this group that you brought with you would be the person in charge of the snap audits? Does anybody know the name of that person?

Mr. SCULLY. Probably Steve Belovitz, I assume.

Chairman MANZULLO. What is his name?

Mr. SCULLY. It is not you? No.

Chairman MANZULLO. What is the name of the person who is in charge of snap audits? I want his name for the record.

Mr. SCULLY. I do not believe there is such a thing as a snap audit. There would be a follow-up audit.

Chairman MANZULLO. Well there is such a thing as a snap audit. That is what happened to them. What is the name of the person? Mr. SCULLY. Mr. Chairman, I will fully investigate it-

Chairman MANZULLO. No, no, no. I want the name of the person. Mr. SCULLY. I do not know the name of the person-

Chairman MANZULLO. Does anybody from HCFA know the name of that person? Anybody here?

Mr. SCULLY. The person in charge of the audit area is Tim Hill. Chairman MANZULLO. He is the one that came to Rockford and met with Dr. Hulsebus, and Dr. Hulsebus will tell you the experience we had with Mr. Hill.

Mr. SCULLY. Okay. Chairman MANZULLO. Let us move on to Dr. Minore.

Dr. Stephen Minore is a constituent of mine. He comes here in two capacities. First, as an anesthesiologist. In addition to that he is also a clinical assistant professor at the University of Illinois. But in addition to wearing those two hats he also has a business where he does billing and is familiar with the billing practices, reimbursement rates, et cetera, of I believe half a dozen various practices.

Dr. Minore, we look forward to your testimony.

STATEMENT OF W. STEPHEN MINORE, M.D., PRESIDENT, ROCKFORD ANESTHESIOLOGISTS ASSOC.

Dr. MINORE. Thank you, Mr. Chairman and members of the Committee. I appreciate the ability to offer testimony today with regard to issues that physicians have been experiencing with CMS. I wish to thank you whole-heartedly for the opportunity and to help contribute to improve the services of CMS. Furthermore, I would like to thank Secretary Tommy Thompson for his efforts to date in reforming a bureaucracy that has been plagued with inefficiencies, confusion and obfuscatory regulations that contribute to the general feelings that physicians have when they are confronted with CMS and other bureaucracies.

I wish to offer several points of view that are representative of a physician in private practice. In addition, several of my views can be carried over to the academic practice model. I also wish to offer testimony on the impact that CMS has had on small businessmen such as my group and on myself personally.

For background, I am the President of a physician group that provides anesthesia services and pain management services to the second-largest city in Illinois, that of Rockford, Illinois. There have been several problems that have arisen through the coding and billing of Medicare.

I brought a study from the GAO showing that the carrier call centers gave full and accurate answers to Medicare billing questions only 15 percent of the time. Indeed, GAO representatives made 61 calls to five area call centers and asked a series of three billing questions that were culled from the frequently asked questions section of the carrier's own web sites. Eighty-five percent of the answers were wrong, incomplete, and would subject the physicians to the False Claims Act.

One of the major problems that occurs on a daily basis in our office is that of correct coding. Two days every week I spend entirely in non-patient care duties. As the President of a 37-physician group I am responsible for all of the billing and also for the billing of several other physician practices including surgeons and primary care physicians.

As physicians we ask only to do the right thing, however, it is very difficult and impossible when physicians are given multiple responses from multiple sources. In medical school I was taught that 50 percent of the information we were told was correct. The other 50 percent was incorrect. The professors always said it is your job to figure out what is correct and what is incorrect. I am faced with 85 percent incorrect when I call a CMS help line. Certainly, several days before getting here, I was brought a billing question from one of our certified coders. We called our local carrier and got seven different responses. We then called the CMS help line and got four different responses. In all, for one procedure, there was a 28-fold possibility of picking the correct answer. We went back, recertified it, looked historically, and still came up with four different answers. that question is still sitting on my desk.

As we proceed, it is also significant to add that the increased costs of regulatory documentation, confusion and disagreement has increased our billing costs over 100 percent in the last three years. The revenue that we spend on billing is revenue that can no longer be used for patient care.

This cost shifting also causes problems in other ways. Our fees to private carriers have to rise in order for us to stay in business. This is cost shifting of the highest degree.

Insurance companies and small businesses cannot afford to provide health care because of the increase in costs that they are seeing. Next to the malpractice crisis this decreases our physician availability and liability. Treating critically ill patients in the operating room at all times of the day or night is much less terrifying to me than sitting down in the office trying to determine what I did the night before in cogent, correct and legal fashions. Physicians are to take care of patients. When the average physician must spend 5 to 12 percent of their time to determine their billing codes, something is wrong with the system. We need to have the system efficient, reproducible, and the information freely exchanged between carriers and providers.

In closing, I wish to thank you for allowing me to participate. I also wish to add, three years ago my group contracted with an outside agency, a large nationally known accounting firm to do our billing. The end result of that was that we ended up paying over \$560,000 back to the Medicare program. The disputes were questionable. Some were simple mistakes. A lot of them were totally acceptable with the ways we were currently billing as advised by our local carrier. That amount of money caused several physicians to leave my group and to relocate into areas that they would "not have to take care of Medicare beneficiaries because of the fear of government reprisal." We felt that we had no way to appeal that, and certainly as the person that signed on the bottom line I was fearing criminal penalties. As a result, we were forced to settle those cases.

I ask that this Committee look into such things as that and to help us take care of our patients, because really, that is all we ever wanted when we went to medical school was to take care of our patients. Thank you.

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

Chairman MANZULLO. Thank you very much.

Our next witness is also a constituent and my personal chiropractor, a man that I have known for so many years that I do not even want to—about 1967, 1968. We welcome Dr. Michael Hulsebus who is here also with his brother Roger. Roger, would you stand up, please?

Thank you. I appreciate your being here.

Dr. Hulsebus' father, Bob Hulsebus, was a pioneer. He passed away a few years ago. In the development of the practice of chiropractic in this country and actually in the world. He served as a personal inspiration to the three Hulsebus sons that continue in the chiropractic profession. He has worked tirelessly nationwide, Michael has worked tirelessly with his brothers and his colleagues to bring chiropractic to the level where it is now recognized by the VA. Where now federal employees have chiropractic coverage. And Dr. Hulsebus has also been the type of person who has always been in contact with our officer and has the most extraordinary story of abuse by the Health Care Financing Administration.

This is the second time he has had the opportunity to come to Washington to tell the story. Michael, why do you not take a glass of water, sit back, take a deep breath, and I want you to tell the American people what happened to you and your family.

STATEMENT OF MICHAEL HULSEBUS, D.C., HULSEBUS CHIROPRACTIC

Dr. MICHAEL HULSEBUS. Thank you, Mr. Chairman and members of the Committee. I am pleased to have the opportunity to appear before this Committee to address the ongoing problems and challenges that face doctors of chiropractic.

As you know, chiropractors continue to work very hard to serve the nation's elderly through the Medicare program. I regret, Mr. Chairman, that since I was here last time not a whole lot has been changed. In fact, we were here last July, unjust and the targeting of doctors of chiropractic and myself continues, I believe totally unjustly, not for fraud or abuse but to reduce chiropractic utilization. This has been going on since the last time I testified. There has been no change.

As you just stated, doctors of chiropractic are mostly independent practitioners who have deep roots in the communities they serve and who strive to provide the highest quality care to every patient. They take their clinic responsibility very seriously. Our goal is optimal care. That means exactly as much care as is clinically indicated, no more and no less.

Chairman MANZULLO. Doctor, Michael, if I could interrupt you a second. I have your testimony here. But I would like you to tell your story about the audit. Just put your papers down and tell us the story as though you were seated across from us having a cup of coffee, and I want Mr. Scully personally to hear this and the people here, to tell what happens to three little guys in small towns that get picked on by a federal agency. Dr. MICHAEL HULSEBUS. In order to do that I am going to ask my brother to come up here, because he was involved as much as I am.

Chairman MANZULLO. That would be fine. Roger, do you want to come up, please? If we can squeeze another chair in there—Can somebody provide the second Dr. Hulsebus with another chair there?

Dr. MICHAEL HULSEBUS. I do not know if all the dates are right.

Chairman MANZULLO. That is okay. You do not need the dates. Dr. MICHAEL HULSEBUS. To start out with, we kind of told the story in July and we will kind of repeat it now, but as our Congressman Don Manzullo stated, my father started his practice in 1949 as an entrepreneur, small business, and all three sons are chiropractors. We are in the northern Illinois, primarily in the Rockford-Freeport area and Byron. We have been serving under the Medicare guidelines ever since the beginning of Medicare. We have always tried to understand and abide by what is needed in order for us to take care of the elderly people. We have always put ourselves in a position to understand everything we can to the best of our ability with Medicare so we could continue to take care of the Medicare people.

I believe it was about two, two and a half years ago, is that correct?

Dr. ROGER HULSEBUS. Yes.

Dr. MICHAEL HULSEBUS. We received a letter from our carrier at that time that asked if they could audit thirty of our patients at four of our facilities. We did not see any problem with this so we sent them the necessary documentation. By the way, each one of the clinics had different documentation.

When they finished looking at the documentation they wrote us a letter and stated that we had approximately 30 days to pay back fines of up to \$250,000 for care that they felt was medically unnecessary. Now none of this was in fraud or abuse, it was just their decision that all the care we had been rendering since way back whenever was absolutely not necessary at any time.

Now this same care had already been reviewed by the other carrier. The other carrier had said no problems. When the new carrier came on and reviewed it they said the care was no longer necessary.

So they gave us choices, and the choices were not very popular, if I can say that. We were guilty, guilty, guilty. The first choice was just to pay the fine and they would leave us alone and they would not look at this any more. The next one was to continue to put more information to their hands and let them look at it, and they would decide whether or not the fine would still be there or not. The third one was to not pay the fine and they would come in and look through all of our records from all four clinics, from day one basically.

So we really did not know what to do. At that time all of us got together and said, "What are we going to do here?" We all had different clients and we started contacting different attorneys. So Dr. Roger Hulsebus, I will let you go from there.

Dr. ROGER HULSEBUS. I contacted Arthur Andersen, as it was— [laughter]—and Arthur Andersen had represented—[laughter]— and they told me to talk to Don Manzullo, so here we go. They asked me if we had a congressman we could work with, and they said, "You are really being harassed."

The sad and the ironic part of it is that we saw letters after the Balanced Budget Amendment happened, saying that the best way to eliminate chiropractic was post-payment review to get rid of the providers and scare the providers and have them so they no longer wanted to participate.

Chairman MANZULLO. Where were those letters from?

Dr. ROGER HULSEBUS. WPS.

Chairman MANZULLO. Which is Wisconsin-

Dr. ROGER HULSEBUS. Physician Services.

Chairman MANZULLO. Which is your Medicare provider.

Dr. ROGER HULSEBUS. Carrier. And they inherited the taking over, underwriting Blue Cross and Blue Shield from Blue Cross and Blue Shield of Illinois after there was some fraud in Blue Cross and Blue Shield of Illinois, so WPS took it over. But guess what? They had the same people running it in the same office in downtown Chicago.

So we kind of knew what we were up against. When they said they were going to scare us with the post-payment review, they sent the four Hulsebus offices that they audited a bill for \$256,000. The options we had were probably the same ones that Dr. Minore had, I would assume, within 30 days if you do not do this and you do not do that.

We came to our congressman and we asked our congressman. Our congressman, being an attorney, looked at it and you said, "Well this is nuts." And we had no fraud.

I have been around chiropractors all my adult life, and I do not think there is a lot of fraud in chiropractic. Chiropractors would rather see patients than not see patients. They are so passionate about what they do.

But at any rate, we had no fraud, so we stood up to WPS with the government's help, with Congressman Manzullo's help, and we did prevail but it cost us lots and lots of time. We had 18, 19 chiropractors in our group who left our group, who were afraid of Medicare. We have had people bail out of Medicare. And we have had harassing letters to Medicare recipients saying they are looking into our office for fraud.

Chairman MANZULLO. At the meeting that took placer in my office in Rockford, Michael, were you there or was Roger—

Dr. MICHAEL HULSEBUS. We were both there.

Chairman MANZULLO. You were both there. Would you state for the record what happened when Allen McGarry from my staff HCFA if they had looked at the X-Rays. Do you recall that statement?

Dr. MICHAEL HULSEBUS. Yes we had a meeting with them, and a lot of the meeting regarded communication and looking at what was going on. They asked how you determine medically unnecessary? They said the only service a chiropractor provides and the only thing they take care of is the vertebral subluxation. At that time, the only way we could determine whether or not someone has a vertebral subluxation was by an X-Ray, so that is the only document you can use to determine whether or not the care is necessary.

So Dr. Hulsebus, my brother here, asked the Medical Director, "Did you look at the X-Rays?"

Chairman MANZULLO. The Medical Director for WPS.

Dr. MICHAEL HULSEBUS. Right, of the carrier. The response was, "No, we have never looked at the X-Rays, we have never looked at anything. We just determined that on the basis of. . . ." We do not know the basis. They never even looked at the X-Rays. It was the only documentation we have. And we offered to send the X-Rays to them and they refused that.

During that meeting, Mr. Manzullo, Adam Magary was there, and we asked very graciously if we could have some kind of communication with the Wisconsin Physicians Service so we did not have to go down this road again, so we could take care of any problems we have. We did not want to go through this again, and this harassment we received from our carrier was totally unjust as we prevailed. But we have yet to this day never heard from Wisconsin Physicians Service. And I believe when I talked to your office, you also asked for communication, and the communication has been about the same in your office as it has been in my office.

Chairman MANZULLO. The only communication from WPS was when the fine went from \$250,000 down to zero, then up to \$40,000, then down to \$1500. The only communication I saw from WPS was when they decided to appeal the \$1500 that you took to the Administrative Law Judge.

Dr. MICHAEL HULSEBUS. If your office had not stepped in and if we had not had the heritage of chiropractic that we received, I do not think any chiropractor would have been able to withstand what they did to us. There is no doubt in my mind that a normal chiropractor, if I call it that way, would not have been able to take care of the problems that the Wisconsin Physicians Service and Health Care Finance Administration imposed upon our family. There is no doubt they would have surrendered and they would not be practicing today.

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

Chairman MANZULLO. I appreciate that. Let us go to the next witness. Mr. Blanchard?

STATEMENT OF TIMOTHY BLANCHARD, ESQ., PARTNER, McDERMOTT, WILL & EMERY

Mr. BLANCHARD. Thank you, Mr. Chairman and the Committee for the opportunity to speak with you about a topic that has been of great interest to me for many years. In particular the manner in which the Medicare program handles medical necessity determinations; the manner in which medical necessity policies are put in place; and some of the burdensome situations that providers find themselves in, which a have become much riskier in recent years as a result of increased focus fraud and abuse.

I have written two Law Review articles regarding these topics. In 1990, I focused mainly on the vast amount of secret law. You had to very much guess at that time.

I can report that by 1999 when I wrote my second Law Review article then the Health Care Financing Administration had taken great strides in the right direction to tell providers more often what was going on. Now they have done even better with the establishment of a couple of web sites, LMRP.net; and DraftLMRP.net.

There is a problem, though. That notice actually in some respects makes the conundrum more difficult for physicians. Because when a physician is faced with a local policy that says something is not covered under these circumstances and the physician does not agree with that, even if they know for sure what it is, and frequently they are faced with competing interpretations, but even if the physician does know there is no effective way for the physician to get a timely determination about what standards will ultimately apply. This puts the physician in a terrible situation.

First, the claims appeal process is not very effective. It takes years to resolve and they cannot rely on that necessarily going forward anyway.

The other thing to keep in mind about the appeals is at the end of the day very frequently the contractors' determinations are reversed. They are found to be incorrect when reviewed by an Administrative Law Judge who is not shackled by those same local policies but rather with a statutory requirement.

Physicians do not have the luxury of waiting to figure out what that is going to be at the end of that appeal process. They have to treat patients every single day. This gives them four untenable alternatives.

First, they could decide to withhold the services being questioned by the local policy. That is inconsistent with their medical practice, inconsistent with the best interests of the patient and the treating physician's belief.

Second, they could seek to shift the risk of a denial to the beneficiary through what Medicare calls "advanced beneficiary" notices or ABNs, which basically would require the patient to pay personally for the cost of those services in the event Medicare denies the claim. The risk here is that the patients will be financially strapped and will forego what might turn out to be a medically necessary service at the end of the day. Too bad for the patient, too late. Many physicians are not willing to do that.

Provide the service for free, the fourth option. Do not bill the Medicare program. Unfortunately, the Health Insurance Portability and Accountability Act, we got a new set of rules regarding patientinducements that indicates that a physician who engages in a pattern of giving free services to patients can be subject to civil money penalties and potential program exclusion. So, even if the physician had the financial wherewithal to give away services for free there is that additional potential risk.

Finally, the physician could decide to provide the service, go ahead and bill Medicare for it. After all, they think it is the right thing to do, they believe it is medically reasonable and necessary, they have signed the claim form and made the medical record documentation. The risk here of course is denied claims, more likely a post-payment review and large overpayment determination down the road, potential false claims investigations because the statute was also amended to make a pattern of furnishing services not considered reasonable and necessary, a basis for false claims. A possible payment suspension based on "reliable" evidence that the claims might not be right. This is the death penalty for small businesses and small providers and not so small providers because they lose their Medicare payments, do not have the wherewithal to defend themselves, and simply close down.

Congress did take action to correct this problem in the Benefits Improvement and Protection Act of 2000, Section 522. There are two problems, one created by Congress and one created by CMS. The one created by Congress is that the statute limits standing to beneficiaries, not providers. Providers are the real ones at risk; providers are the ones who are in a position to effectively bring those appeals. The problem by CMS is that it has elected not to implement that new appeal mechanism even though it was supposed to be in place by October 1, 2001, pending conducting notice and comment rulemaking.

Now I agree notice and comment rulemaking should be pursued here because it is very important and all parties should be represented, but CMS finds it convenient I think sometimes to stand behind the Administrative Procedure Act when it wants to, but other times is very comfortable issuing policy by program memorandum and by interim final rule.

I think there should be a moratorium on claims denials and overpayment recoveries based on local medical review policies, and for that matter national review policies, until such time as CMS implements the Congressional intent to establish this very necessary appeal mechanism.

That is the most important point in my written statement, but there are others.

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

Chairman MANZULLO. Thank you very much.

I am going to start the questioning with Dr. Christensen who has to go to another meeting. She is a family physician, esteemed member of our Committee from the Virgin Islands. Dr. Christensen.

ber of our Committee from the Virgin Islands. Dr. Christensen. Mrs. CHRISTENSEN. Thank you. I am really going to ask just two questions. I was going to ask one. But the last point that Mr. Blanchard made, I have asked in at least two of these hearings about a moratorium on denials and on audits and I want you to respond to that, Mr. Scully. As I understand it, and correct me if I am wrong, the audits turn up almost nothing in terms of fraud. It is almost negligible the amount of fraud that is uncovered. As a matter of fact, as I understand it, the OIG cannot even tell you what the error rate that is attributable to fraud is. Given the two stories from Mr. Evans and Mr. Seeley, given the fact that you are not yielding any real fraud and abuse from these audits, and the denials are continuing and you have not implemented the new process, I think that there should be a moratorium.

Mr. SCULLY. Congresswoman, this is a tough balance. I would love to bring you over to talk to Senator Levin and Senator Grassley who would probably be jumping up and down right now.

Mrs. CHRISTENSEN. I will go over and talk to them, too.

Mr. SCULLY. I get stuck—

Mrs. CHRISTENSEN. It is unfair what is happening to the providers. It is just unfair.

Mr. SCULLY. I agree.

Mrs. CHRISTENSEN. And on top of that you are cutting their payments.

Mr. SCULLY. We are not cutting their payments. I understand the tension and we should talk about that, but—

Mrs. CHRISTENSEN. You are not?

Mr. SCULLY. It is all statutory. Congress cuts the payments as-

Mrs. CHRISTENSEN. I am coming to that in a minute.

Mr. SCULLY. But I just want to address the issue, I have my own horror stories from the hospital business and it is one of the reasons I came and took this job. I had a lot of my own providers who are no longer in business.

There is a lot of tension here. The great mantra of Medicare the last ten years has been fraud, fraud, fraud, and I think some of it has been legitimate, some has not. The IG would tell you that 12 percent, I do not happen to agree with the number. We do issue a joint press release, that there is \$12 billion a year Medicare fraud. I am not sure the number is quite that high, but I will tell you—

Mrs. CHRISTENSEN. Improper payments, maybe.

Mr. SCULLY. I would agree with you, I think it is improper payments, not fraud. But I can tell you that every year there is a headline in the newspaper that says \$12 billion of fraud. I have pushed back on that a little from my own agency, but a lot of this is driven by Justice and the Inspector General—

Mrs. CHRISTENSEN. Have you testified regarding those improper payments as to what constitutes fraud in that \$12----

Mr. SCULLY. I have never been asked to testify, but I think you will find that in the joint press release that came out this year with the IG and me, the language is significantly tempered. Janet Rehnquist is the new Inspector General, is an old friend of mine. She is also a health care lawyer. I have been trying to work with Justice and the IG to change the rhetoric a little bit. There are a lot of overpayments in the Medicare program, a lot of it is not fraud, a lot of it is fraud. There is a lot of fraud.

But I can tell you that I get hammered and as recently as last week by many other committees in Congress for not being tough on fraud, so finding the right balance is difficult.

Mrs. CHRISTENSEN. I still think that a moratorium ought to be put into place and I can tell you from experience of some of my colleagues at home that in some cases the overpayments are because HCFA or CMS has established a fee and then gone back and said we established the wrong fee. It was not supposed to be \$6, it was supposed to be \$4.50, then the provider is required to pay that back. So this fault on the side of CMS, and I still think there should be a moratorium.

Let me just ask this very important question. It goes back to provider payments and your refusal to correct the errors in prior years because you say you cannot do it.

I have a quote here, this goes back to 1985, but where it days, "Because the Bureau of Labor Statistics has periodically retroactively revised some of the statistics on data on which the earlier economic indices were based it is necessary for us," this is CMS saying this, "to recompute some of the values and ratios for earlier years in order to obtain an accurate index for the current year."

Now granted you are using a different index to set the payment fees but you have gone back and you have revised your payment schedule based on finding errors.

Could you put up the error thing?

There is \$20 billion I think in errors that are owed the physicians over these years. Physicians offices are closing, I repeat. Other provider offices are closing. I know I am saying physicians and providers, but this translates into services that are not being provided to some of the people who most need it. And as you know, whatever Medicare does, private insurers are going to jump in and start doing the same thing.

So we are looking at a major crisis.

Mr. SCULLY. This could be a three hour discussion alone.

Mrs. CHRISTENSEN. We want you to adjust that figure, to make the corrections.

Mr. SCULLY. We have made a number of corrections including this week the projection and it is clearly a hard to conceive number, the projection statutorily for next year for physician services was going to go down negative 5.6 percent. Our actuaries did go back and reevaluate a number of growth assumptions and it is now going to come out in a few weeks as negative 4.4 percent.

So we have made the adjustments we can. The issue-

Mrs. CHRISTENSEN. On what you are paying now?

Mr. SCULLY. On what will be paid next year. The actual—

Mrs. CHRISTENSEN. Which is an incorrect calculation.

Mr. SCULLY. No, these are just actual assumptions about what future growth rates are going to be.

The two things that have generated I would say this catastrophe in physician payment, because I was the White House Health Care staffer in 1989 that helped push this through and I happen to believe the SGR formula is generally structured right. There are two—

Mrs. CHRISTENSEN. Structured right?

Mr. SCULLY. I would argue, and I think it is a very credible argument, that if you look back to 1989, home health payments have been a big up and down cycle; hospitals have had a big up and down cycle. Every other part of Medicare is a very unpredictable roller coaster. The physician payment structure has been much more predictable and reliable than others, and in fact the last year and a half it has been broken because of two big errors. One was in 2000 and in 2001 under the law we were supposed to pay a certain amount and HCFA made a large mistake. We added a couple of hundred codes each of those years and we did not, we spent \$3.5 billion in 2000 that we were not supposed to spend. Physicians—

Mrs. CHRISTENSEN. You work for an Administration. Have they asked for that money to be reinstated? You know that you have miscalculated. You know that physicians are losing money.

Mr. SCULLY. In those two years, Congresswoman, on the contrary which is not very well understood, physicians, and I know you do not like to hear this, in bulk nationally were overcompensated by \$3.5 billion in 2000 and by \$2.3 billion in 2001. That is part of the problem, is that by mistake physician spending under the law those years was supposed to go up 6 percent in 2000 and 5.5 percent in 2001. In fact they went up 11 percent and 10.5 percent. We accidentally, I was not there then, and I do not want to get into that, but we accidentally overpaid them. The formula is very exacting and——

Mrs. CHRISTENSEN. But you made some miscalculations in the prior years, so I would imagine that it probably still does not add up.

Mr. SCULLY. Actually the 1998 and 1999 SGR which we discussed during the break which I believe is wrong and should be fixed is statutory. We were told we had to use estimated numbers in 1998 and 1999. I spent a lot of time with the AMA trying to do that, to fix it last year. That is the \$40 billion issue and I cannot fix it. The Justice Department has told me I cannot.

Mrs. CHRISTENSEN. You agree that that 5.4 percent cut this year is_____

Mr. SCULLY. Is wrong.

Mrs. CHRISTENSEN [continuing]. Wrong.

Mr. SCULLY. I do not think it is substantively defensible.

Mrs. CHRISTENSEN. You do not think that cut is defensible.

Mr. SCULLY. I do not think it is sustainable. I think if it goes on we are going to have an access problem with physicians. I have said that repeatedly. I think we should fix it. I have been working with the committees to try to fix it. I think it will be fixed. The law does not allow me to do anything else, unfortunately.

Mrs. CHRISTENSEN. We do not agree with that.

Mr. SCULLY. Unfortunately, Congresswoman, I have gone to the General Counsel of HHS, the highest level of the Justice Department, I spent a month with the AMA trying to fix it last year. If I could have I would have and I think the AMA knows that. The fact is legally I cannot. I wish I could. I have been through this with them for a year.

Mrs. CHRISTENSEN. I am going to give up here, but Mr. Chairman I do not agree.

Chairman MANZULLO. I think we are talking about two different things. I think Mr. Scully is talking about the overall amount that has to be reduced by 5.6 percent and that is, HCFA has to work within those parameters.

But the other issue is who actually sets the fee schedule per, whatever it is, that is set by HCFA. So I think you might be talking about two different things.

Mrs. VELÁZQUEZ. Would the lady yield?

Mr. Scully—

Chairman MANZULLO. Let me go to Mrs. Kelly.

Mrs. VELÁZQUEZ. It is a follow-up question regarding his answer, Mr. Chairman.

Chairman MANZULLO. I do want to let everybody take their turn on that.

Ms. Kelly.

Mrs. KELLY. Thank you.

Mr. Scully, I think basically what people have indicated here in their questioning of you and what we have seen with the witnesses is a very strong need that this formula get changed, and it get changed in favor of quality medical practice for the seniors in this nation. I am very concerned about some of these things.

One of them, I found in Dr. Minore's testimony, the fact that he was going to certified coders, that really truly I find offensive. That any doctor, any practice in this nation has to go to someone who is a professional coder? That means that this whole coding system needs to be reevaluated. It means we have an industry that has grown up that is costing the medical people and the patients money to support because people like Dr. Minore have to go to someone who is a professional coder to make sure that they are coding this right.

I have a instance in my district where a doctor got into all kinds of trouble with HCFA. This did not happen on your watch. I do not know how much of the witnesses' testimony actually revolves around things on your watch, but I would beg you, sir, to take a look at the whole coding system. I think that it is going to have to be reevaluated. And the other factor that I am very concerned is this whole formula of payment.

If we need to do that at the congressional level, then let us work with you because it is affecting too many people, too many small businesses that are involved in ancillary ways with the medical profession.

I also feel very strongly that the whole instance of post-payment review, the people who are doing that out of your agency need a great retraining course. They need to learn when they are going in it is not aha, gotcha, I am going to pay my salary and the salary of several others when I go into evaluate on a post-payment review. And I would hope, and I would like to as you if you will commit here today to promising those of us who are concerned with the medical profession that you will try to reevaluate the people who are doing that because there are some people who think they have a lot of power and they are going to exercise it and they slam the doctors, which only hurts the patients. It only hurts the quality of medical care of the seniors in this nation.

Can you commit to us that you will try to change that? Do the best you can?

Mr. SCULLY. I have been trying to change it and I would encourage you to talk to, and this is my agency, but the overwhelming, and I saw this from running a hospital association, trend the last ten years has been pressure on our contractors. Their evaluations have been on fraud enforcement. There is an \$800 billion fund called the Medicare Integrity Fund that no one talks about much. This all came out of the last ten years. There was a lot of fraud.

But there has been a very aggressive push from the Inspector General, from Justice. Our contractors, the number one way they are evaluated is how aggressive they are on fraud. And I would say there probably was a great need for that in the early '90s and I have said publicly, I think I was the chair of the Fraud Task Force with the then-Attorney General in the first Bush Administration, we probably were not doing enough. The Clinton Administration aggressively went after it. I would argue the pendulum, and I have publicly said it has swung a little too far and we need to come back and find a balance. But I think every incentive, and just to defend the contractors a little bit, every incentive, everything they have been told to do for the last seven or eight years has been fraud, fraud, fraud, be aggressive. And I would argue there are a lot of instances and I have seen a lot of them personally where people have suffered from that. But that is what they have been driven to do for the last seven or eight years and they have responded to the federal incentives.

I think a healthy debate about finding the right balance is crucial and I have tried to do that with the agency. But I also think when you look at Medicare fraud enforcement, which we have been pushed very very hard and appropriately to be tough on, it is a partnership between the Justice Department, the Inspector General, and CMS, and my experience has been, and I have tried to aggressively work with Justice very cooperatively so far, and the Inspector General who I have known for many years, to have a three-way partnership. For the last seven or eight years it was very much a partnership where CMS got dragged along. But there is a lot of momentum behind this and I think it is important for Congress to find a balance because a lot of what you are hearing is the fact that the pendulum has swung very aggressively on the fraud enforcement side. In many cases appropriately, but in many cases not appropriately. It is a big challenge to get that balance back.

But I can tell you that I still go to hearings on a regular basis and get beat up for not being tough enough on Medicare fraud.

Mrs. KELLY. I know that, and I read the same papers you do. My concern about fraud, yes, I think early on there was a lot of fraud and the attitude, we have to go out and stamp out fraud is still there. But I agree with Dr. Christensen, I think the figures show that the fraud has leveled off and probably as a result of heavy fraud enforcement.

What I am asking you is not only for an attitudinal change, but also my office has worked with your office to resolve a serious issue we have with regard to ambulances in New York state. What I have found is that the people in your office and you for yourself are willing to be creative in trying to find a result.

I think what is happening here with regard to fraud is perhaps the entire basis of the way that you are approaching it may need to have a shift. It may need to be shifted in not only its emphasis in finding fraud, but the way you go about it. If a doctor has to change a code, is that truly fraud? If the patient presents in the course of treatment for another illness? Is that truly fraud? That is what happened to one of the doctors that I represent. Is there a way that you can put some people in a room and try to think about how the process of going after the fraud is currently done and look for new ways to do it so that it is first of all more accurate? And secondly, the doctors have a chance to defend themselves right away before somebody comes in and says we are going to assess you a fine, you pay the fine and then we will figure out where the true facts are, which is really what is happening with a lot of the doctors now.

Mr. SCULLY. I am certainly trying. I can tell you that obviously we have had problems with WPS and let me talk about that in a minute. I am a little irritated because I actually talked to the Chairman of WPS last summer and I am amazed that they did not do a better job of communicating about the specific problem.

Generally what you find with doctors is that, and I am not trying to pass the buck here, the issue here is frequently local U.S. attorneys that are driving this, and a lot of times they are dealing with CMS. It is a three-pronged approach on fraud and the more reasonable approach is going to take all three agencies. I actually got beaten up in a Senate committee a few weeks ago for not being aggressive enough in supporting the Justice Department because I asked some questions about some of the things they are doing and some lawsuits I did not agree with.

I understand your concerns. We are trying to find the right balance. I believe there is a lot of Medicare fraud out there and we are going to be incredibly aggressive in going after it. I also know there are an awful lot of good providers, some of whom I used to represent, who get harassed unnecessarily and trying to find the right balance is tough.

Mrs. KELLY. I would ask you to take a look at the two things I have asked you about. One is coding. The coding situation is a mess.

Mr. SCULLY. Can I just add one thing? I mean philosophically I do not want to, I was about to defend my predecessor who is a good friend as well, but philosophically, I run a \$260 billion insurance company where we set the prices for every doctor, every ambulance, every nursing home, every hospital, and then we enforce it.

The Administration's position, obviously, is we would just as soon buy private insurance for all of you like the Federal Employee Health Benefits Plan. I am doing the best I can to run this huge price fixing insurance agency, but clearly our preference would be to go out and do what we did for federal employees. We believe the way the Medicare program is run is insane.

Mrs. KELLY. The problem that I have is when a doctor gets accused by your agency of fraud, the doctor's guilty until the doctor proves themselves innocent. That is exactly the reverse of the Justice situation that ought to be available for everyone in the United States of America. That seems to me to be almost unconstitutional. And I would ask you please to go back and take a look in your agency, think about the way that this agency is operating.

Most of us who receive the complaints and concerns of both patients and doctors feel the agency is broken and I know you are working to fix it. Those are two areas I feel very strongly need fixing.

Thank you very much.

Chairman MANZULLO. Before we go to Ms. Velázquez let me announce that on July 17th at 10:00 o'clock this Committee is going to hold a hearing on the harassment by HCFA and its providers of the Presidents of two organizations whose representatives appeared before this Committee. This is nothing less than witness tampering. I am not going to tolerate it. I am going to ask, Mr. Scully, that within 14 days you provide this office with the names of every single person involved in that snap audit, plus the names of people that authorized it. I am going to issue subpoenas. I am going to have the Federal Marshals issue those subpoenas. I want those people here on that date. I want Mr. Hill here on that date.

Prior to that date I am probably going to take Mr. Hill's deposition under oath and everybody else that is involved in this outrageous, outlandish harassment of America's health providers.

It is not by coincidence that on the day of and the day before two witnesses appear before this Committee, testify about the abuses of HCFA, that HCFA personally and through its agents conduct audits on them. That is not by way of coincidence, that is by way of design, possibly criminal design.

The reason that this Small Business Committee is involved with all of these physicians, they came to us because they were being tortured by Health Care Finance Administration. They could not go anywhere else to get relief. And to have them subject to this type of administrative abuse, that is not going to be tolerated in this Committee.

Mrs. Velázquez.

Mrs. VELÁZQUEZ. Thank you, Mr. Chairman.

Mr. SCULLY, clarify to me. I guess that your answer to Dr. Christensen was that you sought clarification from the Department of Justice regarding 1998 and 1999 projection errors, and that the Department of Justice said to you that you do not have the authority to change that.

Mr. SCULLY. That is right.

Mrs. VELÁZQUEZ. If we correct the 1998, 1999 projection errors, we have that CMS actuaries have calculated that correcting the errors will put \$46 billion back into the physician expenditure pool over the next ten years, right?

Mr. SCULLY. Yes.

Mrs. VELÁZQUEZ. So assuming that the agency is correct and cannot go back and fix the errors, Mrs. Kelly made reference to the fact that you have been very creative in dealing with the issue of the ambulance in New York State. Would you be creative enough, knowing that you do not have the authority to change the errors, the calculation, to propose language to Congress to give you the authority to deal with this?

Mr. SCULLY. We would love to have the authority. I think there is no question the policy is wrong, and the 1998 and 1999 data that we use which was projected data under the law, if we used the right data the problem would be fixed largely and we would like to do that.

The issue is, the law is clear that I cannot do it administratively and—

Mrs. VELÁZQUEZ. I understand that the law is clear.

Mr. SCULLY. And if Congress-

Mrs. VELÁZQUEZ. Would you propose-

Mr. SCULLY. Oh, I have. Mr. Thomas and Mr. Tauzin and I have been talking about this since the first day I told them last September, the issue is that if they pass that law they have to finance it under the Budget Act and they have to find \$46 billion. They would like me to do it, and believe me, I talk to Chairman Thomas almost every day and Mrs. Johnson and Mr. Tauzin and Mr. Stark, they would like me to find a way to do it because it is a financing issue under the Budget Act, and I think everybody wants to get to the right result which is to fix the formula. The issue is can it be done administratively without—There is going to be new spending. If we do it administratively it does not have to be financed in Congress under the Budget Act. If Congress passes the law they have to pay for it and it is extremely difficult. But we all are on board about fixing it.

Mrs. VELÁZQUEZ. I guess that we were able to come up with \$15 billion to bail the airline industry. Can we find \$46 billion to do this?

Mr. SCULLY. We have worked—

Mrs. VELÁZQUEZ. Okay-

Mr. SCULLY [continuing]. Extensively. I think we can.

Mrs. VELÁZQUEZ. Mr. Sullivan, has the Office of Advocacy re-viewed the issue to determine whether CMS has the authority to correct the 1998 and 1999 projection errors? And if not, will you do so?

Mr. SULLIVAN. Congresswoman, with regard to CMS' compliance with the Reg Flex Act and Mr. Scully's statements before this Committee and in letters back to us and back to this Committee on statutory prohibition of acting in one way or the other, one thing that we offered this Committee in April was in those points where CMS should do a Reg Flex analysis and flush out less burdensome alternatives, if those alternatives cannot be done because of statutory prohibitions

Mrs. VELÁZQUEZ. Excuse me, Mr. Sullivan. I am not asking you about Reg Flex. I am asking you if you have reviewed the issue of correcting of 1998 and 1999 calculation errors

Mr. SULLIVAN. No, Mrs. Velázquez, it is not my understanding that we have reviewed that-

Mrs. VELÁZQUEZ. Will you do that? Mr. SULLIVAN [continuing]. Outside of the boundaries of the Reg Flex Act.

Mrs. VELÁZQUEZ. Will you do that?

Mr. SULLIVAN. Will we review the numbers and to-

Mrs. VELÁZQUEZ. No, will you review the facts to determine whether or not CMS has the authority to do that as the Administrator.

Mr. SULLIVAN. Congresswoman, we are happy to try to look at different proposals coming out of agencies and how they comply with the Regulatory Flexibility Act. I am not entirely certain about what authority our office has to review budget calculations.

Mrs. VELÁZQUEZ. Even when this has an economic impact on small businesses?

Mr. SULLIVAN. In that are, Mrs. Velázquez, we actually do have authority to look at economic impact, and I am happy to commit to this Committee and to Mr. Scully to work with CMS to look at how different numbers have an impact on small business and then proffer that back to the Committee.

Mr. SCULLY. We would be happy to do that.

Mrs. VELÁZQUEZ. Mr. Scully, CMS last year in January started a program to reduce the regulatory burden on health care pro-viders. That group was called the Physician Regulatory Issues Team. Over 35 rules were identified as needing reform. Since then CMS has decided to focus on about a dozen of those regulations. Has CMS completed action on that initial dozen? If not, why not? If not, when will they be resolved?

Mr. SCULLY. We have done a number of things on that list including last week we came out with our annual hospital rule and I think the physicians here will tell you one of the bigger issues for hospitals and doctors in MTALA, the emergency room rule. And I think if you will look at that rule you will see there is a significant restructuring and reform, we need to do more, of MTALA, which is probably one of the biggest issues for both physicians and hospitals, and we have started to significantly rein in the regulatory burdens of the MTALA law which has been torturing a lot of hospitals and doctors. We have a long list of things to do. I just hired a doctor, Phil Rogers, I think it has been announced.

I just hired a doctor, Phil Rogers, I think it has been announced. If I did not, I guess I just announced it, to run the Physician Regulatory Team, and I know him because he actually is a real doctor that ran the Alexandria Hospital emergency room, and I have been trying to get doctors who are not in the normal bureaucracy into the agency that actually have to live with this stuff day to day. I know how much it affects hospitals and emergency rooms. So that is one example, but there are a lot of others we are doing.

Mrs. VELÁZQUEZ. Would you commit to providing the Committee with a list of these regulations and an update on the status of each one of them?

Mr. SCULLY. Absolutely. I would be happy to.

Mrs. VELÁZQUEZ. Thank you.

Mr. Scully, can we go back to the letter that I sent to you on March 19th? And you responded to my letter. This is in reference to Mr. Cavalier.

In your letter to me dated April 19, 2002, responding to my inquiry, you stated that an audit of Mr. Cavalier's company had taken place in December by Nationwide but that no such audit has taken place since then by Nationwide. I think that you misled me on your response because we were aware that when Nationwide conducted an audit in December it showed that the company was clean and did not have any problems. But I was not asking you about the December audit. I was asking you about the March 5th audit conducted to him.

Would you please explain to me on what basis that audit was performed?

Mr. SCULLY. To be honest with you Congresswoman, I do not know enough about it but I will find out and obviously—

Mrs. VELÁZQUEZ. But you sent me a response.

Mr. SCULLY. I sent you a response because at the time I got into this initially I thought the question was about the Nationwide audit, and obviously there is more going on. And to be honest with you, I am as interested in finding out the bottom of this as the Committee is. If it turns out that people were—

Mrs. VELÁZQUEZ. I did not in my letter make reference to Nationwide. I spoke about an audit that was conducted.

Mr. SCULLY. They do our audits. And I was not aware that there was any additional audit done. I am going to find out.

Mrs. VELÁZQUEZ. But I do not understand why if in December an audit was conducted that showed that there was no fraud and that he was clean, why then the day that we were conducting a hearing here, Mr. Cavalier was audited?

And you know, I would like to know—

Mr. SCULLY. If that is the case and there is a connection I will be every bit as outraged as you are. I cannot believe that is. I hope I am correct.

Mrs. VELÁZQUEZ. I would like for you to respond to the following question in writing. I want to know what were the costs to CMS to perform such an audit on Mr. Cavalier's company. And further, is an audit of this nature, one that is unannounced, a normal occurrence.

Mr. SCULLY. It is, and I happen to think it is, to be honest with you, I do not think we audit—

Mrs. VELÁZQUEZ. It is normal that after—

Mr. SCULLY. No, this is not.

Mrs. VELÁZQUEZ [continuing]. An audit was conducted in December that showed that there were no problems to conduct another unannounced on the day that they were here in Washington and that they were testifying before our Committee?

Mr. SCULLY. No, that is not, obviously, and obviously I hope that is not the case. We will find out.

My point is we do a very, very small number, of the \$260 billion of claims, less than one-half of one percent are actually—

Mrs. VELÁZQUEZ. What——

Mr. SCULLY. We do federal follow-up audits on a very small number of clients.

Mrs. VELÁZQUEZ. Mr. Evans, can you tell me, Mr. Evans, how normal is it to conduct two audits so close to each other?

Mr. EVANS. It is not normal at all.

Mr. SCULLY. In this case, obviously I am going to get to the bottom of it and find out what happened. But we do do on a limited number of our audits federal follow-up audits because the contractors, the carriers, which in this case was Nationwide, do audits and on a very small percentage of those we do follow-up audits. If it was abused in this case we will find out.

Mrs. VELÁZQUEZ. So you are going to clarify for this Committee that an audit was conducted that day and why was it conducted?

Mr. SCULLY. Sure. I will get as much detail as we possibly can. Mrs. VELÁZQUEZ. Thank you.

Chairman MANZULLO. Mr. Davis?

Mr. DAVIS. Thank you very much, Mr. Chairman.

Mr. Scully, let me try to understand, do we have any kind of breakdown in terms of a projection on analysis of inaccuracies that are found in terms of a percentage of those that might be fraud how much might be error as opposed to fraud?

Mr. SCULLY. There is a long, joint Inspector General/CMS report that is put out on fraud every year and I would be happy to send it to you. I think the latest number from this year is about \$12 billion of inaccuracies. How much of that is fraud and how much of that is—it is a totally extrapolated number which is why I am not always comfortable with it. We actually do audits and find what percentage of Medicare claims are either inaccurate or fraudulent and then it is extrapolated out to come up with that \$12 billion number.

There is clearly fraud and there are clearly inaccuracies, and it is a big, inaccurate program. But it is difficult to come up with exactly what is fraud and exactly what is inaccuracies and I have tried to restrain the rhetoric on inaccuracies being labeled as fraud.

Mr. DAVIS. Mr. Blanchard, would you comment on that?

Mr. BLANCHARD. I would just add that in addition to trying to get a distinction between fraud and inaccurate fee for service overpayment, even the fee for service overpayment estimation appears likely to be exaggerated in that the way the OIG does this review is to select a sample, give it to the same contractor personnel who would have reviewed the claim the first time, and figure out whether they thought it was correct. There is no accounting in the OIG's report for what would likely be appeal determinations and CMS' own data indicates that appeals of fee for service payments are reversed at each level of appeal in the neighborhood of 50 percent. Sometimes more. So to say that those rates are an accurate description of the incorrect payments without accounting for favorable appeals to me is something that very much distorts likely policymaking on that data.

Mr. DAVIS. Mr. Scully, let me ask, what happens say if it is discovered that there has been error on the part of HCFA after an agency or an entity or a physician or whoever have gone through a protracted—

Mr. SCULLY. We try to fix them and it has been a problem. I can tell you a couple of examples I am working on now. Maybe I should not be announcing these either, but a hospital in Washington State had an error that we have worked, I think tried to work out. The entire city of Savannah's hospitals were underpaid by many millions of dollars by virtue of an error that the agency made. My policy in the agency has been, since I got there, if we made the mistake we are going to fix it and we are going to pay you more if you deserve it. Sometimes that is not always popular.

But there is fraud and there is a repayment, and when providers make a mistake and we find it, they are taxpayer dollars and we are going to aggressively try to recover it. When the agency makes a mistake and underpays someone, I have a multi-multi million dollar issue going on in Philadelphia right now, my attitude is we are going to go back and fix it. It is usually the hospital wage index or the physician payment update. But I think we have a big problem, we make a mistake, we need to make people whole. I have tried to do that. I have done it in Savannah, I have done it in Lourdes, Washington, and I hope we are going to do it shortly in Philadelphia.

Mr. DAVIS. Would the same approach be taken with, you mentioned hospitals that are obviously large entities, but what about smaller businesses, physicians or—

Mr. SCULLY. We fix some. A number of them are physicians. I will give you one example of the Power Mobility Coalition, this is not the direct policy. When I first came in we had lots of problems with DMERCs, we are trying to work on that. We had a lot of problems with wheelchair providers. One of the major gripes I think it is fair to say with wheelchair and scooter manufacturers was, believe it or not, the federal government pays a flat rate, \$2,000 for scooters and \$5,000 for wheelchairs and that is it. If somebody wants to buy more than cannot. I changed the policy last summer, and the real reason was fraud. There was a perception that people were going to be, that in fairness, there was a perception in the agency and in Justice and other places that people would sell wheelchairs with 50 different appliances on them, and overbill seniors. I made this policy change last fall that we would allow people to bill more than \$5,000 for wheelchairs, \$2,000 for scooters, to have seniors buy additional things, then we track it closely for fraud. If there is evidence of fraud I would reverse the policy immediately. So far I have not seen any. At least I have not had any reported.

But that was one of the great frustrations of inflexibility of a big government program on the Power Mobility Coalition. I spent a lot of time—the fellow who got audited, by the way, I spent many hours with and have met with extensively on a lot of issues. I think the one who was audited, the President of the Power Mobility Coalition, and that was their number one issue last August and I fixed it. I was not aware of the other issue. Is that fair to say?

Mr. SEELEY. Yes, it is very fair.

Mr. SCULLY. And I went and spoke to their convention in New Orleans and spent a lot of time working on their issues.

Mr. DAVIS. My last question, someone mentioned the issue of culture earlier. And some regulatory and law enforcement agencies from time to time find it necessary to review their approach in terms of how they look at situations. Have you undertaken such a cultural—

Mr. SCULLY. I have very aggressively, and I do not think any of my employees would argue otherwise, have tried to change the culture. I have known a lot of people at HCFA for 20 years. I think there are some terrific, fabulous career civil servants there who work incredibly hard. I also think the culture at HCFA over the years has tended to be a little too insular and I have said that many times. I think, my experience many years ago as a telecommunications lawyer, my experience is if you are a telecom lawyer part of your career development is you work at the FCC. If you are a banking lawyer you go to the SEC. HCFA has always been insular. There has always been a fear of outside providers, hospital administrators, physicians, nursing home people working in the agency. I have tried to change that. I have aggressively tried to recruit around the country. I have doubled the number of doctors since I have been there. They have gone from about 40 to 85. I spent a lot of time trying to recruit people. I happened to come out of the hospital industry. I think it is healthy to have people from the industries that you regulate coming in. I think most people are honest and when they go in the agencies they help open the place up and make people understand what is going on.

I have made a very aggressive effort to try to get new blood into the agency and I think it is fabulous that we have 25 year career civil servants, a lot of great people. I also think we need some people that are running nursing homes or hospitals or physician practices to come in for two or three or four years and come into the agency and bring the expertise from the people we have to deal with every day. There has not been enough of that and I have been very aggressive in trying to bring new people in.

Chairman MANZULLO. Thank you, Mr. Davis.

Dr. Weldon.

Dr. WELDON. Thank you, Mr. Chairman.

Mr. Scully, are you familiar with the fraud alerts that your agency issues to the carriers?

Mr. SCULLY. I am, yes. Usually it is with the Inspector General as well, for the most part. Some of them are directly from us.

Dr. WELDON. Around the same time the President of the Portable X-Ray Coalition received his unannounced audit there was a fraud alert that came out from CMS regarding fraud in that industry.

I looked at that and I looked at it in comparison to other fraud alerts. Most of the other fraud alerts they had documentation to support the fraud alert. They cited cases of particular types of fraud or cases that they had uncovered but there was really none of that for the Portable X-Ray Coalition.

Can you provide the Committee the documentation, the internal documentation from CMS in terms of how they went about issuing that fraud alert? Because it looked to me as well like harassment. And if it is not harassment, great. I would be very pleased with that. But I would like to see the documentation. I would like you to provide it to the Committee—

Mr. SCULLY. Absolutely.

Dr. WELDON [continuing]. As to how CMS came up with the conclusion that a fraud alert was necessary for this industry.

Mr. SCULLY. I would be happy to do that. I do not know the details of it, but I will find out. And believe me, if I have people in my agency harassing providers, I was in the provider business until about a year ago, and I am not any happier about it than you are. I hope that is not happening. If it is, I will be every bit as aggressive as you in trying to go after it and fix it.

There has been a culture, I repeat again, and some of it is healthy and needed for the last ten years, in our contract and every place else of you cannot possibly be aggressive enough on fraud and abuse enforcement. I think there needs to be balance restored. But I do think the fact, and I think this kind of discussion is healthy, and I think probably some people in my agency, I can tell you, have been unhappy because I have asked a lot of those questions and we need to start restoring that balance.

Dr. WELDON. I want to say something about that. In the early '90s we had some real horror stories on fraud. I know in Florida, it was almost like a phantom health care provider. They were not actually seeing patients at all and they were churning through a tremendous volume of billing. I believe some of the perpetrators in that instance actually went to jail.

But essentially what is going on right now is the hot pursuit of up-coding, at least that is the way I see it. A lot of the blatant fraud has been wrung out of the system and now we have this hot pursuit of up-coding.

While certainly I think CMS and the carriers need to be vigilant in pursuing that because it is a problem and I know there are physicians and other providers who do abuse the system, and they give all the honest providers a lot of grief and we all pay a price for that for the dishonest amongst us. But what is going on right now for a lot of providers, at least in the physician community, is when they get these notices they are being audited or they have had a certain number of their charts that have been found to be not properly documented or therefore up-coded, for a lot of physicians the cost of challenging is greater than just paying the money, so a lot of people are just paying the money.

Frankly, I see that as a real problem, particularly for a small medical group or a solo practitioner. They cannot come against the weight of the agency.

We covered a lot of issues, and this has been a very very informative panel, but the testimony Dr. Minore gave to me, I know you are familiar with it, I know you are familiar with the GAO report that he cited. This is a real serious problem.

Now I agree with you, that we need to totally reform the system and that we are in effect tinkering around the edges when we try to address this, and the problem to a great degree is the inability of the Congress to come to any kind of agreement with the White House and get a product through of real reform.

I am certainly fighting for real reform of Medicare to make it a more fair and equitable system and I can vouchsafe to the people next to me here, that they fight for it as well. But until we can come up with a political solution something has to be done to get some clarity on these code issues. For a provider like Dr. Minore, I know what it is like. You see the patients, you are on call all night, you see patients all night, you go into the office the next morning bleary-eyed, and this person who works for you in your billing department comes up to you and asks, and you have typically got it written on a scrap paper, is very often the case, and you say to yourself, I hope to God I have got all of this right and I hope I do not get audited, and you do the sign of the cross and you give it to your clerk.

Something has to be done. I certainly am putting pressure on my colleagues on both sides of the aisle to come to the table on some real serious reform to get a more simplified and more patientfriendly system. But just, again, to reiterate, I would like the details on that fraud alert for the portable X-Ray.

Mr. SCULLY. I would be happy to. It is a very complicated system, and I do not mean to be whining. I spent many years at home being genetically cheap so I am not asking for more than 4800 employees, but when you look at the size of the programs we run, of those 4800 employees probably 1200 work on Medicaid. So let us say we have 3500 working on Medicare which takes care of 40 million people and affects every provider in the country. It is, in my opinion, and again, I am not asking for money outside the President's budget, it is very tightly run.

One of the reasons you get 85 percent of the wrong answers is that the contractors who run the program are largely underfunded. It is a very skimpily funded insurance program and you get what you pay for in a lot of cases, so it is not surprising.

When you look at the appeals, which somebody complained about, which is totally right, Congressman Thomas and Mr. Stark passed through some BIPA appeals two years ago which you have said they have not put in place. There is a good reason we have not put it in place, to be perfectly honest with you. I think those reforms are great. The appeals process is a joke. If you are a patient it takes you two years to go through it. It is run by the Social Security Administration largely, not by Medicare. I want to bring it into Medicare and get it out of Social Security who does not care as much about Medicare obviously. But it costs \$140 million a year and the money is not in our budget.

I spent a lot of time talking to congressmen regularly. Mr. Obey, helping Mr. Thomas try to get the money in our budget. I would like to do it tomorrow. I have spent a lot of time telling the committees that. But it is \$140 million that is not in my budget and I cannot put it in place without the money. The authorizers authorized it and the appropriators did not appropriate it. To be honest with you, it is something that is desperately needed and I would agree with my attorney friend at the end of the table that the Medicare appeals process is broken. But I cannot fix it under the current resource level.

Dr. WELDON. Thank you, Mr. Scully. My time has expired.

Before I yield back, Mr. Chairman, I just want to again thank you for this hearing and thank you and the Ranking Member for allowing me to be here.

I would also ask that the Committee consider in the future investigation of the impact of these problems in CMS on small businesses and providers, that the Committee consider looking at the role the Justice Department plays in all of this, because it is definitely a player. Mr. Scully alluded to that.

Chairman MANZULLO. I appreciate that. Thank you.

Mr. Scully, it does not take one cent to come up with a set of rules that the doctors can follow that is consistent. I mean even before you get to the appeals it is \$146 million for appeals to find out that someone is screwing up?

Why can you not come up with consistent rules? People in Illinois, Kentucky, they have these different rules, different values. Can you not get these 49 contractors together?

We dealt with one who is a tyrant. Wisconsin's Physicians Services, and I talked to the President. This great organization.

When Mike Hulsebus faxed me the appeal and I asked the President—What is his name? I want to get it into the record.

Mr. SCULLY. I completely forgot. I apologize. I will get the name for the record.

Chairman MANZULLO. Do you recall his name that was on the letter? Wisconsin's Physicians Service sent the notice of appeal. It was signed by the President or Vice President, and I called him and I said did you read the Administrative Law Judge's order? He said no. I said who authorized the appeal? I said I did.

Maybe you can start with something real simple that you have at least some orderly rules.

Maybe we ought to get Chairman Rosotti, Commissioner Rosotti from the IRS, who has worked marvelously with that organization. I have worked with him on three huge, monstrous issues. He has been in my office a half a dozen times. He has cleared them up very easily because he believes in consistency of rules.

What these providers are asking for is something very simple. Just be consistent in what you are asking for. That does not take one dime. And to come here with 4,800 employees and to tell this Committee that you need more resources, which is more money, in order to conduct an appeal because you do not have consistent rules—Am I missing something?

Mr. SCULLY. I do not think I said that.

Chairman MANZULLO. You did not say you need more money?

Mr. SCULLY. We do not do the appeals. The Social Security Administration does the appeals, largely.

Chairman MANZULLO. I am talking about WPS. Before it got to the point—

Mr. SCULLY. I would argue with you, and I do not think there is any question about it, that most of these insurance companies, and WPS is a little different, most of them are Blue Cross plans. WPS clearly has a significant problem in your case. Most of these are Blue Cross plans. They—

Chairman MANZULLO. Then why do you not get rid of them?

Mr. SCULLY [continuing]. The level of funding—I cannot, number one. First of all, on the physician side I can, the hospital side I cannot. The hospitals get to pick their contractor. That is part of contract reform. I have no control over that. That is why I am trying to get 49 down to—

Chairman MANZULLO. The hospitals get to pick theirs?

Mr. SCULLY. The hospitals get to pick their own.

Chairman MANZULLO. And you used to work for the Hospital Association.

Mr. SCULLY. I did, yes.

Chairman MANZULLO. All right, then why cannot the providers pick their own?

Mr. SCULLY. Statutorily. The hospitals are allowed to pick their own, the doctors are not.

Chairman MANZULLO. But under the statute the hospitals are allowed to pick their own.

Mr. SCULLY. I am trying to change that, yes. And I am trying to get the contractors consolidated down from 49 to 20 so I can find the 20 best to work with and come up with more consistency.

Chairman MANZULLO. What I am asking you is the fact that Dr. Hulsebus, this was the internal appeal before it got to the formal appeal, is that right, Michael? It was the internal appeal. The guy at WPS who was the President or the Vice President, I cannot think of his name. Ned Boston.

Mr. SCULLY. That is right, yes.

Chairman MANZULLO. I believe he is the one I talked to on the phone and I said this is extremely significant. I said first they started out with a \$250,000 fine; and then because I got involved and started raising hell it went down to zero and I take credit for that. Because the only way that we get anything done is through threat of hearings, through Members of Congress intervening on behalf of little bitty people like these providers here, to get in there and rattling the cages, otherwise nothing gets done, including they do not even answer letters.

Mr. SCULLY. Congressmen, to them I can tell you that the total contractor budget is roughly \$1.2 billion to run a \$260 billion program. I used to be on the board of one of the biggest insurance companies in the country and nobody runs an insurance company on that kind of budget. It cannot be done effectively.

Chairman MANZULLO. That is a matter of fairness. The guy who authorized the appeal did not read the judgment of the appellate law judge. That is incompetence.

Mr. SCULLY. Well, you-

Chairman MANZULLO. And you are contracted with them.

Mr. SCULLY. I am trying to defend the contractors. I think the contractor system is screwed up. I do not think they are funded enough to do an appropriate job. And when you have—

Chairman MANZULLO. It is not a matter of funding. These are decisions that have nothing to do with money. How much time was he wasting on the appeal? \$1500 after we fought for two years to get it down from \$250,000 and he is the President of this organization. He is wasting all of that money and all that time and all the king's horses on \$1500 to continue to harass Dr. Hulsebus.

Mr. SCULLY. I agree, and that case was clearly mishandled. But I think the problem is systemic.

Chairman MANZULLO. But it is continuous. Ask the providers here. It goes on nationwide, that is why they are here.

Mr. SCULLY. I have been very involved in this issue as a provider for years and I agree with you. But I am saying the reality is you cannot take care of 40 million people with 900 million claims a year and process it effectively and answer their calls and not—

Chairman MANZULLO. Let me suggest-

Mr. SCULLY [continuing]. Make 80 percent of the answers. The system is screwed up.

Chairman MANZULLO. But it is your job to straighten it out.

Mr. SCULLY. I am doing the best I can.

Chairman MANZULLO. Okay. But let me give a suggestion. This is really really simple, okay? I have practiced law for 20-some years and we have books, we have the Federal Rules of Evidence, the Illinois Civil Code, it has some very, very basic rules that say this is what is expected of you. It is very simple.

Mr. SCULLY. Part of our 110,000 pages of regulations are pretty clear guidance to these 49 carriers. The problem we get into and the reason we leave regional flexibility, 25 percent of our coverage decisions are made nationally, and I can give you hundreds of examples. Every time I get us to make a national coverage decision or a national policy people scream you need more flexibility. Seattle operates different than Rockford and San Antonio is different than Philadelphia. So no matter what you do it is a catch-22.

If you make a national coverage decision about how to cover one physician payment whether it is a gastroenterologist or an anesthesiologist, people who do not like it come in and say you guys are bureaucrats in Baltimore and—

Chairman MANZULLO. That is because it got set up that way in the first place. That is not a matter of federalism, that is a matter of 49 different pieces of the worm being chopped up.

Mr. SCULLY. We would agree. I mean philosophically our approach would be that we would rather have, my guess would be the anesthesiologists probably do not like the private insurance companies but they probably have a more rational relationship. We would rather buy private insurance for seniors. But in the system we are, we have to—

Chairman MANZULLO. No, what I am saying is this. As the Administrator of HCFA you have the authority to issue a simple letter to every one of your 49 health care providers and saying these are the simple rules of an internal health care appeal.

When I took a look at Dr. Hulsebus', one of those that it did not mention is this. It was well, you can pay your \$256,000 immediately. That is great. I said where is your checkbook?

The second one was, you can request a meeting with somebody from HCFA. Well, that is exciting. You did not know if it was a person with authority or who it was. Maybe the same person that did the audit on it. Then you could have 30 days to have that meeting.

The third one was well, you can do a separate, informal appeal, but oh by the way, it is 13 percent interest on the \$256,000 if you proceed to go to the appeal.

I mean there are some things in there, some very basic fundamental rules of fairness that you are in a position as the Director of CMS, of HCFA, as the Director, to put out some very basic guidelines, just a matter of fairness to these providers.

Mr. SCULLY. I agree totally, and I am trying to do that.

Chairman MANZULLO. Nothing has happened.

Mr. SCULLY. I would be happy to come and give you more of the things we are trying to do to change it. But my point separately is if you take Blue Cross of, I do not know if it is Anthem that does Northern Illinois. But if you took somebody, an anesthesiologist in their hospital and looked at the administrative costs of the private sector Blue Cross plan for a private insurer in that area, it is 11 percent on average, 11 or 12 percent. That is the standard administrative loss ratio to run a good insurance program.

The administrative loss ratio in the Medicare program is about three-tenths of one percent. All I am saying is if you want good service, you want rational appeals, you want it to be run like a private insurance company, it is not structured to be run that way. It is a very bureaucratic, slow moving monster that is funded to be inefficient.

Chairman MANZULLO. You are in charge of cleaning this thing up.

Mr. SCULLY. I am trying very hard.

Chairman MANZULLO. I noticed that you have no interest at all in my suggestions.

Mr. SCULLY. I will try, and I am happy to work with you.

Chairman MANZULLO. Maybe Dr. Hulsebus, maybe something like this. How about you are innocent until proven guilty? [Laughter] Is it not time that medical providers get the same rights as criminals in this country? [Laughter]

Mr. SCULLY. Mr. Chairman, I totally agree with you, and I am trying to find that balance. But I can tell you—

Chairman MANZULLO. No, it is not a balance. This is not a balance. This is a matter of fairness.

Mr. SCULLY. I agree. Then I have Chairman Grassley in the Senate Finance Committee, not chairman any more, Ranking Member, and Senator Harkin, every bit as aggressively telling us we are not tough enough on fraud and that we ought to be going more after providers. Chairman MANZULLO. You mean the fraud committed by HCFA? Mr. SCULLY. Committed by providers. That is their argument. I am just telling you—

Chairman MANZULLO. The number of people out there with all these audits, how many people do you have from CMS that are out roaming the country doing these audits? Do you have any idea?

Mr. Scully. CMS that do audits?

Chairman MANZULLO. Yeah the ones that went to-

Mr. SCULLY. The people that do audits generally are employees of the contractors.

Chairman MANZULLO. No, who did the audit-----

Mr. Evans. CMS.

Chairman MANZULLO. CMS employees did the audits personally. Mr. EVANS. Correct.

Mr. SCULLY. There are very few if any that actually work for CMS that do audits.

Chairman MANZULLO. How many showed up in Mr. Cavalier's office that day? Is Mr. Cavalier here?

Mr. Evans. He is here.

Chairman MANZULLO. Would you come up to the table, Mr. Cavalier?

Mr. EVANS. It is John Cavalier.

Chairman MANZULLO. Could you please state your name and spell it for the record?

Mr. CAVALIER. John Cavalier, C-A-V-A-L-I-E-R.

Chairman MANZULLO. Tell us your background and your position, and tell us what happened.

Mr. CAVALIER. First of all, I am President of the National Association of Portable X-Ray Providers. I own Cavalier Mobile X-Ray in Youngstown, Ohio.

Our carrier is Nationwide Insurance out of Columbus. Back in December they did send us a letter asking for 40 requisitions on patients, and what they asked for through Nationwide, they asked for reason for the X-Ray, they checked the type of views we did consistent with the CPT codes that we bill for, and for that audit they told us that we billed a very high level of certain procedure codes and that is what caused the audit to happen.

In our area, we are a fairly medium sized company, so they were looking at certain codes that were billed and it looked like it was a 710 code which is a chest X-Ray, and our company does do many chest X-Rays so they came in and they did check for why we did so many.

Chairman MANZULLO. This was Nationwide?

Mr. CAVALIER. This was Nationwide.

Chairman MANZULLO. When did that occur?

Mr. CAVALIER. That occurred in December.

Chairman MANZULLO. December of 2001?

Mr. CAVALIER. Yes.

Chairman MANZULLO. Go ahead.

Mr. CAVALIER. What they found was nothing. They found that we were within regulations, why we did so many, and the transportation charge, they also looked at that. The R Code, why there were so many single visits. So the R Code was broke down. What the R Code does is that when you have a transportation rate if we go to

a facility and do more than one patient we have to break down that R Code. Medicare allows one transportation code for each visit that we make to a facility. So if we go into a facility and do eight patients, that is divided by eight, so that amount of money is divided by eight. So they do watch the transportation codes.

Chairman MANZULLO. Did you feel that the audit was done fairly?

Mr. CAVALIER. That audit I thought it was.

Chairman MANZULLO. Did you feel it was justified because of the high number of that particular code?

Mr. CAVALIER. No, because you know what? Being in business, we have been in business 12 years now. I know the background of our company. I know what is ordered. I think CMS, when they look at some things like that, certain codes that are done, you will find if they did data on mobile X-Ray companies they are probably going to find that the Code 71010 is the most used code in the country because it is a chest X-Ray. That is the most common X-Ray that is ordered.

Chairman MANZULLO. So they said you were being audited because you did the most used——

Mr. CAVALIER. Code in our area, in the State of Ohio.

Chairman MANZULLO. When did the second audit occur? The snap audit?

Mr. CAVALIER. The second audit occurred March 5th.

Chairman MANZULLO. Of 2002.

Mr. CAVALIER. Of 2002. I was here for our National Association convention, first of all. That was one of the reasons I was here, plus for the hearing that was taking place here in Washington. My wife usually does travel with me, she is an X-Ray tech, she is part owner of the company. She happened to stay back this trip. And on that morning I got paged here when I was in Washington that we were going through an inspection from CMS. I said what are you talking about, we are going through an inspection? We just went through an audit. She goes well, CMS called and said they would be at the office within ten minutes.

Ten minutes later they came through our front door.

Chairman MANZULLO. How many people?

Mr. CAVALIER. One person came in. One person. She was there six hours. She looked at all our records. She looked from employees to registration of radiation sources, looked at education on employees, she asked us to pull ten Medicare folders at a time of patients that were done at random, and in the past, I know what they look for. What they look for is fraud on views.

Chairman MANZULLO. Fraud on?

Mr. CAVALIER. On views of X-Rays. Like if I would do a wrist X-Ray and I bill CMS for three views and it happens in that film jacket there are only two views, I just committed fraud because I billed them for three views instead of two. That is what a lot of audits look at. They look at type of X-Rays done and what type of views are done because if you say you did four X-Rays or four exams on that patient you better have four exams in that X-Ray jacket.

Chairman MANZULLO. What happened as a result of the audit?

Mr. CAVALIER. Well the audit, they found nothing. The first audit, though, to get back to the first audit, I am a little confused on little things. There is a thing called place of service when we do—We have to explain where our place of service is which is a nursing home or a private home. In that place of service, that is where a lot of data could come from. That is where I think CMS could really find a lot of data that where the X-Ray was done. Was it done in a private home. What I mean by private home is a residence of a patient. We have the capability of going right into a home patient, right inside their house. Or is it done in a nursing home.

One of my techs did mess up on one of our requisitions, and what he did is, there is a question on the requisition that Medicare asks us to answer, is why was the patient done portable. And we put that the patient is either home confined or nursing home confined. That is why the X-Ray is done portable.

So one of my people, instead of putting nursing home confined they put home confined, but in fact it was done in a nursing home and they caught it. They caught it real quick.

and they caught it. They caught it real quick. They said well, Mr. Cavalier, out of the 40 slips that you sent in we found out you put home confined when you really did the patient in a nursing home. They did their job because we should have had nursing home.

But the place of services is very important in our industry and I think this is a little bit going over the question that you asked me, but place of service is the most important I think question that could be asked from CMS to give data on our services.

Chairman MANZULLO. Is that asked?

Mr. CAVALIER. It is asked by us. We have to put that down where we do a patient. But that can keep great numbers on what is done, where it is done. I think physicians like getting on to the EKG level, on the physicians, if an EKG was done by a physician in a skilled nursing facility or if it was done in a home patient, they do not have to place of service. So really there is no data keeping.

So when the EKG issue came up years ago I believe there was really no data there.

Chairman MANZULLO. We will get into that. I have some other questions on data but I want to get to Congressman Ferguson then I can come back.

Mr. FERGUSON. Thank you, Mr. Chairman. I appreciate your holding this hearing and for your leadership and your energy with pursuing this because clearly the treatment of small businesses by CMS and other agencies is crucial not only to making sure that they have the ability to provide the services that they provide, but also to help ensure the solvency and the success of those who work so hard in our small businesses. So I am delighted that you held this hearing. I am familiar with Mr. Evans' testimony and appreciate your being here.

A gentleman from New Jersey, where I am from, Norman Goldhecht, who I am sure many of you know Norman, he has not testified today but he has done so in front of this Committee frequently in the past. Unfortunately Mr. Goldhecht, because of some of the burdensome regulations that he had had to deal with as a portable X-Ray business owner, forced him to sell his business. So although he is still active with the association he is no longer an owner of his business, unfortunately. That simply speaks not only to some of the problems that we see with CMS and with other regulations that these folks are forced to deal with sometimes, but also with the urgency of this issue and how it affects real people and real lives in a very direct way.

So I want to again thank the Chairman for your pursuit of this and for your energy in wanting to work with Mr. Scully and CMS to see how we can make this more efficient and to enable CMS, frankly, to do their job and to do it in an increasingly efficient way, an increasingly effective way, that does not lead to harassment or forcing folks out of business but does protect the taxpayer dollar, but does it in a way that allows small business people and others who work so hard to provide these services and to run their businesses and provide for their families, give them an opportunity to succeed and grow and to prosper.

I want to change gears just for a second to talk about prescription drugs for a second. Prescription drugs is a big issue that we are dealing with in the Congress right now and something that we are working very very hard on as we look at reforming our Medicare program to include a prescription drug benefit.

In my State of New Jersey we have been a leader in providing prescription drug benefits to our seniors in New Jersey. In fact we were I believe the first state, and we still, we remain as the most generous state in terms of providing prescription drug benefits for seniors in our state. In fact 20 percent of the seniors in this country who are covered by a state program are covered in my State of New Jersey. Twenty percent. That is an extraordinary figure.

Like a lot of other states, our state in New Jersey is dealing with some budget crises right now. We are working on dealing with the effects of a recession, the effects of debt and spending and whatever else.

As we look in New Jersey at ways of being able to still provide these types of benefits, a whole host of different benefits including our prescription drug benefit, to folks in our state with our serious budget situation, our state has applied for a waiver from CMS and has yet to hear back, and I know CMS has granted waivers to other states that are newer to the prescription drug coverage issue than New Jersey is. They provide less generous benefits than New Jersey's program does. New Jersey is really the leader as far as state programs in this. We have not heard back from CMS and we sent a letter, I know I led our delegation and sent a letter and our delegation has 13 members of congress and two senators. There is not a lot that we all agree on. We are seven Democrats in the House, six Republicans in the House, two Democrat senators. We are a diverse group of people from all walks of life and when you think about New Jersey and its diversity, and the amazing differences between folks in New Jersey, this is something which unites us and something that we all agree on is the urgency and the need for the waiver from CMS for our state, I do not know if you are familiar with this letter. We sent a letter to you three weeks ago which has the signature of every member of our delegation on it laying out the case for New Jersey to receive a waiver from CMS. We have not heard anything back yet. I know our office

faxed a copy to your office yesterday in fact. Can you give me an update?

Mr. SCULLY. I will get back to you. I have not seen it. I know that New Jersey has a waiver in, I think there has been some back and forth with New Jersey and the staff. We have been inclined to give waivers, especially for drugs if they work out financially. As you know, the number one issue for us is budget neutrality. We cannot spend more money, we have to find more ways to do it creatively.

Mr. FERGUSON. Sure.

Mr. SCULLY. In Illinois, we gave Illinois a waiver to cover 368,000 seniors two months ago so every senior in the State of Illinois up to 200 percent of poverty will now have drug coverage. We are happy to do that if we can work it under the law. And if we can work it out in New Jersey in a way that we can get through the budget neutrality rules, I am sure we will try to approve it.

Mr. FERGUSON. Sure. I know my time is up, Mr. Chairman, if I could ask your generosity for a moment.

Our program was installed in New Jersey in 1975. Since then we have spent over \$4 billion on prescription drug coverage for seniors in our state without a dime of federal matching funds, without a dime.

I know the issue of budget neutrality is a serious one, but if we are not able to have this waiver there is no question that New Jersey will be forced to cut back on the prescription drug benefit that we currently give and provide to our seniors which is going to end up in I think huge new costs for institutionalized care, for hospitalized care, which is going to end up coming from a federal dollar and not from the very generous benefits that we are providing on the state level right now. So I think, and in our letter when you have a chance to read our letter we lay out I think a very strong case for meeting the budget neutrality criterion.

The second, I know, contingency for the waiver is the maintenance of effort requirement. We also lay out an argument on that. I would be happy to give you a copy of this—

Mr. SCULLY. I would be happy to come and meet with you but I have not seen the letter. I apologize. But I will look at it and call you back.

Mr. FERGUSON. This letter is dated April 25, I understand you have a lot of letters to read. This letter is dated April 25, it is three weeks ago, and I know we faxed a copy to your office yesterday, to your staff who we were talking to in preparation for this hearing.

So if I could ask you please to simply expedite your reading of this letter, number one—

Mr. SCULLY. I will read it and call you back.

Mr. FERGUSON. I really look forward to working with you on this. This is a crucial health care issue in our state, it is a crucial budgetary issue in our state, it is something which has united our delegation which does not happen often, and it is something that is very very important not only for the health care of New Jersey seniors, but frankly, to the federal taxpayer, because if this does not happen we are going to explode costs on the other end. So I appreciate your willingness to take a look at this. Mr. SCULLY. I hope we can work it out. I think we did some very creative stuff in Illinois based on some unusual flexibility, and I was surprised OMB actually looked at it as creatively as they did. But if we can work it out obviously we would be happy to. We are trying to give states the flexibility to cover drugs.

Mr. FERGUSON. Thank you. And as I said, there have been states that have received waivers that provide a less generous benefit and who have not been in this, who have been doing this on a state level nearly as long or nearly as generously as New Jersey has. This is a crucial issue for us. I appreciate your willingness to work with us on it.

Thanks.

Chairman MANZULLO. Thank you. I have got a couple of questions.

We sent you a letter, Mr. Scully, and then you responded timely. It is your letter dated May 13th. Do you want to put it in front of you there? Your letter to me dated May 13th.

On page one at the bottom you state, it is the third line from the bottom, Mr. Scully, "We use interim rules with comment only when justified by particular circumstances such as the need to implement a change in law quickly, and even in these cases we include appropriate impact analyses."

Then on page three the first full paragraph, let me start it there. "I would also note several points in RFA. Over 100 of our staff spent 600 combined hours." That is a total of six hours apiece. " being educated on their statutory responsibilities under RFA."

I think they need to go back to school. I think six hours is totally inadequate. That is the only buffer that small businesses have, and Mr. Sullivan would be glad to go to Baltimore to conduct a school on how to comply with the RFA.

I guess I volunteered your services, Mr. Sullivan, but—

Mr. SULLIVAN. Actually, Mr. Chairman, in a meeting with Mr. Scully's deputy last week we talked about this very issue of going back up to Baltimore because that is in fact where this training that Mr. Scully talks about occurred a few years ago. We are happy to go back up there and in fact under the President's plan to improve agency responsiveness to small business, that is a commitment that we have already made in a memorandum of understanding with Dr. John Graham over at OIRA in OMB.

So we are happy to do that and that commitment actually has already been made with Mr. Scully's deputy.

Chairman MANZULLO. I do not see that winding its way through into this letter. Let me complete it here. It says, "We are very focused on RFA and believe our regulations meet the requirements of the RFA," which they do not. "We do not believe," and here is the key statement. "We do not believe the RFA requires us to do an analysis of issues on which the federal government has no industry data and where obtaining data would be burdensome for small businesses."

Who makes the determination as to whether or not obtaining the data would be burdensome? You or the small businesses?

Mr. SCULLY. Under this analysis I believe it is the HHS General Counsel, but we try to be sensitive to the burden for small business.

Chairman MANZULLO. Let me tell you where you are not sensitive. Mr. Evans, would you tell him what happened when you submitted data HCFA about portable X-Ray providers?

Mr. EVANS. Sure.

Several years ago there was a CPEP panel that—That stands for Clinical Practice Expense Panel in which a couple of our members sat on, were invited to sit on. It was a panel put together by CMS. It was CMS' panel. They spent long hours, in fact I believe it was two full days in this panel, testified twice. The panel unanimously voted in favor of the information that we brought forward as far as costs are concerned.

You requested yourself that they provide this data and obviously it does not exist any more. They must have thrown it away.

Chairman MANZULLO. How old is the data?

Mr. EVANS. I believe it was 1995, I am not sure on it. But as I sit here

Chairman MANZULLO. Would those figures still be good today?

Mr. EVANS. No, they would not, obviously, because a lot of things have changed since 1995, but we did turn in data since then. Chairman MANZULLO. What happened when you turned in the

data on home X-Ray? What was HCFA's response to that?

Mr. EVANS. We never received a response. In fact Mr. Scully wants to sit here today and tell this Committee that we received a 5.4 percent decrease in our funding, and that is flat not true.

Mr. SCULLY. I said it was 11 percent.

Mr. EVANS. Even at 11 percent, it does not take into consideration all of the components. It does not take into consideration what the Balanced Budget Act of 1997 did to the portable X-Ray provider as far as PPS is concerned and the discounts that we had to take by CMS' hand. It does not take into consideration that as you stated earlier, Chairman, that physicians are leaving and not taking Medicare patients.

Well, let me tell you something. Radiologists do not have to take Medicare patients except for the ones that are in their hospital. Therefore they walked out and we have that new burden to deal with too.

Chairman MANZULLO. My question here was again, to the portable X-Ray, let me tell you why we have made this an issue.

My mother was in an assisted living center. She had a leg ampu-tated. I was there one day when a portable X-Ray fellow came in the room and I said mom, what's going on? She said well, the doctor called and I might have a touch of pneumonia and she had called the doctor. Within a very short period of time the portable X-Ray man was there, took the picture, and as it turned out she was fine. I stopped by and saw mom, she said I had to have an X-Ray and I went to the hospital. She said what do you mean you had to go to the hospital? She said well the guy came along with this truck, it was not an ambulance, it was a special vehicle that had a lift on it. She did not have to lay down on a stretcher. I said what happened? She said we went to the hospital and had the X-Ray taken.

I was sitting there thinking, my brother was the one that handles the bills. Instead of getting just one bill, these X-Rays are ordered by physicians. They are not optional. They are not the types of things that the patients say they want. They are all ordered by physicians. So HCFA had to pay for the ambulance. I think one exhibit up there showed just a transport ambulance cost was \$168.

Mr. EVANS. One way. They obviously have to get back.

Mr. SCULLY. Can I ask you a question? What year was this?

Chairman MANZULLO. Mom died two years ago in April.

Mr. Scully. So it was 1998 or '99 probably. \overline{I} will explain to you. Was it within 100 days after she left the hospital?

Chairman MANZULLO. No, it had nothing to do with that. She was at the nursing home.

Mr. SCULLY. So she had not been in the hospital recently.

Chairman MANZULLO. Well, she had been in and out of the, you know, seniors are in and out. But what I am saying is the fact that that is when the portable X-Ray people had gone out of business.

Mr. SCULLY. There are a lot of perverse incentives in Medicare. What happens, and this is one of the major changes that is shaking up this industry, in 1997 Congress passed Prospective Payment for Nursing Homes. So the nursing homes now get prospective payment and if the nursing home wants to do an EKG within 100 days after discharge from the hospital, it used to be they just billed it to Medicare. Now they get one cap dated payment, the services in that, and if the nursing home wants to do an X-Ray or an EKG they have to pay for it out of their set payment. Believe it or not, if they send the patient to the hospital that gets paid out of a different pot. That is a statutory—

Chairman MANZULLO. It gets paid out of the taxpayers' pot to the tune of \$2 billion a year.

Mr. SCULLY. That is not a HCFA rule, Congressman, that is statute.

Chairman MANZULLO. One of the things you can do if you do not like the statute is to change the darn thing. But one thing you do, Mr. Scully, you can up the rate for home health care, home X-Ray provider. You have the authority to raise that. Not statutorily, you have to work within the budget guidelines.

Mr. SCULLY. Well we do not believe we do, but we are----

Chairman MANZULLO. Let me give it to you. I want to read the statute to you. Now I know I do not sit there and change 7500 different reimbursement rules. HCFA does that. Do you disagree with that statement?

Mr. SCULLY. Yeah. We definitely have, adjust many reimbursement rules but many of them are very strictly statutory.

Chairman MANZULLO. But you have the authority to adjust it up or down on these categories.

Mr. SCULLY. the vast bulk of these are done by the AMA's resource utilization—

Chairman MANZULLO [continuing].—The AMA, it is HCFA.

Mr. SCULLY. Congressman, in the \$66 billion physician pot the AMA convenes every doctor group in the country in something they call the Resource Value Utilization Committee and they make recommendations and 99 percent of the time we take them.

Chairman MANZULLO. Recommendations. Now you listen to the AMA but you would not listen to them.

Mr. SCULLY. I—

Chairman MANZULLO. No, you did not. Let me stop right here.

Mr. EVANS. They will not give us any representation. We asked to be represented. They will not give us representation. We give them the data, they will not do anything with that. And in fact under the physician's fee schedule which they put us under several years ago, all the rest of the physicians are excluded from PPS. They do not have to bill it. But we, as one individual group, have to bill it.

I think what is happening to us is the same thing that has happened to the chiropractors down there. They do not want us around any more.

Chairman MANZULLO. Well they have succeeded, because when mom went to the hospital—

Mr. SCULLY. Are succeeding.

Chairman MANZULLO. Tell me what you would prefer for your mom. Would you prefer, if you had a mom with one leg who was 84 years old, would you prefer to have a home X-Ray, portable X-Ray provider come to her in the privacy of her room, take the picture, have him take it over to the radiologist, report back to the doctor, or would you rather have her carted to a hospital in an ambulance or whatever vehicle she had, to go to the waiting room, emergency room, to have the picture taken there, and to come back several hours later.

One of the reasons seniors get X-Rays is because of a fear of pneumonia. And have her to go out in the rain or whatever, regardless of what it is. Would you not prefer—

Mr. SCULLY. Clearly better.

Chairman MANZULLO. Then why do you not look at their data? You can still do it.

Mr. SCULLY. I am happy to look at their data and I have not met with this gentleman, but I would be happy to and I have met with them extensively.

Chairman MANZULLO. But what you say in the letter here is, "We do not believe the RFA requires us to do an analysis of issues on which the federal government has no industry data and where obtaining data would be burdensome for small businesses.

Mr. SCULLY. I was not referring to that specifically. And I also in the letter, Congressman, I also think I offered later on to try and work with the AMA which does run this group to get them on there. I had found out only recently that they did not have representation on there. I am happy to work with the AMA's groups which do in fact make recommendations to us, but the fact is they are almost always followed, to get their recommendation on this committee.

Mr. EVANS. But the problem is, Chairman, if they turn around, and you are talking about the AMA and we are talking about budget neutrality. If those physicians or the AMA says give the portable X-Ray people more money, it is less to them.

Chairman MANZULLO. So it does not work.

Mr. EVANS. Not only that, but in a letter to you again-

Chairman MANZULLO. Is that correct?

Mr. SCULLY. That is the statutory construct. That is just a fact of life, Congressman. We have \$66 billion. I have—

Chairman MANZULLO. I have heard those figures. You also have 4800 employees, one of whom could take the time to read the data and see we are wasting \$2 billion a year.

Mr. SCULLY. Well, that will just go up.

Chairman MANZULLO. If I were you, Mr. Scully, I would be incensed over the fact that here comes a group that shows you how to save \$2 billion a year-

Mr. SCULLY. I will be happy to come back and have a multi-hour discussion about that data and how it works. I think there are clearly some efficiencies that can be had from sending portable X-Ray providers to nursing homes, but I am not sure I would agree with their total perception of that. But the fact is that their major burden right now that they are feeling is the reduction, an 11 percent

Chairman MANZULLO. I understand that, but you also have the authority, let me read it to you. Let me tell you what you can do.

It says, "The numerical value of each procedure consists of HCFA's combination of three separate components. A, the time that physician spends on a procedure; B, the cost of running a business; and C, the cost of malpractice insurance." The statute provides that "The Secretary shall develop a methodology for combining." The Secretary's authority has been delegated to you.

In other words in a contradiction of the claim on your letter, HCFA has unlimited discretion in how it combines these three components. Congress told HCFA to combine them, not how to combine them. That combination is called the relative value unit in Section 1848 of the Social Security Act.

Mr. SCULLY. I agree. And I could, at my discretion, take that \$66 billion, which is budget neutral, and divide it up any way I chose. Since 1989 when the statute passed, and I was one of the people that helped write it, I believe the best way to do is we have had the AMA convene every specialty group and every device manufacturer-

Chairman MANZULLO. Do you know what the best way to do it is?

Mr. SCULLY [continuing]. And decide what the right approach is. If there was a better way, Chairman, I would be happy to— Chairman MANZULLO. There is a better way to do it. And let me

tell you how simple this is. Watch how simple this is.

Tell me which is cheaper, having a portable X-Ray person go to the nursing home or home and taking an X-Ray, all right? Or taking that senior by ambulance or other specialty vehicle to a hospital and paying a hospital charge, an X-Ray charge, whatever it is, whatever the hospital charge and the standard X-Ray charge, and then having that person wait three or four hours, exposing the senior to all kinds of germs and things in the waiting room which is what Dr. Weldon said. In addition, he even said on sometimes a minor bump, a senior at the nursing home instead of calling the ambulance they would just call the X-Ray provider.

Is that not common sense that it is much cheaper?

Mr. SCULLY. Congressman, I agree with you. The issue is not what we pay for it, the issue is they do not think we pay them enough.

Chairman MANZULLO. That is the whole point.

Mr. SCULLY [continuing]. Discretion—

Chairman MANZULLO. If you paid them more you would save money.

Mr. SCULLY. My own view is I do not substitute my view for the physicians on this group. We would be happy to have—

Chairman MANZULLO. Well maybe you should because they are trying to be on the group and they are excluded.

Mr. SCULLY. Every single physician, that \$66 billion, Congressman, tells me he needs more money, he is underpaid.

Chairman MANZULLO. Mr. Scully, the portable X-Rayers have been excluded from the party.

Mr. SCULLY. Well, they will not be any longer and I do not believe I have excluded them. I have met with them repeatedly.

Chairman MANZULLO. No, no, no. They do not want to meet with you, they want to be——What is the group you want to be on?

Mr. Scully. And I volunteered in this letter to put them in the group.

Chairman MANZULLO. What is the group?

Mr. EVANS. I believe the PEAC was what we asked for initially, and then one was suggested—

Chairman MANZULLO. What is PEAC?

Mr. EVANS. The Practice Expense Advisory Council.

Chairman MANZULLO. The letter from-

Mr. EVANS. Which is the one we asked for.

Chairman MANZULLO. He granted you that request.

Mr. EVANS. No, it was never granted.

Mr. SCULLY. There is no such thing as the Practice Expense Advisory Committee.

Mr. EVANS. What is the name of it?

Mr. SCULLY. What they have asked for, they asked by a slight-ly—

Mr. EVANS. It is the RUC, excuse me. They renamed it. Which we will be more than happy to. That is not what he offered us in the letter. What he offered us in the letter was to submit data. That was it. We have submitted data before, it has always been thrown away.

Chairman MANZULLO. Mr. Scully, is there a portion we missed in the letter? Please.

Mr. SCULLY. I wrote it into the letter myself, I put it in the letter that—

Mr. EVANS. It says that we could ask to sit on it, but it also states that we could submit data.

Chairman MANZULLO. Do you want to sit on that?

Mr. EVANS. We would be more than happy to sit on it.

Chairman MANZULLO. Can he sit on it? Does he have permission to sit on it, Mr. Scully?

Mr. SCULLY. I cannot tell the AMA to do it but they usually take my recommendation so I will certainly recommend that.

Chairman MANZULLO. Will you recommend that they sit on it? Mr. SCULLY. Yes, I will.

Mr. EVANS. I would like to ask another question that is very vital, too.

Chairman MANZULLO. Sure. Mr. Scully is on a roll here. He has come here, he has been very patient, he is in the middle on it, he is doing a very good job of responding. Go ahead and ask your question. That is one of the reasons why we put people together.

Mr. SCULLY. Actually, Mr. Chairman, I think it is the Health Care Professionals Advisory Committee which is on the RUC which is the one that makes these recommendations. It is in the letter.

Chairman MANZULLO. Is that the one you had reference to?

Mr. EVANS. I believe that is the one that he is recommending and that is fine, we would be more than happy to.

Chairman MANZULLO. That is fine.

Mr. EVANS. On March 12th, however, Chairman, Mr. Scully wrote a letter to you and I believe on page three, yes, page three about halfway down he references again the 5.4 percent reduction which is not a 5.4 percent reduction.

Chairman MANZULLO. Right, into your profession.

Mr. EVANS. Entire profession.

Chairman MANZULLO. It is 11 percent—

Mr. EVANS. "We do not—". Mr. SCULLY. To clarify, it is also for all radiologists, I mean I am not happy about it but it is for all radiology services across the country. It is 11 percent.

Chairman MANZULLO. Go ahead, please.

Mr. EVANS. "However, with our specific codes to our industry, the Q and the R code, the Q which is a setup, Q0192, and the R code which is a transportation code. It says, and I quote, "We do not require that the carrier-priced services be reduced by 5.4 percent because that would have been inconsistent with the notion of the carrier setting, the price based on their knowledge of the local situation.

So-

Chairman MANZULLO. Now-

Mr. Evans. Let me continue.

Chairman MANZULLO. I want-

Mr. SCULLY. I want to clarify that because I do not think he understands it.

Chairman MANZULLO [continuing]. Know what you are reading from.

Mr. SCULLY. What I also offered in the letter was, there are two components of this.

Mr. Evans. March 12, 2002.

Chairman MANZULLO. Did you have that, Mr. Scully?

Mr. SCULLY. No I do not, but I have the issue and I can find the letter.

Chairman MANZULLO. Okay.

Mr. SCULLY. The issue here which I think we have offered to be helpful to them as well, there are two major components when you go to do an X-Ray and I cannot give you the exact numbers, but the X-Ray itself is reimbursed at, I cannot remember the number, but it varies anywhere from \$10 to \$30 roughly. But the most more important component is transportation which can go from \$60 to \$120.

Over the years, and this is my understanding, I may be wrong, but we offered, in one of my responses, we have left carrier pricing which means the 23 original carriers by flexibility have tried to come up with the local price that they think is right for transportation, whether it is rural or urban.

If the national association wants to come in and work out a national rate, they have preferred to have the local flexibility in the state in the past and in fact that local carrier rate was not reduced. You do not want it to be reduced. If it were not a national rate it would be reduced by 5.4 percent. It is not because we have left that—

Mr. EVANS. That is not true. It was reduced. In fact we have a gentleman sitting in the room——

Chairman MANZULLO. Transportation—

Mr. EVANS [continuing]. That talked to his carrier in Florida, just got a letter back from them, and they said we are not going to restore the 5.4 percent—

Chairman MANZULLO. Oh, so the carrier did not have to cut it but they cut it anyway.

Mr. EVANS [continuing]. Because the——

Mr. SCULLY. I will—

Mr. EVANS [continuing]. Exactly what he says here, that they do not have to cut it and a more important point, if he wants to—

Mr. EVANS. Excuse me. Excuse me.

Chairman MANZULLO. Just a second.

Mr. EVANS. The carrier said no, we cannot do that because his office said they could not do it.

Chairman MANZULLO. What I think Mr. Scully—Go ahead, Mr. Scully.

Mr. SCULLY. What I have offered to do if you would like to come and talk to us, is to sit down. If they want to have a national rate for transportation based on geographical variances, I am sure we would be happy to work that out with them. In the past they have wanted the regional variation. If they have changed their mind, we will be happy to talk to them about it.

Chairman MANZULLO. The second point is that if this carrier is reducing the transportation component based upon the 5.6 percent, then that carrier has acted improperly.

Mr. SCULLY. I may be mistaken. I will check. Maybe they have to—

Chairman MANZULLO. You think that—

Mr. SCULLY. I may have misspoken, I will check.

Chairman MANZULLO. Okay. That is fair enough.

Did that answer your inquiry?

Mr. EVANS. It answers my question and I guess the situation is, we are forced now to sit down. However in 1999 they came out with a rate, a national transportation rate, which they must have had cost data for, which they also say that you cannot have an RVU unless you have cost data. They came out with the cost data for the R Code. They already have the Q Code under an RVU without cost data.

So we would be more than happy to sit down and work with them in a friendly manner.

Chairman MANZULLO. Okay.

Mr. EVANS. But they cannot turn around and put in well—I am not—he cannot turn around and—either have it or you don't have it and they will not work with us. Chairman MANZULLO. I understand this.

Mr. SCULLY. Well, there is a reason why some of the data is not what it was pre-1997. And we would be happy to talk about it. Before 1997 every one of these services were reimbursed on cost. After 1997 a huge number of these services went under the Protective Payments for Skilled Nursing Facilities. The database changed. If there is better data, newer data, we would be happy to talk to them.

I apologize if I have missed some providers, but I can tell you, I think if you talk to most provider groups, I have sat down with the vast bulk of them to talk about every range of issues in the agency, and if we cannot fix it I will tell them, but I have tried to work lots of them.

Mr. EVANS. I would have to ask you, Chairman, that we could have an assurance that it would be wrapped up quickly, that we would talk and there would be some decision within an amount of time.

Chairman MANZULLO. What decision do you want?

Mr. EVANS. If we could wrap this up in 90 days I would be happy.

Chairman MANZULLO. What exactly do you want wrapped up? Tell me what you want and we will see if Mr. Scully can comply with it.

Mr. EVANS. I would like to have meetings in which we discuss going to a national transportation rate. I would like to have meetings in which we discuss their Q Code which is particular to our industry, and have solutions ready to go in place within 90 days that would be retroactive back to January 1 of this year.

Mr. SCULLY. That cannot be done. Mr. EVANS. That is when it started.

Chairman MANZULLO. I do not know if you can make it retroactive, but Mr. Scully-

Mr. EVANS. If we do not start doing something within 90 days you can kiss the industry goodbye. It is that easy. Chairman MANZULLO. You will be broke.

Mr. EVANS. Exactly.

Chairman MANZULLO. Mr. Scully, the things that he is asking for, can those be done by way of regulation?

Mr. SCULLY. The change to the national, the variation between having the transportation being regionally varying and national can be changed and we have offered in the letter I think to sit down if that is what they would like to do, and I would be happy, I do not know who the best person is but I will probably Tim Triss who is one of my senior staff, probably is the best person and I will hook him up with them and we are happy to work with it.

All right, Mr. Scully.

Anything else with the X-Ray providers?

Mr. EVANS. Excuse me just a moment. Chairman MANZULLO. Okay.

Mr. EVANS. We do have the situation where the physicians, were treated as physicians and paid under the physicians fee schedule, however, we are still stuck in PPS. It is like they want their cake and they want to eat it too. It is a problem. It is something we have to resolve.

I do not have a problem taking this to this meeting, but I would like to have some reassurance that they can fix the problem.

Chairman MANZULLO. Can that be fixed by regulation or does it take a statutory?

Mr. SCULLY [continuing]. Paying for nursing homes as it is. Once you are out of the hospital, 100 days out of the hospital as a senior, everything is under the Nursing Home Prospective Payment. I understand that is different than pre-'97, but that is the statutory issue.

Mr. EVANS. But I do not understand because the physicians are exempt. We were even exempt at one point.

Mr. SCULLY [continuing]. Statute.

Mr. EVANS. On—

Chairman MANZULLO. Did you hear what he said?

Mr. SCULLY. Physicians are exempt by statute, services are not. It is just a fact of the statute. I will be happy to look into it further and sit down and explain it to you, but when we went to the skilled nursing facility PPS in 1997 which was extremely unpopular with lots of people, it capitated the payments for everybody but doctors.

Mr. Evans. If it is statutorily—

Chairman MANZULLO. Blame me, not him.

Mr. EVANS. Exactly. [Laughter]

Chairman MANZULLO. We are trying to find out who is responsible for what around here. This is a great discussion.

Dr. Hulsebus, let me conclude with you. When you testified earlier you said that after this incredible ordeal, you guys could write a book on it. This is the second time you have been to Washington to testify about it. But you said things had not changed much in the last year or so. What has been going on with Wisconsin Physicians Service? They got royally scolded by Mr. Scully, I understand. What has happened? Anything different in how they are treating you?

Dr. MICHAEL HULSEBUS. Basically our treatment is about the same. Right now what I do is I take all my claims from the Judge, the ALJ and he reviews them and says everything is okay, go ahead and pay it, but it has to go through, approximately a year process for each one of these claims.

Chairman MANZULLO. Just a second.

Mr. Scully, that is done through Social Security what he is talking about? ALJ?

Mr. SCULLY. That is a shockingly complex—What happens is if you go to Wisconsin Physicians Services they deny your claim and have the fight they have had and you appeal it. Then you go to an ALJ who works with the Social Security Administration. The appeal is to the ALJ who works for Social Security. The first round is to the carrier which is Wisconsin Physicians Services.

Chairman MANZULLO. All right.

Dr. MICHAEL HULSEBUS. And I guess, Mr. Manzullo, I get comments from all over the chiropractic profession regarding these horror stories I am telling you about. I think the biggest problem we have is we do not have any input with Health Care Finance Administration, CMS, as to chiropractic. We need to have chiropractic, we need to have a voice for chiropractic regarding Medicare. It is my opinion, being on the Board of the International Chiropractic Association that there is no input from our association, that we have no contact to work with anybody on those higher levels.

Chairman MANZULLO. At HCFA?

Dr. MICHAEL HULSEBUS. HCFA, yes. CMS. And I would ask if you could—

Chairman MANZULLO. Go ahead and ask Mr. Scully.

Mr. SCULLY. I will give you two people. One is Barbara Paul who ran the Physician Resource Group that just, is now our Head of Quality. But Barbara Paul and Phil Rogers who I mentioned, I guess I announced hiring who, maybe prematurely, but he is the new Chief quality person and he is a physician who ran the emergency room at Alexandria Hospital for years. They are both physicians, they are both I know very involved and know a lot because I have talked to them about chiropractic issues, and they both know a lot about it. I think both of them would be happy to talk to you and I will tell them to talk to you.

Dr. MICHAEL HULSEBUS. The Executive Director is here from the International Chiropractic Association. He has written several letters to your office to please let us have a voice, please let us have an input regarding the chiropractors' industry. We never get a response, we never get anything back. It is like we do not exist. The only time we exist is when we have problems like this.

I would like to open a dialogue to-

Mr. SCULLY. I will be happy to. I will tell you, because I am not trying to make excuses, I am trying to fix it. When I have people that send me letters, and I apologize, the Congressman obviously sent one last week I have not seen. A lot of them, I see them not directly, sometimes I do not see them at all. But I do in fact answer a couple of hundred e-mails a day and some at night, and I will give you my e-mail address and if you have problems I strongly urge you to send me an e-mail or call me and I will try to get into it.

Dr. MICHAEL HULSEBUS. Is there something the chiropractic industry can do to make it better?

Mr. SCULLY. I think I will just have you sit down and talk to Barbara Paul and Phil Rogers who are my two chief physicians on my staff and talk to them about trying to find ways to be more sensitive to chiropractic issues.

Chairman \hat{M} ANZULLO. Dr. Hulsebus, is it a matter of the reimbursement rates? You are able to live with that?

Dr. MICHAEL HULSEBUS. Oh, I think-

Chairman MANZULLO. I know you would like to have a higher rate, but for the——

Dr. MICHAEL HULSEBUS [continuing]. Talk about but it is not just reimbursement. It is guidelines, there are different guidelines throughout the nation. The chiropractors all over the nation say they do not understand what is going on. Some people get this many visits, some people get this many. Nobody understands how it is worked at all. We would just like to have some clarity.

Chairman MANZULLO. Mr. Scully, is there anybody in CMS that is assigned the task of dealing with chiropractors? I know you have MDs, in fact we talked to one of the ladies in your office that came to our office and visited. On staff, I know you have some MDs. Mr. SCULLY. I do not think we have any in Baltimore. I think we have chiropractors in at least one of the regions. I will have to check. But we do not have anybody that specifically does chiropractic. We also—

[°] Chairman MANZULLO. You cannot have one for each discipline, I understand.

Mr. SCULLY. In some that are big, like I am trying to hire a dialysis coordinator right now because it is \$14 billion a year to dialysis clinics and I think we need somebody to coordinate dialysis issues which we do not have.

I will have to find out. I do believe we have a chiropractor on staff in one of the regions. But I think the fact is what you are really looking for is entry to the agency to have more direct contact and I am sure we can do that.

Dr. MICHAEL HULSEBUS. Thank you.

Chairman MANZULLO. Before we finish, does anybody else on the panel have anything else that you would request of Mr. Scully?

Mr. SCULLY. Can I just make one suggestion?

Chairman MANZULLO. Of course.

Mr. SCULLY. I know some people do not think these work. I actually spend a couple of hours a week on these open door policy meetings with lots of staff and lots of people and the people who are participating have found them helpful even if they are calling from around the country, and I would suggest we will be happy to get any of you involved, but I believe if you get on these calls and ask the questions you will find that they are very helpful, and if they are not, then I would be even more happy to sit down and try to find other ways to help you out, but we do have a physician open door group that includes chiropractors, a number of chiropractors have called in. Ruben King-Shaw is my Deputy and Jeb Bush's former Secretary of Health in Florida, runs that one. I sit on most of them, and I hope you would find those are helpful. I think the people that are on mine I think almost universally find them to be helpful and we have solved a lot of problems.

Chairman MANZULLO. Dr. Minore?

Dr. MINORE. The one thing I would like to add is that universally listening here, I feel that my problems are not unique of all other providers. But again, trying to find a uniform set of guidelines to use would be so helpful. It is like being told to go sit in a corner in a round room. You keep going around and around in circles and you just never know where you end up. [Laughter]

Chairman MANZULLO. Has anybody quantified the amount of time that doctors waste trying to ferret out inconsistent HCFA guidelines?

There is some groaning going on in the back of the room there. Mr. EVANS. You make sure that when you call in that you get it in writing because you are going to get seven different answers.

Mr. SCULLY. Mr. Chairman, I would just tell you this is a common problem. I will give you one example yesterday. I did not look in the papers today, but we cover a few billion dollars a year outpatient prescription drugs. Congress last year told us to start covering more and a broader group of self-injectable drugs usually done in doctors' offices. We did a polling of our 23 carriers over the last four months and found unbelievable inconsistencies for, one example, Avinex, the number one MS drug, was covered in about 13 regions and not covered in 10 others. So we just put out direction yesterday that I think will be clear which drugs are covered nation-wide.

But there is a tough balance. We are trying to come up with regional flexibility so that you are following the regional practice guidelines of various types of physicians and providers and also having national standards that are consistent.

Chairman MANZULLO. Why would you have somebody that is regional for something, I mean transportation is easily regional because some places are mountains and some are inner cities. Why would you have regional?

Mr. SCULLY. Believe it or not, every time someone comes to us for national coverage they get the wrong decision. I can tell you, I can give you 100 drugs and devices. Then they all say well, you should not be making bureaucratic national coverage decisions in Baltimore, you should give us regional flexibility.

So it is forum shopping. Twenty-five percent of the decisions are made in national coverage decisions. Inevitably, I can give you a bunch of examples. People are not happy when we do that. One example is PET scans. I spent a vast amount of time trying to decide what PET scans to cover last summer. We made, I think, a pretty fair national coverage decision and we got people saying oh, it is outrageous, limit it to the regional flexibility.

So one thing—We need to come up with more consistency, but sometimes more consistency leads even to more unhappiness so there is a balance to be had there as well.

Chairman MANZULLO. Mr. Blanchard

Mr. BLANCHARD. I think that is right, but at least to the extent there is a national rule it sets up two possibilities. One, a provider can conform to that rule and in that way protect themselves from this downstream overpayment, payment suspension, False Claims Act investigation. And they can lobby you, Congress, if they do not like the result, to expand that particular coverage in that particular area. They know what the answer is.

Now there are still variations that make absolutely no sense. I will just give you one because I looked it up so I would have a good example. I might as well use it. In the Los Angeles area for MRI of the lumbar spine, there are at least 70 fewer, it was an informal count on the plane coming here, but there are at least 70 fewer indication for MRI of the lumbar spine depending on which side of the avenue that separates Los Angeles County from San Bernadino County.

The same metropolitan area, 70 fewer-

Chairman MANZULLO. Same spine.

Mr. BLANCHARD. Same MRI scan. Seventy fewer indications on one side or the other.

What is surprising here is not that, because you will find that in a lot of parts of the country where carrier areas come together. What is surprising in southern California is it is now the same carrier. It used to be two, but it has been one carrier for a year and that is just one example. Mr. Scully. That does not surprise me. I am sure he is right and that is one of the reasons I would like to go from 49 carriers down to 20.

Chairman MANZULLO. Wait a minute. This is the same carrier. Mr. SCULLY. I can tell you what happened. Blue Cross of California and Candor were a former client of mine and I think one of the better run insurance companies in the country, got out of this business because it is a rotten business to be in, and they happened to be a pretty well run insurance company, so they gave a lot of their staff, I am sure, and some of their old rules, to probably Blue Shield of California, or Noridian I think is the carrier out there now. I am sure they are trying to fold them in. Eventually I would like to have 20 carriers that have more consistent rules, have those 20 medical directors talk to each other more often, and come up with more consistency and also keep some national flexibility.

Chairman MANZULLO. I appreciate that.

Is there somewhere in that process where Mr. Blanchard can have input?

Mr. SCULLY. Sure, I would be happy to talk to him, however he wants to—

Chairman MANZULLO. I guess I volunteered you, Mr. Blanchard. I volunteered Tom to go over there and teach and everything, but do you have any recommendations, Mr. Blanchard, as to what input you would like to have into the system so you do not have those 20 different—

Mr. BLANCHARD. Providers are up against, and the reason I gave that example is there are providers who have offices on both sides of the street in this particular case. There are providers who have offices in New York City and in New Jersey. There are providers who span carrier boundaries all the time.

In addition there are companies that have nationwide practices or large regional practices. Actually we have talked about some of those types of companies today. They have a very difficult time keeping track of which rules ought to apply. You would think in running a business you want to build in the efficiency of common rules, standard rules, and those sorts of things, but you cannot if there is not a good way to get all these folks together. So there are a couple of things.

In the BIPA provisions as well, there is also a provision for petitioning for national coverage determination. I agree with what Mr. Scully says. You ask for one of those, you may not get what you ask for but that is the nature of rulemaking, and informal rulemaking which this is sort of. But at least it is an ability to ask someone to arbitrate this issue, which one of these rules ought to apply.

That rule has a problem as well in that it too is limited to beneficiaries, so providers are not even granted standing to make that request. And the statute does not even make clear, really, and this again is the statute, does not even really make clear whether providers are authorized to represent beneficiaries. Unlike the claims appeal where it is clear that they can, on these it is not clear.

So an opportunity to present those issues would I think alleviate a lot of concern among a wide range of providersChairman MANZULLO. What form would you want present those issues?

Mr. BLANCHARD. I think that the national coverage determination process has merit to it. We do not have enough experience yet with petitions for national coverage determinations to see whether the machinery will work smoothly. There are a lot of variables there.

Chairman MANZULLO. Can—

Mr. SCULLY. Mr. Chairman?

Chairman MANZULLO. Yes, sir.

Mr. SCULLY. I do not know if you were there. We had tried these open door meetings, we had the American Health Lawyers Association had a big meeting in Baltimore last month and we had very well attended, very lengthy open door policy meetings there for the physician group, for the hospital group, and I think one other, and we had a lot of participation from health lawyers around the country that had a lot of good suggestions. I think that is one forum to get people involved and there has been a lot of feedback from that.

Mr. BLANCHARD. I agree with that. I was actually on the planning committee for that program and I serve on the board of the American Health Lawyers Association. That is a good way to go.

Chairman MANZULLO. Mr. Scully, what would it take to treat the spine the same? The indications in Los Angeles.

Mr. SCULLY. Since I am spineless it is hard for me to tell, Mr. Chairman. [Laughter]

Mr. SCULLY. That was too easy.

Chairman MANZULLO. I did not say that. I said you were in contempt of Congress. That is the legal one. [Laughter]

Spineless is physiological. Contempt of Congress is intentional. Please.

Would that take a—See, we could have had fun like this if you had showed up about a month ago.

Mr. SCULLY. I will try to be better in the future, Mr. Chairman. Chairman MANZULLO. All right?

Mr. SCULLY. Yes, sir.

Chairman MANZULLO. And I have accepted your apology.

Mr. Scully, in order to put this spine in one indication, could that be done regulatorily or statutorily?

Mr. SCULLY. I personally believe, and you certainly could do it by regulation, you could certainly do it by statute, that most providers including MRI clinics probably prefer some regional flexibility to work with the carrier and most of them have had better luck than with WPS.

Chairman MANZULLO. Okay.

Mr. SCULLY. I think the reality is that we have 49 carriers and it is unwieldy to get the 49 to talk to each other and come up with consistencies. If we had 20 of our best carriers and we competitively bid the business and we had the 20 medical directors talking to each other we would have much more consistency, and that is what we are striving to do in the contract reform and I think we are getting there slowly. Even without contractor reform there has been a contraction in the industry. Companies like Blue Cross of California are dropping out. We have gone just by contraction in the industry because it is not a fun business to be in, from about 110 contractors ten years ago when I was involved, to 50, and I think you are going to see further contraction.

We would like to speed that up and make it a better business, give people better margins to run the business, and identify the best contractors that can come up with more consistent policies.

Chairman MANZULLO. Okay.

For the record, we are going to be asking you for, is it three things?

Mr. SCULLY. I think I made a pretty good list. Chairman MANZULLO. How long is it going to take the letter to get ready? Oh, that is right, you are going to be submitting some further questions.

Mr. Day, how much time would you need? Tomorrow? All right. Then I think you said 14 days is what you need to respond to these?

Mr. SCULLY. Yes, if you give us 14 days we will get back to you. Chairman MANZULLO. Okay.

Thank you very much, all of you, for participating. This Com-mittee is adjourned.

[Whereupon, at 1:25 p.m., the Committee was adjourned.]

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 Washington, DC 20515-6515

Statement of Donald A. Manzullo Chairman Committee on Small Business United States House of Representatives Washington, DC May 16, 2002

On July 25, 2001, Administrator Scully voluntarily appeared before this Committee and stated that he intended to meet the goal of not simply changing the name of HCFA but changing its culture. Nearly a year later, the new name has been on HCFA's door but this hearing examines whether it is still the same old game. By that I mean, is HCFA still being intransigent and unresponsive to healthcare providers and to the elected officials that make the laws – the United States Congress? Is HCFA still imposing undue and unnecessary regulatory burdens on small business?

At our last hearing, which if Mr. Scully had decided not to stand on ceremony and comply with a validly issued subpoena from this Committee, he would have heard devastating and heart-wrenching testimony from various providers about the regulatory burdens that are driving physicians out of Medicare. Dr. Warren Jones, the President of the American Academy of Family Physicians, noted that there are physicians who are now funding practices out of their own financial resources. In such a situation, it will be impossible for young physicians, with substantial debts, to provide care to Medicare patients. Mr. Scully also would have heard from Dr. David Neilsen, the incoming Executive Vice President of the American Academy of Otolaryngology, about how reimbursements from Medicare do not take into account new regulatory burdens, such as the availability of translators for patients whose first language is not English. Mr. Scully could have answered questions about what discretion he has, and it appears to be substantial, to modify the various components of the physician fee schedule to help physicians.

Today's hearing will present equally wrenching testimony. We will hear about the economic and emotional toll that occurs when health care providers are audited without rational basis. We will hear about physicians following the advice of their carriers only to be told by HCFA to complete reimbursement forms in a different manner. We will hear about carriers in one state denying coverage for medical procedures that are covered in a bordering state. We will hear from non-physician provider of durable medical equipment supplies about their need to second-guess certificates of medical necessity signed by physicians.

HCFA is the agency charged with protecting the health of the Medicare Trust Fund. But as we will hear today, HCFA makes decisions that squander those resources by driving portable x-ray and electrocardiogram providers out of business. Without this service, residents of skilled nursing facilities must be transported, via much more expensive and reimbursable ambulance service, to hospitals or clinics.

Given these facts, it is no wonder that physicians and other healthcare providers are abandoning Medicare patients in record numbers. To them, it simply is not worth wading through the morass of red tape to obtain paltry payments that fail to meet their costs and then have their integrity second-guessed in the guise of protecting against

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waste, fraud and abuse. The question remains who will protect the providers from harassment and unnecessary regulatory burdens. Something must be done and must be done soon. This Chairman will do all in his power to help these small healthcare providers.

HCFA needs to step up to the plate. First, it must reduce bring consistency to decisions made by its contractors. If this requires HCFA to proffer more nationally applicable regulations, such as national coverage determinations, so be it. Second, HCFA must direct its carriers to develop an audit process that is fair and rational. Third, HCFA must do more to ensure that its regulations and guidance are properly assessed for their impact on small healthcare providers. By doing this, HCFA will meet the President's goal that all agencies comply with the RFA. Finally, HCFA must demonstrate that it is responsive not just to the Ways and Means Committee or the Energy and Commerce Committee but to all committees on Congress. We are willing to work with HCFA to help it improve compliance with the RFA and take other actions to reduce regulatory burdens on small healthcare providers. That requires Administrator Scully and the rest of HCFA to be responsive to this Chairman, the Ranking Member and our staffs.

Before turning to the Ranking Member, the gentlelady from New York, Ms. Velázquez, I would like to welcome, as ex officio members to the Committee, my good friend Dr. Weldon.

DONNA M. CHRISTENSEN DELEGATE, VIRGIN ISLANDS

COMMITTEE ON RESOURCES RANKING MEMBER, SUBCOMMITTEE ON NATIONAL PARKS, RECREATION AND PUBLIC LANDS

COMMITTEE ON SMALL BUSINESS MEMBER, SUBCOMMITTEE ON WORKFORCE, EMPOWERMENT AND GOVERNMENT RELATIONS MEMBER, SUBCOMMITTEE ON RURAL ENTERPRISES, AGRICULTURE AND TECHNOLOGY

> Member, Congressional Black Caucus Member, Congressional Caucus for Women's Issues Member, Congressional Travel and Tourism Caucus

Congress of the United States House of Representatives Washington, DC 20515-5501 PLEASE RESOND To:
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STATEMENT OF CONGRESSWOMAN DONNA M. CHRISTENSEN BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE HEARING ON

CMS: NEW NAME, SAME OLD GAME

Thursday May 17, 2002

Thank you Chairman Manzullo and Ranking Member Velazquez for your steadfastness in pursuing the legislative and administrative changes that are needed to improve CMS outreach, awareness and sensitivity to small businesses concerns.

Over the past two years, this committee has held numerous hearings on the issue of CMS's lack of compliance with the Regulatory Flexibility Act. What we have found is that although the name has changed from HCFA to CMS, the problems that small health care providers experience with the agency remain the same.

Today's hearing, gives the members of this committee an opportunity to not just recount these issues with Administrator Scully present, but more importantly, to explore solutions.

For me and my colleagues in medicine, the most important issue is that of the Medicare Physician Payment Crisis.

Effective January 1, 2002, Medicare payments for physician services were cut 5.4%. Under current law, CMS projects will continue steep payment cuts for 3 more years. Physicians will be compensated less in 2005 than they were in 1993 – in constant dollars – and its forcing doctors to close clinics, lay off staff, and worst of all, to stop seeing Medicare patients. Seniors everywhere will find it harder and harder to get timely care.

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And, I will tell you, that minority physicians are especially reeling from the impact of the cuts. As I told a group the other day, when I left practice 6 years ago, I didn't think there was anything left to cut.

Prior to the 5.4% cut, there were press reports of access problems in a number of areas, including Denver, Atlanta, Phoenix, Albuquerque, Austin, and Maryland. Since January of 2002, reports of access problems have appeared in West Virginia, South Dakota, Florida, Kansas, North Carolina, Wisconsin, Alabama, California, and Washington state. In my district, the U.S. Virgin Islands, where costs are very high, our Medicare reimbursement is far below 100%.

This and other cutbacks in reimbursement to home care agencies and skilled nursing facilities has closed down our only home care service and severely threatened the latter facility. There are emerging data and increasing anecdote about elderly patients unable to find doctors, and nurses because they have stopped taking new Medicare patients.

The current method for determining the Medicare physician reimbursement is flawed and is counter productive to keeping healthcare providers in business. The combination of declining Gross Domestic Products and CMS error was the basis for the current cut in physician Medicare reimbursement. Further, the Substantial Growth Factor/Rate (SGR) does not adequately reflect input costs, such as technological advances, improved efficiency of procedures and protocols, and skyrocketing malpractice costs, and is not sensitive to beneficiaries' need for care, which can fluctuate over time.

If left uncorrected, the faulty reimbursement formula, using SGR by 2005 would cut physician Medicare reimbursements nearly 20 percent compared to 2001 payments. CMS has argued that it lacks the authority to correct the errors by increasing futures, even though it admits that the mistakes lowered payments to physicians by more than ten and a half billion dollars over the past four years.

But, Legal analysis done on behalf of American College of Physicians-American Society of Internal Medicine indicates that CMS has the discretion to substantially change the formula used to calculate Medicae physician payments and to correct for past projection errors. According to ACP-ASIM, "These changes would substantially reduce the cost of replacing the flawed formula with a more fair

and accurate method based on input prices." Most importantly it would begin to at least partly restore the cuts almost immediately, which is what we need to do. This is what I want to see happen today as an outcome of this hearing, that Mr. Scully and the agency commit to making the corrections which it is clear they can do administratively.

Another area of concern for small business healthcare providers is the expanding regulatory and paperwork burden. Small Business Administration statistics show that the per employee regulatory compliance cost to small firms is approximately 50% more than the cost to large firms. The actual dollar cost is up to \$5,000 per employee in some small companies. Part of this regulatory and administrative burden has been created by CMS. CMS has imposed overwhelming regulatory burdens on health care providers – and caused many physicians to reassess their commitments to patients under the Medicare system.

Many in the health care field have expressed their dissatisfaction with CMS' coverage process - which result from the mountain of required health care forms each medical provider, must fill out.

For example, after a doctor or other health care provider is visited by a Medicare patient, they are required to classify and accurately document their services in specified codes. Based on this CMS determines what it should pay back to these providers. With an estimated 3 to 4 hours spent on filling out this paperwork, physicians often rush through these forms in order to ensure enough time is spent with their patients. Consequently, many health care providers either omit irrelevant data or forget to fill out the required checks on each form. The result – in many cases these omissions or mistakes trigger an audit by CMS.

But very often, as is demonstrated by the records of Dr. Robert Bucher in St. Croix, even the correct coding may be deemed a mistake by CMS and result in denials and months of correspondence which without intervention may never be resolved.

Which brings me to the issue of carrier reform. At our earlier hearings it was established that the Carrier system was "broken" and needed to be "fixed." Now we are hearing that this is being delayed and we will have to put up with that same unsatisfactory and very frustrating system.

This is akin to a broken promise. Based on that promise, I agreed and called on my constituent physicians to be patient on many of the complaints until the system was reformed and new intermediaries were in place.

I can speak for the U.S. Virgin Islands, but other jurisdictions would probably agree, we cannot work under the current system. It must be changed, or our Part B carrier must be changed.

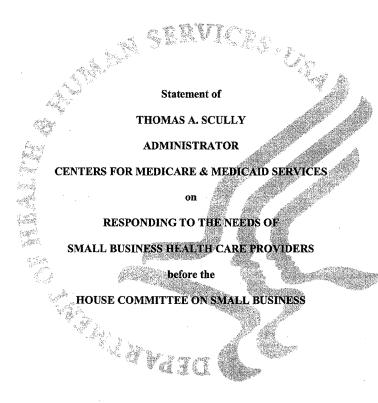
I am pleased that Administrator Scully has joined us today. It is critical that CMS remain committed to examining their regulations and procedures and making the necessary changes to ensure that the unique needs of small health care provider businesses are met.

We are on the verge of a healthcare calamity. Doctors are opting out of Medicare, retiring early or going bankrupt and being forced to close. The sick will get sicker, and the chasm between the healthy and the ill will grow to engulf us all.

We have an opportuity to get the health care system back on course, and to ensure that access to quality healthcare remains a reality for generations to come. This hearing must begin that process.

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Thank you, Mr. Chairman.



May 16, 2002



TESTIMONY OF THOMAS A. SCULLY ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES ON RESPONDING TO THE NEEDS OF SMALL BUSINESS HEALTH CARE PROVIDERS BEFORE THE HOUSE COMMITTEE ON SMALL BUSINESS

May 16, 2002

Chairman Manzullo, Congresswoman Velázquez, distinguished Committee members, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to be more responsive to small business health care providers. I want to apologize to you, Mr. Chairman, and members of the Committee, as well as the others who participated in your hearing last month, for the events of April 10. These events had the unfortunate effect of shifting the focus away from what you and I care about—small business providers. The President, the Secretary, and I strongly believe small businesses are critical to the future of our country. As the President noted earlier this spring, when he announced his initiative to assist small business, "Small businesses create jobs, and this is incredibly important for our economy at this time. Small businesses embody the American values of hard work, risk-taking, and independence." This is true of small businesses everywhere, and in all sectors of our economy, including those in health care. That's why it is important that we continue to tear down regulatory burdens for small businesses and ensure we listen closely as they voice concerns in our regulatory process.

Small businesses provide a variety of health care services. They include individual physicians, small group practices, and providers of durable medical equipment, orthotics, and other supplies and services. They help to ensure that Medicare beneficiaries receive the care they need and play a vital role in the Medicare program. I recognize the importance of helping small businesses continue to fill this need. Since I took over as CMS Administrator, my number one priority has been to improve the Agency's responsiveness and make it a better business partner. At CMS, we

are committed to simplifying our rules, making them easier to understand and less burdensome. We also are committed to opening up CMS and creating more ways for the entities we regulate – including small business – to interact with us. This helps all sectors of the health care industry, of course, but we are paying particular attention to small business providers.

In addition to reducing unnecessary regulatory and paperwork burden stemming from the Medicare rules already on the books, we review the new regulations we issue to see if there are ways we can reduce burden on small businesses, and ensure compliance with the Regulatory Flexibility Act (RFA). We include an analysis of the regulations' impact on small businesses so that we understand how these entities will be affected by the regulation in question, and whether there are alternative ways for us to accomplish the same policy goals. Moreover, in accord with the President's recent initiative to assist small business, we are strengthening our commitment to analyze the impact of our regulations under the RFA.

As part of this commitment, we intend to work more closely with our colleagues in the Small Business Administration's (SBA) Office of Advocacy to ensure that our regulations sufficiently consider the special needs of small businesses. We have met with SBA representatives on a number of recent occasions, including lengthy meetings in the last two weeks. We look forward to continuing our constructive dialogue with them. More than 100 of our staff have spent more than 600 combined hours being educated on their statutory responsibilities under RFA. And we plan to redouble our efforts to raise awareness of small business concerns, and to ensure that all of Medicare's rules and requirements take into account the unique challenges faced by small businesses.

As someone who has worked on health care issues in both Bush Administrations, as well as in the private sector, I know how frustrating Medicare's complex regulations can be. Simplifying the requirements and generally making Medicare a better business partner has been a top priority of mine for years. This Administration takes very seriously the importance of assessing the impact of its decisions on all Americans, including small business owners, and I look forward to working with you to further improve the system. One of the President's principles of Medicare

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reform is regulatory relief for all providers. We support contracting reform and other ways to relieve burden that are under active consideration by Congress. The President's effort to improve and strengthen Medicare will also move the program away from detailed price regulation required by the current statute. In the meantime, we are pursuing a host of administrative efforts to provide as much relief as possible within current law.

IMMEDIATE STEPS TO EASE MEDICARE'S BURDEN ON SMALL BUSINESSES

Secretary Thompson and I are already taking action that is in accord with the President's small business initiative by making the Department, and CMS in particular, more open and accessible to our partners and beneficiaries, including small businesses. Last summer the Secretary created an Advisory Committee on Regulatory Reform, which includes patient advocates, providers, and other health care professionals from across the nation. This Commission is helping to guide the Secretary's efforts to streamline unnecessarily burdensome regulations and to eliminate inefficient regulations that interfere with the quality of health care for Americans. Providers should focus on patients, not on paperwork. We recognize that these requirements can have a disproportionate impact on small providers who often do not have the resources that larger providers use to mitigate the effects of such burdens. Today, the Advisory Committee on Regulatory Reform is holding a field hearing in Denver, Colorado to gather insights from consumers, doctors, health care providers, and businesses. Similar hearings were held in Miami, Pittsburgh, Phoenix, and Denver. The Secretary is reaching outside the beltway to hear from patients and the providers who care for them. The input gathered at these hearings is helping the Committee develop recommendations both to change specific regulatory requirements and to develop broader reforms, even as we speak today. This group is determining what rules need to be better explained, what rules need to be streamlined, and what rules need to be dropped altogether, without increasing costs or compromising the quality of health care services.

To support this initiative, we have developed a program at CMS, focusing on listening and learning, to get us on the right track. For example, I personally travel around the country, meeting with and listening to literally thousands of providers, suppliers, physicians, beneficiaries, and others who live and work with the regulations we create, so I can hear their concerns and

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better understand the changes we need to make. So far I have had 21 of these town hall meetings with CMS constituents, most of them with their Members of Congress. I have two more meetings scheduled this month. My Deputy and Chief Operating Officer, Ruben King-Shaw, and other senior leaders have similarly participated in outreach efforts around the country. Additionally, health care providers across the nation have been working with members of my staff, who spend several days with providers in their offices, learning about their practices, understanding their daily challenges, and seeing how Medicare's rules and regulations impact their ability to serve patients.

We also have created 11 "Open Door Policy Forums" to interact directly with beneficiary groups, providers, suppliers, physicians, and health plans to strengthen communication and information sharing between stakeholders and the Agency. These regular forums are open to all providers -rural, urban, small, large, for-profit, and nonprofit – and to the public. Many of these groups include small business providers. One group in particular - our home health, hospice, and DME open door group - specifically includes providers like portable X-ray and EKG suppliers. In fact, the first "Open Door" meeting, for long term care providers, took place last summer. Over half the meeting was spent discussing portable X-ray and EKG issues. Outside groups meet with senior CMS staff on a regular basis, most of them monthly, to bring to our attention those nagging little problems that they encounter when dealing with the Medicare and Medicaid programs. I personally chair three groups: long-term care, rural health, and diversity; and I regularly attend the meetings of the others. As you can see in the attached chart, we have had overwhelming success with well over 3,700 attendees participating in person or calling in to more than 50 of these meetings since late last year. In fact, just last week we had 4 meetings involving more than 300 public participants. Importantly, our open door forums have aided small businesses by prompting us to take steps to ease regulatory burdens on small business health care providers.

Let me give you a specific example of how we have responded to the concerns of small businesses. Recently, a physician assistant in rural Montana raised a concern with our implementation of the statutory prohibition on paying physician assistants directly. Some of our

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contractors found our guidance on this issue confusing and were denying payment to any physician practice or practice management group that had a physician assistant as an owner. Because of that confusion, this physician assistant was unable to have an ownership interest in the physician group with which he practiced. We understood and agreed with his concern, and we agreed to look into it. As a result of this review, we issued a program memorandum to our Medicare carriers, effective April 1, 2002, clarifying our policy. Now, if state law permits a physician assistant to have an ownership interest in a medical practice or practice group, our policy is to reimburse the practice notwithstanding the physician assistant's ownership.

In another example, at one of our open door meetings, a group of durable medical equipment (DME) suppliers aired their concerns about paperwork burden. After reviewing their concerns, we put together a high-level group of DME suppliers, CMS policy staff, and the private contractor DME carrier medical directors, to work through their concerns. We are in the process of doing the same thing for small home health agencies and orthotic and prosthetic suppliers. We have a meeting scheduled for the end of the month with DME suppliers, suppliers of prosthetics and orthotics, DME Regional Carrier medical directors, and CMS staff to hammer out a solution to their concerns. Is it helping? We know that it is, at least, a start. In fact, after a recent DME open door meeting one gentleman, who owns a small DME supply company in South Carolina, stood up and said he wanted to thank us for all that we were doing to try to improve our partnership with small businesses.

We are making headway, but we know we have much more to do. So in addition to working with small business health care providers, we want to enhance our relationship with small businesses. We have a designated liaison with the SBA, Tony Mazzarella, who maintains an ongoing relationship with the SBA's Office of the National Ombudsman and serves on the National Ombudsman's Interagency Task Force. Among other duties, the Liaison is responsible for ensuring that, when possible and within our resources, CMS staff attend the regularly scheduled SBA "RegFair" field hearings when CMS issues are on the agenda. Most recently, on April 29, the Deputy Assistant Regional Administrator for Health Plans and Providers in our Kansas City Regional Office attended the SBA field hearing in Wichita, Kansas. Consequently,

we are working with the SBA's national ombudsman to better inform the SBA of our efforts to reduce burden for small business and rural health care providers. CMS staff have attended two out of three of these field hearings since February, and we plan to participate in the upcoming field hearing in Richmond, Virginia.

Additionally, CMS' SBA Liaison is responsible for ensuring that comments filed with the SBA concerning CMS' programs are assigned to the appropriate CMS staff and addressed in a timely manner. Moreover, the Liaison currently is working to ensure that when CMS conducts a compliance audit on a small business, the owner is informed of his appeal rights under the Small Business Regulatory Enforcement Fairness Act.

We also are working directly with physicians and other health care providers to improve our communications with them and ensure that CMS is responsive to their needs. We are providing free information, educational courses, and other services through a variety of advanced technologies. In particular, we have a broad selection of training materials available on our Medicare provider education website, <u>www.cms.gov/medlearn</u>. This site provides timely, accurate, and relevant information about Medicare coverage and payment policies, and serves as an efficient, convenient education tool for all providers, including small businesses.

Secretary Thompson and I have been clear: we need to be more responsive to the people who participate in our programs, and our efforts to reduce paperwork burdens on small business health care providers is just one way that we are trying to do that. In the months ahead, I am confident that the Secretary's regulatory reform task force, the Open Door initiative, and our other, similar administrative initiatives we have ongoing will accomplish much, much more. Through these efforts, we are taking administrative action where we are able, and we want to work with you and Congress to make appropriate modifications in other areas.

CMS COMPLIANCE WITH THE RFA

Mr. Chairman, in recent correspondence you have raised a number of very specific concerns with CMS policies and their impact on small businesses. I have addressed these concerns in a letter to

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you earlier this week, and I want to reiterate a few of those points now. For instance, you expressed concern about updates to our payment systems. As a general matter, we make the periodic updates to our payment systems using notice-and-comment rulemaking in accord with the Administrative Procedure Act (APA). We use interim rules with comment only when justified by particular circumstances, such as the need to implement a change in law quickly, and even in these cases we include appropriate impact analyses.

Each year, we use the APA rulemaking process to develop the Medicare physician fee schedule that will apply to payments for the following year. We publish a notice of proposed rulemaking, provide a 60-day comment period, and, as required by statute, publish a final rule by November 1 of each year. For 2002, we published the final rule in the *Federal Register* on November 1, 2001. Pages 55321 to 55328 of the November 1, 2001, *Federal Register* present the regulatory impact analyses, including the analysis required by the RFA, for this rule.

You also raised concerns with documentation guidelines for evaluation and management (E&M) services. The current documentation guidelines were developed in 1995 and 1997 to supplement the definitions of E&M codes contained in the American Medical Association's (AMA) Current Procedural Terminology (CPT) coding system, the system used for coding physicians' services. The guidelines were developed with the active involvement of the AMA and specialty societies. The guidelines were designed to assist physicians and medical reviewers to determine which of five coding levels would be appropriate for an E&M service and what documentation would be appropriate to document that choice. In annual financial audits required by the Chief Financial Officers Act, CMS frequently has been criticized for inadequate documentation on claims Medicare paid for E&M visits by physicians. The guidelines attempted to strike a balance so that physicians could accurately report the services they furnish without undue burden.

Practicing physicians, however, have criticized the existing guidelines. We agree that the current guidelines can be burdensome, and one of our highest priorities is to find ways to reduce these burdens. The Secretary has asked the AMA to consider possibilities for simplifying the CPT E&M codes as we pursue ways to reduce the burden of the documentation guidelines. A

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resolution of this issue could be facilitated greatly if the E&M codes were simplified, since there would be less need for supplemental documentation. The AMA's CPT Editorial Committee subsequently established a work group to consider possible revisions. This group is expected to make recommendations to the CPT committee shortly.

Furthermore, concerns have been expressed regarding the Minimum Data Set (MDS) for longterm care facilities. We use the data from the MDS as a part of the assessment and care planning process required by law, and the MDS was established through rulemaking. The current version of the MDS was developed in 1995 with considerable input from countless individuals representing associations, beneficiary groups, and State governments with which we have worked in partnership in implementing the MDS nationally. We recognize the value of including different perspectives and areas of expertise in establishing clinical guidelines and plan to continue this open and inclusive approach with refinements to the MDS to streamline it and get nursing staff back to the bedside and caring for patients, not filling out paperwork.

We are very focused on ensuring regulatory flexibility for small businesses, and believe our regulations meet the requirements of the RFA. We are committed to opening up the Agency to be responsive to the concerns of all our stakeholders, and we are happy to work with this Committee, small businesses, and others to ensure that we continue to improve.

MEDICARE EKG REIMBURSEMENT

There has been some confusion surrounding Medicare EKG reimbursement, and I would like to take a few moments to explain this issue for the Committee. It is worth describing this complex system in detail because it illustrates the limitations of relying on price regulation in a government-run health plan, rather than giving seniors reliable options to get innovative private coverage that pays for innovative medical services. Medicare pays for EKGs, including those provided by portable EKG suppliers. An EKG service consists of two components: first, a nurse or a technician performs the test, called the technical component. Second, a physician or other qualified clinician interprets the test results. This interpretation is called the professional component. In traditional Medicare, Part B pays separately for the professional component,

regardless of where the service is performed. However, under the Medicare fee schedule, payment for the technical component depends on where the service is provided. The law does not allow Medicare to make a separate payment to either a portable EKG supplier or a physician for transportation of the EKG equipment to a skilled nursing facility (SNF). Some of the confusion about paying for EKGs may be related to the complexity of the statutory Medicare benefit for patients in a nursing facility. Let me try to clarify the situation.

The Medicare statute has a very specific SNF benefit. During the time that a beneficiary is in a SNF and covered under Part A, Medicare's prospective payment system (PPS) makes a per diem payment to the SNF. That payment is bundled, meaning it includes payment for EKG tests as well as other diagnostic tests provided to the beneficiary. The SNF cannot submit a separate bill to either Part A or Part B of Medicare for the technical component of the EKG. Because payment for the EKG test is bundled into the SNF PPS rate, Medicare does not receive separate billing data on the number of EKG tests furnished to beneficiaries in Part A-covered SNF stays. We do know, however, that in 2000, Medicare paid for approximately 47 million Part A-covered SNF days for beneficiaries.

Once the beneficiary has resided in the SNF for 100 days, thus exhausting his Medicare Part A benefit, Part A will no longer make a per diem payment to the SNF. However, Medicare Part B will pay the SNF for certain services and tests that would otherwise be covered for the beneficiary under Part B if the beneficiary was not in a nursing facility. So, if a beneficiary in a SNF is no longer covered under Part A, and needs an EKG test, Medicare Part B would cover the EKG test just like Part B would cover the EKG test if the beneficiary received the EKG test in a physician's office.

The situation is further complicated by the fact that a variety of providers can furnish an EKG to a SNF beneficiary who has exhausted the Part A benefit and be reimbursed for the technical component by Part B of Medicare. The SNF itself can furnish an EKG test, using its own EKG machine in its facility, to a Medicare SNF beneficiary who has exhausted his Part A benefit. In this case, the SNF would be paid by Part B of Medicare for the technical component. This

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payment was previously based on reasonable cost, but since January 1, 2002, it has been based on the physician fee schedule as required by law. An outside supplier also can furnish an EKG test using portable equipment. In this case, the portable EKG supplier would bill Medicare Part B for the EKG test. Medicare would pay the same amount for the technical component of an EKG to the portable supplier as Medicare would pay to a physician who furnishes the test.

A physician also can bring an EKG machine to the facility to provide an EKG test to the beneficiary. In this case, the physician would bill Medicare Part B for the technical component. Additionally, as in any other case where the physician interprets the EKG test, the physician in this case would bill Medicare Part B for the professional component of the EKG test. The "place of service" code on the physician's bill should then reflect that the test was performed in the nursing facility. However, because the place of service code does not affect payment, physicians might not be accurately reporting the place of service as a SNF. Unfortunately, that means EKG data that considered only billings for SNFs as the place of service would likely undercount EKGs furnished to Medicare SNF beneficiaries.

Payment for EKGs in traditional Medicare is made under the physician fee schedule. The Medicare statute specifies a formula to determine physician fee schedule payments based on the relative values, that is, the relative resources involved with furnishing a service. These relative values are adjusted for differences among geographic areas, and then converted to a dollar figure by a conversion factor, which is updated annually. The statute also specifies a precise formula to update physician fee schedule payments by comparing actual spending for a year to target spending for that year. If spending in a certain year is greater than allowed by the formula, payments are reduced in future years, and if spending is less than allowed by the formula, payments are increased in future years. This year, physician fee schedule payment levels for all services paid under the national physician fee schedule, including EKGs, have been reduced by 5.4 percent. We recognize that the 2002 rates may be difficult for some providers, but the Medicare law governing the physician update formula is extremely prescriptive and does not give CMS any administrative flexibility to provide different payments or updates to the physician fee schedule.

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Moreover, Medicare law does not allow administrative flexibility to treat one type of provider who furnishes a service differently from another provider who furnishes the same service. In fact, the Medicare statute explicitly prohibits such differential treatment. One of the fundamental elements of the physician fee schedule since it was originally legislated is the statutory prohibition against variation in the amount of payment among different physician specialties for the same service. Whether an EKG or X-ray test is furnished by a physician, a portable supplier, or an independent facility, the statute requires that the Medicare relative value, conversion factor, and payment in a geographic area be the same.

The RFA requires agencies to consider alternatives to their rules to ease the burden on small businesses, but it does not override the Medicare statute or allow us to violate the very precise payment provisions in Medicare law. To comply with the RFA, we examined the physician payment regulation, including its impact on small businesses and all providers affected by the rule. Our November 1, 2001 final physician fee schedule rule discusses our review to ensure compliance with the RFA. Medicare law requires us to annually adjust Medicare payments for all physicians' services, including EKGs and X-rays, using a statutorily specified formula. The law does not allow us, for example, to suspend the adjustments in the physician fee schedule, or to establish temporary payment rates or increase rates for specific provider types or particular services. We recognize that the size of the payment reductions this year may be difficult for some providers, but we do not have any administrative authority under the law to adjust payment levels for specific provider types or particular services. The Administration is willing to work with you to find a way to ensure that physicians receive appropriate payment for Medicare services, this year and in the future, as part of an overall budget-neutral package. The Administration also hopes to work with you to enact legislation that does not leave health care providers, including small businesses, so dependent on complex medical price regulations that are micro-managed.

CONCLUSION

Through both legislation to strengthen and improve Medicare and administrative actions, this Administration is strongly committed to easing regulatory burden on small businesses, including small business health care providers. We are working hard to make Medicare a better business partner for all health care providers, including small businesses, and reducing burden administratively where we can. I appreciate the Committee's dedication to protecting small businesses, and I am happy to work cooperatively with you to find appropriate ways that we can make Medicare a better business partner for them. Thank you for the opportunity to discuss these issues with you today.

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| | Open Door Meetings Since | November 2 | 001 |
|---------------|--|------------|-------------------|
| Date | Open Door Group | Number of | Number of Call-in |
| 이 영국 영화 영화 영화 | | Attendees | Attendees*** |
| 11/19/01 | SNF/long-term care | 35 | ** |
| 11/27/01 | Home health | 20 | ** |
| 12/11/01 | Rural | * | ** |
| 12/11/01 | SNF/long-term care | * | ** |
| 12/13/01 | Diversity | 10 | ** |
| 12/17/01 | Physician | * | ** |
| 12/19/01 | Rural | 15 | ** |
| 12/19/01 | SNF./long-term care | 30 | ** |
| 1/7/02 | Home health | 25 | ** |
| 1/8/02 | Rural | * | 70 |
| 1/8/02 | SNF/long-term care | * | 65 |
| 1/9/02 | Pharmacy | 10 | ** |
| 1/15/02 | Hospital | 10 | 34 |
| 1/15/02 | Disabilities | 10 | 37 |
| 1/17/02 | Nurses/allied hcalth | 10 | 26 |
| 1/18/02 | ESRD | 85 | ** |
| 1/23/02 | Health plan | 10 | 48 |
| 1/28/02 | Physician | * | ** |
| 1/29/02 | Rural | 15 | 67 |
| 1/29/02 | SNF/long-term care | 20 | 58 |
| 2/5/02 | President's budget | 41 | 150 |
| 2/12/02 | Hospital | 15 | 84 |
| 2/20/02 | Health plans | 10 | 40 |
| 2/25/02 | Physician | ** | 163 |
| 2/26/02 | Rural | 20 | 71 |
| 2/26/02 | SNF/long-term care | 25 | 82 |
| 3/6/02 | Pharmacy | 10 | 43 |
| 3/7/02 | Home health | 25 | ** |
| 3/12/02 | Hospital | 30 | 114 |
| 3/13/02 | HIPAA | 85 | 770 + 220e = 990 |
| 3/13/02 | Nurses/allied health | 10 | 30 |
| 3/14/02 | Diversity | 10 | ** |
| 3/14/02 | ESRD | 95 | 68 |
| 3/16/02 | Disabilities | 10 | 9 + 68e = 77 |
| 3/18/02 | Physician | 10 | 133 |
| 3/20/02 | Health plans | 10 | 55 |
| 3/26/02 | Rural | 20 | 139 |
| 3/26/02 | SNF/long-term care | 20 | 115 |
| 4/4/02 | American Health Lawyers Association | | ** |
| | (physician) | 20 | ** |
| 4/4/02 | American Health Lawyers Association | | ** |
| | (hospital) | 50 | ** |
| 4/5/02 | American Health Lawyers Association | 20 | ** |
| | (health plan) | 30 | ** |
| 4/11/02 | Nursing home open door special meeting | | 3.50 |
| | in Chapel Hill, NC | 75 | 350 |
| 4/15/02 | Physician | 2 | 59 |
| 4/17/02 | Rural | 15 | 43 |
| 4/18/02 | Hospital | 15 | 92 |

| 8 | 9 |
|---|---|
| | |

| 4/18/02 | Home health | 15 | 32 |
|---------|--------------------------|------|------|
| 4/30/02 | SNF/long-term care | 30 | 120 |
| 5/1/02 | Pharmacy | 10 | 29 |
| 5/7/02 | Home health | 20 | 50 |
| 5/8/02 | Hospital | 5 | 99 |
| 5/9/02 | Nurses and allied health | 8 | 10 |
| 5/10/02 | ESRD and clinical labs | 75 | 67 |
| | TOTALS | 1021 | 3710 |

* Conference call only
** Data currently not available
*** The "e" represents the number of callers to the "encore" playback feature for each forum (up to 48 hours after its conclusion).



Testimony of The Honorable Thomas M. Sullivan Chief Counsel for Advocacy

U.S. House of Representatives Committee on Small Business

Date:May 16, 2002Time:9:30 A.M.Location:2360 Rayburn House Office BuildingTopic:CMS: New Name, Same Old Game?

Created by Congress in 1976, The Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. The Chief Counsel for Advocacy, who is appointed by the President and confirmed by the U.S. Senate, directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Issues are identified through economic research, policy analyses, and small business outreach. The Chief Counsel's efforts are supported by offices in Washington, D.C., and by Regional Advocates. For more information on the Office of Advocacy, visit <u>http://www.sba.gov/advo</u>, or call (202) 205-6533.

92

Chairman Manzullo and Members of the Committee, good morning and thank you for the opportunity to appear before you today to address how government agencies, specifically the Centers for Medicare and Medicaid Services (CMS), can benefit small business by considering the consequences of their mandates on small employers before they regulate.

On April 10, 2002, I appeared before this committee to testify on the Centers for Medicare and Medicaid Services' (CMS) compliance with the Regulatory Flexibility Act (RFA), and whether such compliance could be expected to resuscitate small healthcare providers. I testified that it was Advocacy's goal that CMS consider more fully the consequences of their regulatory actions on small healthcare providers prior to finalizing their rules as required by the RFA. Advocacy has learned that early intervention with administrative agencies prior to the promulgation of their rules works and serves to minimize the impact of rulemakings on small businesses without compromising the underlying mission or statutory requirements of the agencies. During my closing remarks in April, I indicated a desire and willingness to work with CMS early in its rulemaking process. This, I felt, was consistent with President Bush's vision on how to protect small businesses from burdensome regulations and Secretary Tommy Thompson's plan to reform the regulatory process within the Department of Health and Human Services.

I am pleased to announce that since my testimony on April 10, my commitment to this Committee to work with CMS has begun to take shape. On April 22, 2002, I met with representatives from CMS and from the Department of Health and Human Services' General Counsel's office. Last week I met with Mr. Ruben King- Shaw, who is CMS's Deputy Administrator and Chief Operating Officer. These meetings helped start a new dialogue between my office and CMS. The meetings focused on general small business issues and data gathering mechanisms. The meetings resulted in a commitment between the Office of Advocacy and CMS to work together in a concerted effort to reduce the impacts associated with CMS's rulemakings on small healthcare providers.

It is my hope that the recent contact between Advocacy and CMS is only the beginning. I look forward to maximizing the new relationships that have been developed since I last appeared before this committee. This can only result in better communication and action between my office and CMS on the issues that are of concern to this Committee.



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National Association of **Portable X-Ray Providers** Mailing Address: 1333 Village Drive • St. Joseph, Missouri 64506 • 1-800-252-4927

TESTIMONY OF ZACHARY EVANS

Chairman of the Board NAPXP

May 16, 2002 Small Business Committee US House of Representatives

Testimony of Zachary Evans, NAPXP May 16, 2002

Mr. Chairman, Ranking Member Velazquez and members of the committee, my name is Zach Evans and I currently serve as the Chairman of the Board for the National Association of Portable X-Ray Providers. I am pleased to have the opportunity to testify before you again today.

Mr. Chairman, the plight of portable X-Ray providers has been described by CMS as very complex. They inform us that they have no cost data on our industry and therefore cannot perform the regulatory flexibility analysis required by law. They assure us that their policies are appropriate although they cannot provide any empirical evidence to support their position and discard any data that supports opposing views. They refuse to answer the most basic questions posed by providers or to meet with us when we come to Washington seeking guidance, yet boast of their openness and responsiveness.

I appear before you today to explain simply, accurately and fairly the costs of our services and the costs of the alternative. You will see that, in fact, this situation is not particularly complex. You will see that the side-by-side comparison of the cost of portable X-Ray service versus the cost of transporting a patient to the hospital provides a clear healthcare delivery choice.

The charts we have prepared illustrate the cost of providing the 3.5 million portable x-ray procedures which were performed, according to CMS, in 2000 and a very conservative estimate of the cost of those services had they been performed at a hospital after transport by ambulance. The chart displaying the portable service costs is based upon national averages for the three component costs of portable services; transportation, set-up, and the technical component. Again, using the

Testimony of Zachary Evans, NAPXP May 16, 2002

CMS figure of 3.5 million procedures, we find average costs of \$284 million in transportation, \$38.5 million in set-up, and \$63 million in the technical component for a total of \$385.5 million. If we, very conservatively, estimate the costs of performing those same 3.5 million procedures at hospitals, which will be the outcome if current CMS policy is continued, we see the costs in the second chart. The technical component cost remains unchanged at \$63 million. The ambulance transport cost, based upon CMS ambulance transport cost data contained in the March 12, 2002 CMS letter to Chairman Manzullo, is \$1.2 billion. The hospital admissions cost is \$945 million. These costs total \$2,810,500,000. This means that the result of a collapse of the portable x-ray industry, an eventuality made nearly certain under current CMS policies, would result in an increased cost to Medicare of nearly \$2.5 billion annually. Viewed alternatively, the portable x-ray industry saves Medicare nearly \$2.5 billion annually while providing higher-quality, patient preferred services than the alternative.

To further illustrate our point, we have provided several examples of actual remittance documents or, plainly speaking, Medicare benefit bills. In the interests of time, I will not take the Committee through these line-by-line but offer them as examples of the costs of ambulance transport, emergency room treatment, etc., as compared with portable provider costs. I would be happy to address the specifics of these documents during the question and answer period.

In summation, Mr. Chairman, Congresswoman Velazquez, Committee Members and distinguished guests, our industry provides vital, cost effective services that, if CMS is allowed to proceed on their current policy course, will cease to be available to the public. Not only will this policy failure result in dramatic cost increases, the quality of patient care will suffer significant declines. In the face of

Testimony of Zachary Evans, NAPXP May 16, 2002

this obvious truth, my industry is confronted with punitive audits, regressive policy initiatives, unwillingness to respond to basic guidance inquiries, and overall contempt from an agency which spends millions of our tax dollars telling America that they support small business and are solving problems through "Open Door Policy Forums." Mr. Chairman, I have attached a letter sent on December 13, 2001 to Mr. Scully requesting answers to fundamental guidance questions posed by our industry. CMS has never responded to that letter. Sadly, this is not the exception, but the norm. Speakers are unavailable, correspondence is ignored, and Administrators refuse to appear before the Congress and small businesses because they don't like the seating arrangements. This was the behavior of HCFA, this is the behavior of CMS. We applaud the tireless work of this Committee in the face of such unrelenting bureaucratic opposition to change. We sincerely hope that, through the work of this exceptional Committee and a handful of caring, conscientious Members of Congress, we might survive to provide our services to our patients. Thank you for this opportunity and I would be happy to answer any questions you might have.

Halsey, Rains & Associates, L.L.C.

December 13, 2001

Mr. Tom Scully Administrator Centers for Medicare and Medicaid Services 200 Independence Avenue, SW Room 314-G Washington, DC 20201

Dear Mr. Scully:

On behalf of the National Association of Portable X-Ray Providers, we were pleased to have Mr. Frank Camozzi, of your San Francisco office, speak at our annual meeting in Las Vegas this past October.

Mr. Camozzi spoke to us about the changes taking place within CMS and more specifically he addressed a program memorandum of great concern to our industry (Program Memorandum Intermediaries Transmittal # A-01-119). His presentation was informative, although there were pending questions on a variety of issues relating to the industry, which he suggested we forward to the main office following his presentation.

The questions are attached. Should you or your staff have questions, please have them contact me. The response may be sent to my attention.

Thank you and we appreciate your efforts on behalf of the portable x-ray industry.

Regards,

Cc: John Cavalier, President, NAPXP

2111 Wilson Boulevard • Suite 600 • Arlington, VA 22201 • Phone (703) 351-5077 • FAX (703) 351-5827 • e-mail: hra@halseyrains.com

What recourse does a provider have when payment is not received promptly from the SNF? Would it be acceptable to have the SNF bill and the providers' portion be paid to the provider directly?

What is the expected result of Program Memorandum A-01-94 (Correction Program Memorandum A-01-119)? What internal process evaluated this to anticipate those expected results?

Request explanation of discrepancy between physician fee schedule and fiscal intermediaries schedule. The difference is an average of 15-20%.

During inspection, the provider is required to show the proper documentation for procedures, including the physician's signature on orders. Often times, the physician signs the chart located with the patient in the SNF. Thus, the provider has no documentation to support the order. We are seeking clarification or a change in the instruction.

We are seeking a detailed explanation as to why the portable x-ray industry does not qualify for a rural modifier. There is clear precedence for what constitutes a rural area and a formula designating the monetary adjustment. As our service to rural areas is comparable to that of ambulance service in rural areas, we should also be entitled to the rural fee adjustment in addition to our base rate to cover additional rural transportation costs.

CMS Policies/Effects Upon Portable X-Ray/EKG Providers

- Total Elimination Of EKG Transportation Component
- PPS Inclusion = Approx. 20% Across The Board Fee Reductions + Slow Or No Pay From SNFs Due To Reduced SNF Profits And SNF Bankruptcies
- 2002 Physician Fee Schedule Impact: Technical Component Reduction - 10% Set-Up Reduction - 10% Transportation Reduction - 5.4%
- Dramatic Decline In Radiologists Willing To Read Medicare Films As Physicians Increasingly Refuse To Treat Medicare Patients

Average Portable X-Ray/EKG Provider Expense Increases

- Radiologists Shortages Cause Fee Increases Of 30% Or More Over Medicare Reimbursement
- Gasoline Costs Dramatic Increases While Medicare Transportation Reimbursements Drop
- Insurance Costs Increased By Up To 150%

| Medicare Part B | |
|------------------|------------|
| P.D. Box 3537 | |
| Topeka, Kensas | 66601-3537 |
| Phone 1-866-839- | 2442 |

| MEDICARE | |
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| RENITTANCE | |
| NOTICE | |

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| 9003510 | 0415 041502 | | | 71010 | TC | | 31.00 | 16.36 | 16.36 | 0.00 | CO-42 | 14.64 | \$.0 |
| 9083516 | 0415 041502 | 32 | 1 | Q0092 | | | 25.00 | 10.61 | 4.11 | 1.34 | CD-42 | 14.19 | 5.3 |
| 9003510 | 0415 041502 | 32 | 1 | RD070 | | | 125.00 | 92.23 | Ū.00 | 18.45 | CD-42 | 32.77 | 73.7 |
| PT RESP | 40.26 | | | CLAIN | TOTALS | | 181.00 | 119.40 | 20.47 | 19.79 | | 61.60 | 79.1 |
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| ANE WINNE | i interv | | | | | ACNT | - | | ICN . | | | ASG COLOR | |
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| 003510 | 0414 041402 | | | R0070 | | | 125.00 | 72.23 | 6.00 | 18.45 | CQ-42 | 32.77 | 73.7 |
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| 003510 | 0411 041102 | 32 | 1 | R0970 | | | 125.00 | 92.23 | 0.00 | 18.45 | C0-42 | 32.77 | 73.7 |
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| T RESP | 52.32 RMATION FORW | | | | TOTALS | | 186.00 | 75.39 | 46.55 | 5.77 | | 110.61 | 23.0 |
| | | RUEL | | | | | | | | 23.07 | NET | | |
| AME | 9417 041792 | 2.9 | | 72100 | | ACNT | 43.00 | 17.68 | ICN O | | | ISE CONTRACTOR | |
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| 003510 | 0405 040502 | | | R0075 | | | 125.00 | 46.12 | 0.00 | 9.23 | C0-42 | 78.85 | 36.85 |
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| T RESP | 14.66 | | | | | | 181.00 | 73.27 | 0.80 | 14.65 | | 107.71 | 58.63 |

MAY 1 0 RECT

IF YOU HAVE ANY QUESTIONS

BETWEEN B:00 A.M. AND 5:00 P.M.

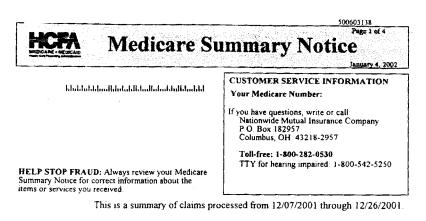
DATE: 5/15/02

| DATE | CLAIM | DESCRIPTION | AMOUNT |
|--------------|---|---|---|
| 12/26/00 | - | BLS NON EMERGENCY | 340.00 - |
| | | BLS NON EMERGENCY | 340.00 - |
| | | MILEAGE | 12.00 |
| | 1 · · · · · · · · · · · · · · · · · · · | MILEAGE | 12.00 |
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| | a she ar an | MEDICARE PAYMENT | 168.61 |
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| 704.0 | 0 | | 97.71 |

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| Claim | Balance | Payment Amount |
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| | Policy: |



PART B MEDICAL INSURANCE - ASSIGNED CLAIMS

| Dates of Service | Services Provided | Amount | Medicare Approved | Medicare Paid Provider | You May Be Billed | See Notes Section |
|------------------------|--|----------|----------------------|------------------------------|-------------------------|-------------------------|
| Claim numb | er (| | | | | |
| | alley Emergen, | | | | | a,b |
| | 7 Po Box 631597 , ni, OH 45263-1597 | | | | | |
| | r, Máry E. DO | | | | | |
| 11/26/01 | 1 Emergency dept visit (99285-25) | \$321 00 | \$154 13 | \$123.30 | \$30.83 | |

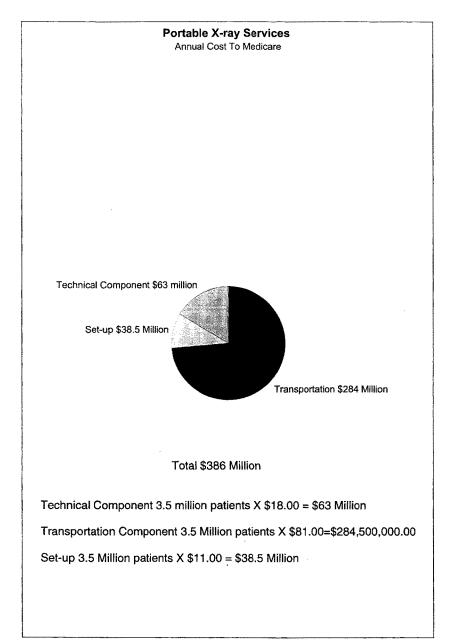
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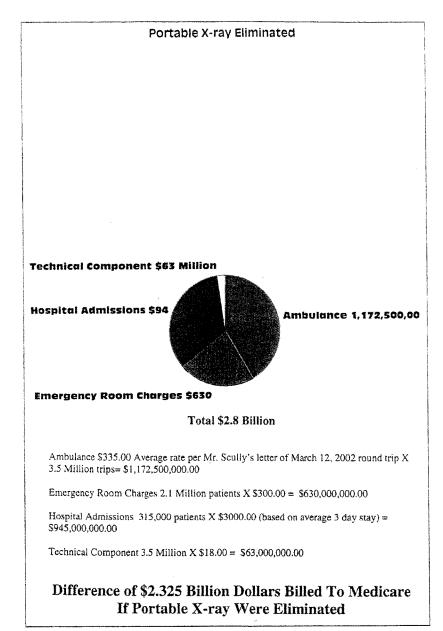
Your Medicare Number:

Page 02 of 03 January 08, 2002

PART B MEDICAL INSURANCE - OUTPATIENT FACILITY CLAIMS

| Dates of Service | Services Provided | Amount Charged | Non- Covered Charges | Deductible and Coinsurance | You May Be Billed | See Notes Section |
|-----------------------------|--------------------------------------|-------------------|----------------------------|----------------------------------|-------------------------|-------------------------|
| Control num | ber | | | | | |
| ST. Elizabeth Health Center | | | | | | b,c |
| 1044 Be | mont Ave | | | | | |
| Administ | rator | | | | | |
| Youngst | wn., OH 44501-1790 | | | | | |
| Referred by: | Mouni E. El-Havek | | | | | |
| 11/26/01 | Advanced life support mileag (A0390) | \$180.00 | \$0.00 | \$36.00 | \$36.00 | |
| | ALS1-emergency (A0427) | 865.00 | 0.00 | 173.00 | 173.00 | |
| Claim Total | | \$1,045.00 | \$9.00 | \$209.00 | \$289.00 | |





House Committee on Small Business

"CMS: New Name, Same Old Game?"

May 16, 2002

Prepared Statement of Brian Seeley

Power Mobility Coalition

Mr. Chairman and Members of the Committee, my name is Brian Seeley. I am President of Seeley Medical, Inc., a supplier of home medical equipment and supplies serving patients in North-Central Florida since 1988. Seeley Medical has two locations and employs 13 people. I serve on the Board of Directors of the Power Mobility Coalition ("PMC") and the Florida Association of Medical Equipment Services ("FAMES") and served as the FAMES President from 1997 to 2001.

On behalf of the PMC, I would like to thank the Committee for holding this hearing and appreciate the opportunity to present testimony concerning the procedural and regulatory problems facing small businesses in their dealings with the Centers for Medicare and Medicaid services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"). The PMC is a coalition of suppliers and manufacturers who provide power mobility equipment and services, such as motorized wheelchairs and scooters, to beneficiaries nationwide. PMC members represent well over half of the nation's power mobility market and our members are located in all regions of the country.

Suppliers of power mobility equipment and services, and other health care providers that serve Medicare beneficiaries, spend much of their time and effort interpreting and complying with Medicare's complex regulatory and procedural requirements. In addition to dealing with Medicare laws and regulations, PMC members must also deal directly with the Durable Medical Equipment Regional Carriers (DMERCs), the entities that are charged with administering payment on behalf of CMS. While CMS has overall responsibility for program management, many of the responsibilities related to reimbursement and medical policy have been delegated by the agency to the DMERCs. Unfortunately, the DMERCs have used this authority to create new policies, often in direct contrast to existing policy published by CMS.

CMS has allowed, and at times encouraged, the DMERCs to administer policies that are in direct contrast to existing agency policy and regulations. This has led to an erosion of the due process afforded to those who choose to provide items and services to program beneficiaries. The

following are examples of policies, established by Congress and/or CMS, that have been often ignored by the DMERCs:

- I. Inconsistent Application Of Certificate Of Medical Necessity Process
- II. DMERC Audit Process Inconsistent With CMS Policy
- III. The Regulatory Process Regarding The Reopening Of Claims Is Being Disregarded By The Carriers

The inconsistent application of policy by the DMERCs has imposed unnecessary burdens on an industry predominantly made up of small businesses. According to CMS's own Medicare data, more than 95 percent of all suppliers of durable medical equipment generate billings of less than \$350,000 in Medicare revenues annually, and 99 percent generate less than \$5 million. See Final Rule, entitled "Medicare Program; Additional Supplier Standards" (October 11, 2000 Federal Register, 65 Fed. Reg. 60366). In this context, we offer the following comments and recommendations:

I. INCONSISTENT APPLICATION OF CERTIFICATE OF MEDICAL NECESSITY PROCESS

The Certificate of Medical Necessity is defined by Congress, developed by CMS, and was formally approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act ("PRA"). During the PRA process, CMS developed the Certificate of Medical Necessity in a manner consistent with congressional intent and declared that the information on the Certificate of Medical Necessity would be "used by carriers to determine the medical necessity of an item or service covered by the Medicare program." <u>See</u> CMS PRA Submission, January 6, 1996, p. 1,

The Certificate of Medical Necessity is completed and signed by the patient's treating physician who certifies, subject to civil and criminal penalties, that the information is true and accurate. Congress further provided that suppliers would be prohibited from completing the medical necessity information on the Certificate of Medical Necessity form, thereby assigning this responsibility to the medical personnel who treated the patient. The Certificate of Medical Necessity is the only medical record required to be collected by a Medicare supplier and only medical record required to be submitted to the program to demonstrate medical necessity.

Despite the explicit rules governing the use of the Certificate of Medical Necessity in the Medicare program, CMS has provided guidance to the DMERCs inconsistent with statements made by the agency to the OMB through the PRA process. The result has often led the DMERCs to disregard the physician completed medical necessity information on the Certificate of Medical Necessity, resulting in the following:

A. Determinations by the DMERC that a supplier is "with fault" for accepting payments on claims in circumstances in which the supplier has submitted a

properly executed and completed Certificate of Medical Necessity in compliance with the documentation requirements set forth in the DMERC's medical policy.

- B. The impression that the DMERCs lack confidence in the physician information on a Certificate of Medical Necessity. Upon signing and completing a Certificate of Medical Necessity, a physician certifies that any falsification, omission, or concealment of material fact with regard to medical necessity information on the form may result in civil or criminal penalty. The DMERCs apparent lack of confidence places the supplier in an awkward position of having to guess whether the information contained on a Certificate of Medical Necessity will justify medical necessity. Suppliers should not be placed in this position and CMS did not intend that suppliers would be placed in such a position.
- C. Prepayment and postpayment reviews on a class of suppliers which establish arbitrary and confusing medical necessity "requirements." These ad hoc policies require suppliers to submit additional medical documentation with all of their claims even though the documentation requirements in the medical policy require the submission of a Certificate of Medical Necessity.

A properly executed and completed Certificate of Medical Necessity, as envisioned by Congress and CMS, is the Medicare medical necessity document developed to ensure clarity and consistency in the claim submission process. A study conducted by the PMC uncovered that the Certificate of Medical Necessity process disqualifies nearly 80% of patients who are seeking power mobility equipment. The medical necessity criteria on the Certificate of Medical Necessity and the physician signed certification effectively ensure that only those beneficiaries qualified to receive equipment and services within the Medicare program do so. In fact, the Certificate of Medical Necessity, which was successfully developed by CMS and the medical community, has been validated by the Administrative Law Judges who review the Certificate of Medical Necessity forms during the Medicare appeals process. A September 1999 Office of Inspector General Report, entitled "*Medicare Administrative Appeals*," uncovered that 78 percent of DME appeals were reversed at the Administrative Law Judge level. <u>See</u> Department of Health and Human Services, Office of Inspector General September 1999 Report p. 8.

The DMERCs disregard of this process has created the exact opposite – an unclear and inconsistent process that imposes additional unnecessary burdens on Medicare participants. The following chart illustrates the discrepancy between the definition and purpose of the Certificate of Medical Necessity, as outlined by Congress and CMS, versus the DMERC use of the Certificate of Medical Necessity.

INCONSISTENT CERTIFICATE OF MEDICAL NECESSITY POLICY

Congress Definition of Certificate of Medical Necessity

"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 a malformed body member." Section 1834(j)(2)(B) of the Social Security Act.

| CMS Formal Written Statements to OMB | Characterization of CMN by CMS/DMERCs |
|---|--|
| Regarding CMN During PRA Process | After Formal PRA Approval Process |
| The information on the CMN "is needed to correctly process claims and ensure that claims are properly paid. This form [CMN] contains medical information necessary to make an appropriate claim determination." (March 4, 2002 CMS PRA Submission to OMB, 67 Fed. Reg. 9741). | "Neither a physician's order nor a CMN nor a supplier prepared statement not a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician." (CMS Medicare Program Integrity Manual, Chapter 5, Section 2). |
| "The use of standard forms (CMNs) facilitates review by HCFA [CMS] and is more efficient for the suppliers because necessary information is specifically spelled out – eliminating the possibility of submitting unnecessary documentation." (November 5, 1996 CMS PRA Supporting Statement of 61 Fed Reg. 56963-56964, p.3). | "The OMB-approved CMN represents nothing more than a Medicare pre-payment tool which has been abbreviated as much as possible to reduce physician paperwork." (Region C DMERC Medical Review Addressing Individual Claims). |
| "The CMN is designed to collect only the pertinent pieces of medical information without having to individually request medical charts from the physician each time a claim is submitted." (November 5, 1996 CMS PRA Supporting Statement, p. 5). | The CMN itself does not provide sufficient documentation of medical necessitySuppliers are not required, nor should they, sell equipment to unqualified beneficiaries merely because they have a physician's written order and a CMN." (Region C DMERC Medical Review Addressing Individual Claims). |
| "CMNs are used by Medicare and its contractors to verify that items and service provided are reasonable and necessaryIn this way, CMNs are indispensable to the Medicare program." (November 5, 1996 CMS PRA Supporting Statement, p. 4). | "The mere existence of a signed CMN is not sufficient evidence of medical necessity." (Region C DMERC Medical Review Addressing Individual Claims). |
| "The CMNs currently in place have provided protection to the Trust Fund by ensuring that only reasonable and necessary claims are being paid." (November 5, 1996 CMS PRA Supporting Statement, p.8). | |

II. DMERC AUDIT PROCESS INCONSISTENT WITH CMS POLICY

CMS developed standards for the audit process in an August 7, 2000 Program Memorandum entitled the *Medicare Review Progressive Corrective Action* plan. Unfortunately, such standards are not being adhered to by the DMERCs.

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Carrier Audit Determination Should Be Consistent With Medical Necessity Standards Established By Congress and CMS

The CMS Medical Review Progressive Corrective Action plan states that "<u>after validating that</u> <u>claims are being billed in error</u>, target medical review activities at providers or services that place the Medicare trust funds at the greatest risk while ensuring the level of review remains within the scope of the budget for medical review."

As highlighted above, the DMERCs failure to apply the physician completed and signed Certificate of Medical Necessity in a manner intended by Congress and CMS has led to much confusion and difficulties for our industry. On numerous occasions, PMC members have been audited and assessed an overpayment even though the equipment was provided pursuant to a properly completed Certificate of Medical Necessity signed and certified by the patient's treating physician. Many suppliers fully comply with the rules established by the Medicare program and still are penalized by new and arbitrary criteria developed by the carrier after the equipment had been delivered to the patient and after the claim had originally been paid. Chairman Manzullo summed it up best in the opening statement of the July 25, 2001 hearing of this Committee entitled "*Reducing Regulatory and Paperwork Burdens on Small Healthcare Providers: Proposals From the Executive Branch*":

Audits often require providers, most of who are small businesses to make reimbursements back to the Medicare Trust Fund for overpayments. Most small businesses do not have the resources to wend their way through the Department's administrative maze and get the contractors audit overturned on appeal. Is the regulatory process fair when it depends not on the correctness of the position but on the ability of a provider to afford good lawyers or intervention from a member of Congress...contractors, in interpreting the guidance provided by HCFA, may require a durable medical equipment supplier to obtain more information before providing equipment specified in a physician-signed certificate of medical necessity. What purpose exists to have a non-physician second guess the determination of a licensed physician.

The PMC encourages CMS and its DMERCs to conduct audits but such audits should be conducted in a manner designed to ensure that the information on the required medical documentation (CMN) was completed properly. For example, the PMC would encourage the

DMERCs to validate that the treating physician reviewed and completed the Certificate of Medical Necessity and validate that the beneficiary received the equipment listed on the Certificate of Medical Necessity. Ensuring that the medical documentation (CMN) required by the Medicare program is completed properly is a valid oversight function of CMS and the DMERCs. The PMC has offered specific recommendations to the agency regarding the audit process and looks forward to continued dialogue.

DMERC Audits Should Not Be Based Solely on Utilization

We have witnessed an increasing number of audits and medical reviews being performed on the power mobility industry without regard to rules established by Congress and CMS. In fact, two DMERCs have recently conducted "general investigations" of our industry without complying with the procedural requirements set forth in the Paperwork Reduction Act. The PRA establishes that the paperwork required during a "general investigation" be approved by the OMB. While CMS has indicated that the DMERCs do not conduct industry audits based on utilization, the facts show a different reality:

- The Region C DMERC recently conducted a medical probe review of the top 30 power mobility suppliers in the region, representing a significant majority of power mobility claims in such region. Each company received a letter stating that they are being audited based on the their specific ranking in terms of utilization for a particular time period. One company received a letter stating that the DMERC is conducting this review on all suppliers with greater than \$1.5 million in submitted charges for calendar year 2001.
- The Region D DMERC, the Medicare Part B carrier overseeing 17 states spanning the entire Western part of the country, has developed a series of pie charts highlighting the top suppliers of power wheelchairs for 3 month periods. Each of the suppliers cited on these pie charts are subsequently targeted for an audit based solely on the "high utilization" of this equipment. What is troubling is the fact that the Region D DMERC's own pie charts demonstrate that the targeted suppliers are providing only between 6 and 8 wheelchairs a month to Medicare beneficiaries. The PMC believes that 6-8 wheelchairs a month does not constitute high utilization.

The DMERC audit process appears to target companies that may specialize in a particular area and/or companies that have developed a reputation for providing quality service and care to Medicare beneficiaries. We are concerned that general investigations of our industry will create a chilling effect on the ability of small businesses to provide equipment and services to patients who qualify for such equipment and services.

III. THE REGULATORY PROCESS REGARDING THE REOPENING OF CLAIMS IS BEING DISREGARDED BY THE CARRIERS

The regulatory process governing the reopening of claims was developed to establish certainty

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and finality in the Medicare program. As outlined in CMS's Medicare Carriers Manual (MCM III § 12100):

When a determination is made on a claim for Part B services, the beneficiary (and the physician or other supplier of medical services) should be able to rely on it with respect to the coverage of the services and the amount of payment. However, there are instances in which <u>strong inequities exist</u>, both for the party(ies) to the determination and for the Government, in favor of reopening incorrect initial ... determinations ... The regulations do not permit unrestricted reopening of <u>determinations and decisions</u>. They do set <u>specific</u> circumstances under which a determination or decision may be reopened.

Accordingly, CMS own regulations (42 CFR § 405.841) delineate specific limited circumstances in which an initial determination of a claim may be reopened. It states in pertinent part that an initial determination of a carrier may not be reopened by a carrier after a 12 month period unless **good cause** has been established or a determination of fraud has been uncovered.

As per 20 CFR § 404.989, good cause to reopen a specific determination exists if:

- (1) New and material evidence is furnished; per CMS's carriers manual, new and material evidence does not apply to information known to exist at the time of the initial determination.
- (2) A clerical error in the computation or recomputation of benefits was made; or
- (3) The evidence that was considered in making the determination or decision clearly shows on its face that an error was made....

Despite this well defined regulatory process governing the reopening of claims, we have witnessed numerous examples in which the DMERCs ignores the rules established by the agency. Often times, the DMERC seeks old information (*i.e.*, medical records or other information readily available at the time of the original claim determination) and still claims that this constitutes "new and material evidence." The DMERC makes this claim even though it was at all times in complete control of the entire review process. It appears the DMERC is arguing that its own internal system for review does not permit it to timely complete review process that does not have finality and certainty as developed in federal regulation. This is unfair and burdensome to Medicare participants.

Documentation Issues Recently Addressed by CMS

The PMC applauds CMS for issuing a recent Program Memorandum (Transmittal B-02-031) entitled "Cessation of Certain DMERC Activities." In this Program Memorandum, the agency instructed the DMERCs to cease specific activity being imposed on power mobility suppliers. Specifically, the agency stated that the DMERCs must not require that additional information

(beyond the required Certificate of Medical Necessity) accompany all Power Operated Vehicle claims and must not require additional documentation (beyond the required Certificate of Medical Necessity) when a beneficiary's medical condition necessitates the use of a higher level piece of equipment. The agency's Program Memorandum is a positive step in the right direction, prohibiting the DMERCs from current onerous activities that were in violation of CMS policy as well as the Paperwork Reduction Act. We do caution, however, that the Program Memorandum does not address the inconsistent and arbitrary manner in which the DMERCs conduct audits. Overall, the Memorandum is good news and we are encouraged by such CMS action.

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Mr. Chairman and Members of the Committee, thank you again for providing the Power Mobility Coalition with this opportunity to discuss these important regulatory and procedural matters. We look forward to working with you to achieve reasonable solutions to the issues highlighted above.

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May 15, 2002

The Honorable Donald A. Manzullo Chairman Committee On Small Business United States House of Representatives 2361 Rayburn House Office Building Washington, D.C. 20515

Dear Congressman Manzullo:

I appreciate the ability to offer testimony with regards to issues that physicians have been experiencing with CMS. I wish to thank you wholeheartedly for the opportunity and also for the ability to help contribute to improve the services of CMS. Furthermore, I would like to thank Secretary Tommy Thompson for his efforts to date on reforming a bureaucracy that has been plagued with inefficiencies, confusion and obfuscatory regulations that contribute to the general feelings that physicians have when they are confronted with CMS and other bureaucracies.

I wish to offer several points of view that are representative of a physician in private practice. I believe that several of my views can be carried over to the academic practice in medicine. In addition, I wish to offer testimony on the impact that CMS has on small businessmen such as my group and myself.

I am the president of a physician group that provides anesthesia services and pain management services to the second largest city in Illinois, that of Rockford, Illinois. There have been several problems that have arisen through the coding and billing of Medicare. A recent General Accounting Office study shows that carrier call centers gave full and accurate answers to Medicare billing questions only 15% of the time. Indeed GAO representatives made 61 calls to five area call centers and asked a series of three billing questions that were culled from the frequently asked questions section of the carrier's own websites. *Eighty-five percent of the answers were wrong, incomplete and would subject the physicians to the Fraudulent Claims Act.*

With regards to fraud and abuse, the Justice Department in the OIG's war on fraud has grown very large indeed. This puts an undo burden on small businesses in medical groups. Federal spending on fighting healthcare fraud is in the final year of the five-year statutory mandated ramp-up. A change in the budgetary funding regime is in the offing

The Honorable Donald A. Manzullo Chairman Committee On Small Business United States House of Representatives Page Two

and providers are concerned whether more money will be spent serving the interest of justice or just squeezing providers for more money to administer their programs. The article that I reference shows that in Fiscal Year 2002 healthcare fraud and abuse control programs annual report which was released on 25 April 2002, indicates the significant amount of money that the government has won from providers 30 September 2001. This included \$1.7 billion from judgments, settlements and administrative awards in healthcare fraud cases. Along the same line, federal prosecutors filed 445 criminal cases, up 2% from the year before. Chapter two in Dr. Manchikanti's book shows graphic descriptions along with statistics that are represented.

One of the major problems that incurs on a daily basis in our office is that of correct coding. While we have been in the forefront of compliance committees, compliance officers and the utilization of only certified coders, the task of coding is a very onerous, expensive and a confusing one. Certainly, I have direct experience when calling our local carrier on how to code a given procedure. On one given day, I received seven different instructions that were dissimilar to code for a specific procedure. Because of the confusion that this caused, we contacted a CMS help line independently in my office to determine what their recommendation was. Their recommendation again was four different opinions. As you can see, on any given day, if a physician's office codes one code wrong, it can be billed in many different ways and subject to interpretation. This not only increases the cost of performing adequate coding, it does subject the physicians and their groups to an investigation for fraud and abuse where really none exists and certainly great lengths are taken to ensure this. However, if the local carriers cannot instruct us on correct coding and refuse to give written instructions, it makes it even more difficult when CMS advisors are contacted and again conflicting data is received.

As physicians we ask only to do the right thing. However, it is difficult and almost impossible when physicians are given multiple responses from multiple sources. As a result of this, individuals tend to undercode or not to code at all because of the fear of reprisals and criminal prosecution for making errors. Certainly errors that are willful and wanton should be prosecuted to fullest extent of the federal law. However, with regards to physician billing, it is an onerous task, which is affecting the accessibility and availability of physicians that are willing to see patients in the Medicare Program.

In the last two years, we have seen a much-improved CMS. Accessibility, accountability and concise answers seem to be more forthcoming than they have previously. However, with a multiple number of Medicare carriers throughout the United States, there are still multiple interpretations. There needs to be a uniform federal guideline that physicians can follow that is written to use for billing effectively. Certainly the Medicare The Honorable Donald A. Manzullo Chairman Committee On Small Business United States House of Representatives Page Three

regulations exceed 130,000 pages of instructions, guidelines and opportunities. I venture to say I read less paper in four years of medical school and five years of residency than I have in 15 years of practice trying to determine the rules and regulations of billing correctly. Indeed, one of the reasons I have become so involved in billing appropriately is because my group, in order to defray overhead, has formed a billing corporation that bills for other physician groups. Because of the need to have experts as employees in the billing process, we felt that it would be prudent, wise and effective to bill for other physicians. Certainly, a group of 37 physicians needs to have such expertise. Smaller groups of 5 to 10 physicians that we bill for certainly cannot afford to have the staff, expertise or time commitment that we have designated to our billing program.

It is also significant to add, because of the increased amount of regulatory documentation, confusion and disagreement, our billing costs have gone from approximately 4% of our expenses to in excess of 8½%. This revenue is due to the fact that we cannot obtain concise definitive instructions from any given entity on how to bill. In addition, as a member of the national board of the American Society of Interventional Pain Physicians, I have been apprised, in my position of Chair of Economics, of several states in which patients do not obtain procedures that are commonly performed in neighboring states and that are approved by the Medicare Program due to coding issues. It is for this reason that there needs to be a national uniform standard billing practices committee which can effectively and efficiently transmit the information to physicians or groups as small as one or two or groups of several hundred the CMS level who interact with billing questions to professionals such as myself are confused, how can physicians be expected to bill in a uniform and correct method.

Next to the malpractice crisis that is enveloping our nation with regards to physician availability and liability, billing correctly is one of the greatest fears that I can express to you as a practicing physician. Treating critically ill patients in the operating room at all times of the day or night is much less terrifying than sitting down in the office trying to determine what you did the night before in a cogent, correct and legal fashion. Physicians are to take care of patients. When the average physician must spend 5% to 12% of their time to determine their billing codes, something is wrong with the system. We need to have the system efficient, reproducible and the information freely exchanged between carriers and providers.

The placement of physicians on CAC Committees or Carrier Advisory Committees is first and foremost. This provides a forum for informational exchange between providers and carriers, a mechanism to discuss and improve administrative policies that are within The Honorable Donald A. Manzullo Chairman Committee On Small Business United States House of Representatives Page Four

the carrier discretion and the formal mechanism for physicians in the state to be informed of and participate in the development of LMRP in an advisory capacity. LMRP is the local medical review panel.

In closing, I wish to thank you for allowing me to participate and offer testimony to such an esteemed committee. I feel that as a physician I have an obligation to my patients to their families, to my family and to myself. The easiest thing that I do is to take care of patients. The most difficult thing that comes to bear on me is to jump through the regulatory hoops and nightmare of billing inconsistencies that are currently the norm. I feel CMS is headed on the right tract and that Secretary Thompson has made significant improvements, but I believe that CMS needs to be streamlined and increase its user friendliness to providers so that they can provide more time for Medicare beneficiaries and spend less time worrying about obfuscatory guidelines.

Thank you for this opportunity.

Sincerely,

W. Stephen Minore, M.D., F.C.C.P., C.P.E. President Rockford Anesthesiologists Associated, L.L.C. Medical Reimbursement Services, Ltd. Vice President American Society of Interventional Pain Physicians

WSM/jmw Enclosures

STATEMENT BY DR. MICHAEL J. HULSEBUS BEFORE THE COMMITTEE ON SMALL BUSINESS OF THE U.S. HOUSE OF REPRESENTATIVES, MAY 16, 2002

Mr. Chairman and Members of the Committee, I am very pleased to have the opportunity to appear before this Committee once again to address on-going problems and challenges facing doctors of chiropractic who continue to work hard every day, to serve our nation's elderly through the Medicare program. I regret that I must state that far too little has changed since I testified before you last July and that the targeting of doctors of chiropractic for extra-aggressive and, I believe, totally unjust efforts aimed not at reducing fraud or abuse, but at reducing chiropractic "utilization", continue.

Doctors of chiropractic are mostly independent practitioners who have deep roots in the communities they serve and who strive to provide the highest quality care to every patient, and who take their clinical responsibilities very seriously. Our goal is optimal care; that means exactly as much care as is clinically indicated, no more and no less. Medicare administrators have historically made doctors of chiropractic a target for enforcement and regulatory restriction because of an abiding and still unabated medical prejudice that is a gross disservice to the beneficiary and doctor of chiropractic alike.

Medicare is not welfare; it is a benefit program for which we pay all our working lives. Chiropractic providers and patients alike find it alarming when Medicare administrators take it upon themselves to use program policies to force health care decisions onto beneficiaries that ought to be left to the patients themselves. How else can you characterize policies that restrict access to one form of care, in this case chiropractic care, regardless of the clinical realities, and force those beneficiaries onto second-choice, specialist-based care that is far more expensive than the chiropractic care that is being denied? This is not only offensive in terms of personal liberties and control over one's own health care, it is also very poor public policy.

The realities of Medicare's policies to contain chiropractic utilization are very immediate and personal to me and my professional practice. My practice has been subjected to a post-payment review at the hands of the program integrity division of Medicare. I was dragged through more than two years of legal and administrative proceedings, and subjected to what I strongly felt to be threats and intimidation, to simply agree with their review findings and then make massive repayments to the Medicare program for care that had been previously reviewed,

approved and paid for by Medicare. The claims for re-payment by Medicare were nearly \$250,000 for care provided over a number of years to a wide range of Medicare beneficiaries. After spending over \$50,000 in direct costs and devoting over 1,000 hours of professional time defending my procedures and clinical findings, all of those demands for re-payment were dropped.

These numbers do not tell half the story however. There is no way to account for the worry, the sleepless nights, and, worst of all, the impression given to my patients that something was terribly wrong with the way I cared for them and with the way I billed the Medicare system. It was particularly disturbing to see the way the Medicare administrators went to unnecessary lengths to leave a damaging impression with my patients. This is clearly an established policy and I have heard from doctors of chiropractic by the dozens from all parts of the nation that these policies are standard and on-going.

The past and current experience reflects the presence of clear intent on the part of HCFA and now CMS policy makers to substantially restrict and potentially eliminate chiropractic benefits under Medicare. For a profession that constitutes such a small element of Medicare benefits paid and which the Inspector General has concluded is not an area of major concern, HCFA's or CMS's actions represent an obvious onslaught, a direct targeting, of the chiropractic profession. These actions range from the unjustified quasi-criminal nature of the proceedings to actions such as refusing to accept a draft in full payment of an alleged overpayment pending appeal. Unfortunately, relief has been obtained only when members of Congress have become involved. There has been minimal cooperation from HCFA until outside force is applied.

This series of events is in clear contravention of the Congressional intent and directives that created the Medicare Program. Medicare's current actions seek to punish providers, not to further the goals of the program. A new name for the agency and new but still vague guidelines, backed up by strong messages from the program administrators to cut access to benefits wherever possible, regardless of the objective need, signals that doctors of chiropractic must expect an increase in arbitrary and random situations involving both pre- and post-payment reviews, unless Congress steps in and demands fairness from Medicare's administrators. What do we have to do as professionals, as honest citizens and as health care providers dedicated to helping people in need to receive what I believe we should be entitled to in the first place, fair treatment?

It seems obvious that a new and meaningful dialogue between the chiropractic profession and Medicare program managers is a place to start. It is clear that the existing physician advisory structures are not an effective means to educate the two key parties in this vital public health relationship. I know that the various chiropractic professional organizations would be very happy to engage in a new dialogue, seeking mutually acceptable ways to achieve program goals. We in chiropractic understand and respect the need for rules and standards and even

utilization controls. What we expect in return is honesty in both stated and actual policies and an end to the bias that has historically dominated the administration of the chiropractic program under Medicare. We also feel that a new focus on serving the needs of Medicare beneficiaries is badly needed, one that recognizes and respects the wishes of those citizens to the greatest possible extent. Most of all, we want to see an end to policy makers and administrators presuming to make health care choices for citizens by arbitrarily limiting access to chiropractic care.

My hope is that educational activities such as this hearing will convince Medicare program managers to take a new, objective look at chiropractic care and recognize the important contribution the chiropractic profession can and should be making to the care of our nation's elderly. This is especially true in light of a number of alarming trends in the care of our nation's aging patients, the most significant of which is the rapidly growing number of health care providers who are dropping out of the Medicate program. I am sure that many Members of the Committee saw the front-page article in the March 17th edition of *The New York Times* that reported that medical doctors by the thousands are refusing to take on new Medicare patients because of the low fees and the massive bureaucratic obligations that accompany the delivery of care to Medicare patients. According to this article, "The American Academy of Family Physicians says that 17 percent of family doctors are not taking new Medicare patients."

Medicare has instituted across the board cuts in payments to doctors of all types, reducing payments by 5.4 percent this year, and with plans to reduce payments by 17 percent by 2005. The impact of the fee squeeze on physician providers appears to be severe and nationwide. The article quotes the President-elect of the Texas Academy of Family Physicians as saying: "I have a hard and fast rule. I don't take any new Medicare patients. In fact, I don't take any new patients over the age of 60 because they will be on Medicare in the next five years."

In light of these developments, I believe that it is imperative that policy makers understand the absurdity of policies designed to keep people away from chiropractic care on the strength of the argument that money is being saved. The drugless, non-surgical nature of chiropractic, and the proven effectiveness of chiropractic for a wide range of conditions, should make greater access to chiropractic both a public health and cost-effectiveness priority. Of equal importance, in the years ahead, it may very well be that doctors of chiropractic are among the very few health care professionals willing to care for America's elderly population.

Thank you for this opportunity to be heard, not just on behalf of the chiropractic profession but for the millions of senior citizens who seek chiropractic care because they know that chiropractic can, above any other science, help provide the two things our older citizens want more than anything else, the ability to

function and be mobile, and clarity of mind because chiropractic is a drugless healing art.

Mr. Chairman, I am personally grateful for your leadership in this historic hearing and for your continuing determination to see that fairness governs the Medicare program. I will be happy to answer any questions you or any Member of the Committee may have on these complex issues and to provide any additional information or documentation on any aspect of my testimony.

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Before The House Committee on Small Business

TESTIMONY OF TIMOTHY P. BLANCHARD

MAY 16, 2002

STATEMENT FOR THE RECORD

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Introduction

Thank you for the opportunity to participate in this hearing.

I am an attorney and partner in the Los Angeles office of McDermott Will & Emery. The past 15 years of my practice have been devoted to assisting a broad range of health care providers in their efforts to comply with the complex federal regulatory scheme governing the Medicare and Medicaid programs, and the interpratations of the Centers for Medicare and Medicaid Services (CMS, formerly HCFA, used as appropriate in this Statement) and CMS contractors..

Although my testimony and statement for the record have been informed by my work with the firm's clients and my colleagues in the firm and in professional organizations such as the American Health Lawyers Association, what I say here today does not necessarily reflect the views of the firm, its clients, or my colleagues.

Background

I understand that I was invited to speak, at least in part, due to the interest I have shown in Medicare and Medicaid coverage and payment policy, and in particular Medicare Part B coverage issues. When I wrote my first law review article on the subject in 1990,¹ I took as a starting point the report and recommendations of the 1987 Medicare Procedures Symposium sponsored by the Administrative Conference of the United States and the ABA Commission on

¹ Timothy P. Blanchard, "Medical Necessity" Denials As A Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make It Right Or Rational, 34 ST. LOUIS U.L.J. 939 (1990) (hereafter "Two Wrongs").

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Legal Problems of the Elderly.² The Medicare Procedures Symposium included representatives of virtually all stakeholders in the Medicare program: Medicare patients; Congress; GAO; the Department of Health and Human Services, the Health Care Financing Administration, and Medicare contractors; administrative law judges and review board members; health care provider

associations; scholars; and the health law bar.³

Among the consensus recommendations resulting from the symposium were several

relevant to our topic today:

- HCFA should promulgate, through notice-and-comment rulemaking, its procedures and decisional criteria for national coverage determinations;
- HCFA should allow for maximum feasible public participation in the development of national coverage determinations;
- HCFA should compile and provide reasonable access to up-to-date Medicare coverage standards and guidelines, including those used by individual fiscal intermediaries and contractors;
- In implementing the new Part B appeal rights provided in OBRA 1986, HCFA should consider combining or eliminating some of the steps that were conditions precedent to an

ALJ hearing, including making the carrier hearing optional;

² Administrative Conference of the United States and American Bar Association Commission on Legal Problems of the Elderly, Medicare Procedures Symposium: Report and Recommendations, 1987 (hereafter "Medicare Procedures Symposium"). See also Eleanor Kinney, The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint, Administrative Law Journal, Vol. 1, No. 1, at 1-103 (Summer 1987).

List of Participants, Medicare Procedures Symposium, at 51-55.

• HCFA should re-think its litigation strategy that made challenges to Medicare policy expensive and time-consuming; and

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expensive and time consuming, and

 Congress should amend the statute to permit judicial review of national coverage determinations.⁴

I wrote my first article as the new physician payment reform initiative was being

implemented. At that time, I was concerned primarily with the issue of administrative fairness and the apparent use by Medicare carriers of coverage policy as a cost-containment strategy. My clients, ranging from individual practitioners to large healthcare corporations, were primarily seeking assistance in obtaining and retaining appropriate payment for the services they furnished to Medicare beneficiaries.

I discussed the frustrating delay inherent in the Medicare Part B appeals "pentathlon," not only because HCFA was already three years late in proposing regulations implementing the new statutory scheme,⁵ but also because HCFA had "informally" mandated exhaustion of four separate steps (review or reconsideration, carrier hearing, administrative hearing, and Appeals Council review) before permitting judicial review of coverage decisions (the fifth step).⁶

Medicare Program Symposium at 28-33.

⁵ In the Omnibus Budget Reconciliation Act of 1986, Congress directed that the new appeal process be in place for claims for services furnished on or after January 1, 1987. Pub. L. 99-509, § 9313(a), 100 Stat. 2037 (1986), *codified at* 42 U.S.C. § 1395ff.

⁶ When the current Medicare Part B claims appeal process, which was required by OBRA 1987, was implemented HCFA did not proceed by notice and comment rulemaking, but instead published a "notice" stating that administrative review "would be governed to the extent possible by existing regulations," but requiring that the carrier administrative review process (carrier review and carrier hearing) must be exhausted prior to the new administrative law judge (ALJ) hearings provided in statute. 52 Fed. Reg. 20023 (June 1, 1988). For ten years, Part B appeals were conducted under the terms of this "notice" and implementing instructions issued to Medicare contractors. Ten years later, when HCFA finally issued regulations implementing the 1987 amendments, 62 Fed. Reg. 25844 (May 12, 1997), CMS chose to waive notice and comment rulemaking⁶ on the ground that it was "impracticable, unnecessary, or contrary to the

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I questioned whether any justification remained for each Medicare intermediary and carrier having the authority to develop and apply its own coverage policies (or, indeed, whether it made any sense to have ten regional HCFA offices making their own policy interpretations). I discussed the adverse impact of these problems on patients (impeding access to care, and encouraging de facto denials - withholding of services from beneficiaries because of denial risk rather than the physician's best medical judgement) and providers (costly and time-consuming paperwork and appeals, cash flow delays, and damage to patient-physician relationships).

I concluded that HCFA's approach to Part B medical necessity determinations "undermines the integrity of its administrative decision-making and thus the legitimacy of its authority and the viability of the program."7 I suggested that Congress take action to clarify the meaning of the Medicare coverage statute8 or require HCFA to do so through notice and comment rulemaking, and that Congress should compel HCFA to comply with the rulemaking provision of the Medicare statute9, with respect to coverage policy as a way to ensure that those policies are "explicit and open to review."10

Two Wrongs at 1032. 8

- 42 U.S.C. § 1395y(a)(1)(A). 9
- 42 U.S.C. § 1395hh 10
- Two Wrongs at 1037.

public interest," because "this rule merely codifies provisions of the Social Security Act and existing agency practices that have been upheld by the U.S. Court of Appeals for the Second Circuit." Id. HCFA's reliance upon the decision of one federal circuit court upholding its questionable position is disingenuous at best, given the agency's long and controversial policy of "non-acquiescence" in decisions of individual circuit courts. HCFA also chose to forgo the regulatory flexibility analysis, effectively arguing that it had already imposed its interpretation of the statute, and therefore issuing the regulation would have "no significant effect on the appeals process." 62 Fed. Reg. at 25851.

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In 1999,¹¹ I returned to these topics with a new-found urgency, given the burgeoning government "war on fraud and abuse" ¹² and its impact upon providers, who were now not only beset by delays and uncertainty in Medicare payment due to inappropriate denials, but also by potentially enterprise- or career-threatening allegations of false claims.

I found the lack of regulations and formal administrative policy development surprising in 1990 when I researched my first article on the topic. Although there was some progress during the 1990s, I felt compelled to revisit the subject in 1999 to address the new and increasing threat of false claims prosecution and Draconian penalties based on medical necessity denials made on the basis of still frequently unpublished (and still largely unappealable) coverage policies, and the continuing lack of consistency among CMS and its contractors regarding applicable coverage criteria and documentation requirements governing when items or services would be considered reasonable and necessary, ultimately undermined the purpose of the Medicare statute by eroding beneficiary confidence in their providers and the program itself.

I also concluded that confidence in the Medicare program, in the administrative process, and ultimately in government were also undermined by HCFA's failure to establish a process permitting effective participation by the provider community and by beneficiaries in the coverage policy process; failure to ensure timely notice to affected parties of the standards that

¹¹ Timothy P. Blanchard, Medicare Medical Necessity Determinations Revisited: Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse, 43 ST. LOUIS U.L.J. 91 (1999) (hereafter "Abuse of Discretion").

¹² No one seriously disputes the need for efforts to detect and deter fraud or the prosecution of those found to have defrauded our health care programs. As one court aply observed, however, in a criminal false claims case involving a dispute regarding the definition of "supervision" for Medicare purposes: "Those who perpetrate [Medicare and Medicaid] fraud deserve relentless prosecution and severe punishment, and nothing ... should ... allow[] such despicable individuals to hide behind the ambiguities of bureaucratic

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would be applied; and failure to establish an effective appeal mechanism for appealing adverse policy decisions as well as the resulting individual denied claims.

Rather than restating the analysis and issues set forth in my articles, I will address the problems that remain and discuss the effect of subsequent developments that exacerbate these problems. In the process, I will make several suggestions regarding improving the efficiency of the process and rebuilding the integrity and legitimacy of the Medicare coverage determination process.

Where We Are Today

Today, although CMS has been making progress, and the Congress has acted to make changes in the right direction, the fundamental problems identified in the late 1980's and 1990's still exist to a discouraging degree. My practice is now increasingly consumed defending healthcare providers against potential and actual false claims allegations. In many of those cases, the providers and their counsel struggle not only to determine the meaning of the law, but also to anticipate how that law <u>might</u> be interpreted by a broad range of players, which frequently reach different conclusions regarding the same issues: CMS, its regional offices, its contractors (fiscal intermediaries, carriers, peer review organizations, and now the new Program Integrity Contractors¹³), the OIG, the Department of Justice (DOJ) and "whistleblowers." Unfortunately, the providers and their counsel must also struggle simply to obtain a meaningful appeal—*i.e.*,

regulations. However, neither can we allow the government to ambush a defendant with that same ambiguity." United States v. Siddiqi, 959 F.2d 1167, 1174 (2d Cir. 1992).

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one that is timely and fair. It is now clearly appears that the government's position that these appeals interfere with, and should be secondary to, fraud investigations, and that providers should accept, and immediately modify their behavior, based upon initial adverse interpretations and determinations by any of these sources.

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Lack of Rulemaking

In an ideal world, the rules would be carefully drawn and widely published; in the real world, all too often, providers face serious jeopardy if they guess wrong concerning which interpretation of the law is the one that will prevail. Furthermore, many providers will be unable to survive while awaiting vindication through the appeals process if their Medicare payments are delayed or suspended. We as counsel are prepared to help health care providers determine what the law requires, but now spend considerable time seeking to divine whether a carrier's interpretation will agree with that of an intermediary or other carriers; whether one CMS regional office will rule in the same way as another CMS regional office or the CMS central office, and perhaps most frustrating, whether the OIG or DOJ will accept the position of CMS on a key issue or seek to impose its own view of the statute and program rules in an investigation.

You might be surprised to learn that there are currently no regulations defining the process for coverage policy making in the Medicare program, with the exception of coverage for certain devices, which was promulgated primarily as a result of a lawsuit challenging CMS

¹³ See Health Insurance Portability and Accountability Act of 1996, Pub.Law 104– 191, § 202, see <u>Medicare Integrity Program Comprehensive Plan</u>, www.hcfa.gov/medicare/FRAUD/CMPL0299.htm

instructions on the issue. As discussed below, there are also no regulations implementing an appeal process applicable to the coverage determinations underlying coverage denials, notwithstanding the requirement imposed by Congress in Section 522 of the Benefits Improvement and Protection Act of 2000 that such an appeal mechanism be in place for claims for services furnished on or after October 1, 2001.

Prior to 1987, HCFA had not even published an explanation of the process for coverage determinations in the Federal Register. Indeed, the fact that anything was published (HCFA again issued a "notice," not proposed regulations) was the result of a settlement agreement in a lawsuit.¹⁴ In 1989, HCFA published the first proposed regulations regarding the Medicare coverage process and received numerous comments on the proposal. HCFA took no action on the proposed rule for ten years. When HCFA finally acted in 1999, it published neither final regulations nor a revised proposed rule, but rather another Federal Register notice describing the process it intend to use in making these fundamental coverage policy determinations of general applicability.¹⁵

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¹⁴ Jameson v. Bowen, C.A No. CV-F-83-547-REC (E.D. Cal. Feb. 20, 1987), reprinted in [1987-1 Transfer Binder] Medicare & Medicaid Guide (CCH), 36,033 (Settlement Agreement and Release of Claims).

¹⁵ Notice Regarding Procedures For Making National Coverage Determinations, 64 Fed. Reg. 22619 (April 27, 1999). In this Notice, HCFA explained:

We have decided not to adopt the January 29, 1989 proposed rule. This notice announces the process we will use to make a national coverage decision under the Medicare program. It sets forth the steps we are taking to make our national coverage decision making process more open and understandable to the public.

The Notice identifies examples of situations in which HCFA would initiate the process internally including:

Conflicting carrier or intermediary policies.

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The process established by HCFA to is better than nothing, but it falls far short of the comprehensive regulations that are necessary to protect the rights of patients and providers in a manner that is consistent with fundamental concepts of administrative law. Establishing the legitimacy of the Medicare coverage determination process and the resulting coverage determinations is essential to the legitimacy of claims processing and medical review and to the ability of law enforcement to rely upon these provisions in imposing fraud sanctions. The integrity of the Medicare coverage determination process is critical to the ability of the Congress and CMS to make sound public policy decisions regarding coverage and payment policy going forward.

Inadequate Notice of Standards and Documentation Requirements

Unless the specific expectations of the Medicare program are published in an authoritative manner, it is unreasonable for the government, whether in claims processing, medical review or investigations, to hold providers accountable for differences of opinion or for allegedly inadequate documentation. Frequently, claims are denied in claims processing or medical review because the provider has not prepared or presented specific documentation that is only necessary when services sometimes not considered to be necessary for a particular condition. The problem is that CMS and its contractors frequently do not define when a service

Services representing significant medical advance with no similar service currently covered under Medicare

Services subject to substantial controversy among medical experts regarding medial effectiveness.

[•] Services currently covered but widely considered ineffective or obsolete.

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is considered to be in such an area and require additional documentation of medical necessity. Continued resistance on the part of Medicare contractors to disclosure of claims processing parameters, which define internally when a contractor should require and review additional documentation to support a claim, is inconsistent with the statutory requirement that they assist providers in complying with utilization guidelines.¹⁶ This state of affairs is unfair and inefficient because providers do not know when additional time consuming documentation will be required (in addition to ICD-9 diagnosis codes, physician certifications and normal chart notes) to establish the medical necessity of services provided to the contractor's satisfaction. If claims processing parameters were published, providers would know when to prepare and provide additional information or explanation with their claims to allow efficient review and prompt claims processing.

Burden of Managing Medicare Medical Necessity Interpretations

The risk and burden for providers associated with uncertainty regarding Medicare medical necessity policy is increased significantly by the lack of accurate understanding regarding practice realities and unreasonable expectations on the part of CMS and the OIG. For example, the OIG's compliance guidance for hospitals states: "The compliance officer should ensure that a clear, comprehensive summary of the "medical necessity" definitions and rules of

> When there are program integrity issues surrounding significant under-utilization or over-utilization of the service.

¹⁶ 42 U.S.C. §§ 1395h(a)(1), (2)(A), 1395u(a)(2)(B).

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the various government and private plans is prepared and disseminated appropriately.ⁿ¹⁷ It is, of course, absurd to suggest that a health care provider could somehow accomplished this feat, which CMS has itself been unable to perform since the inception of the Medicare program.

Moreover, the suggestion that providers should compare the diagnosis code(s) associated with a service with the diagnosis codes identified as supporting the medical necessity for services before submitting the claim does not solve the problem. This is because by that time the provider can do nothing to protect itself from exposure on the claim. By that time it is too late to provide the beneficiary with an ABN regarding the service (ABNs must be given before the service is rendered). If the provider gives the beneficiary an ABN regarding the services that are likely to be denied on medical necessary grounds the patient becomes personally responsible for paying for the service if Medicare denies the claim. (Many other issues surround the ABN process that are beyond the scope this hearing.) I believe, however, that CMS and the OIG underestimate the adverse impact the ABN process may have on beneficiary confidence in physicians and/or the Medicare program.

Lack Of Process For Appealing Validity Of Coverage Policies (i.e., National Coverage Determinations and Local Medical Review Policies)

It is unreasonable for CMS and the OIG to assert that providers should immediately modify their treatment decisions whenever a CMS contractor (or CMS for that matter) issues a new coverage policy interpretation or begins routinely denying a type of claim. It is well

¹⁷ 63 Fed. Reg. 8987, 8992 (February 23, 1998).

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established that contractor interpretations and medical review determinations are frequently reversed on appeal.¹⁸ What kind of system would require someone to change his or her behavior based on an interpretation on a questionable issue by a party that is reversed so frequently? CMS and the OIG consider such evidence to establish constructive knowledge on the part of the provider for purposes of overpayment recoveries and false claims sanctions.

When health care providers do not know (and cannot easily determine) which services will be considered reasonable and necessary, they confront a set of unworkable choices: (1) to accept the risk of non-payment for services until completion of the appeal process, which could easily take years; (2) to withhold services they believe are necessary for the patient's health; (3) to shift the risk of non-payment to the patient through the Advance Beneficiary Notice (ABN) process, which could seriously damage patient confidence, because the provider is prescribing care but advising the patient that the Medicare program does not believe that it is reasonable or necessary; or (4) to furnish the services to the patient for free - with out billing for them, which could expose the provider to allegations under the patient inducement prohibition enacted in HIPAA.¹⁹ If the service in question is not an isolated one, but rather recurs in the provider's practice, the provider further risks allegations of a pattern of inappropriate care and/or billing,

¹⁸ Medicare contractors reversed their own determinations at the first level of appeal in approximately 30% of Part A appeals and 70% of Part B appeals. Of claims appealed to the next level, 40%-45% resulted in determinations favorable to the provider. Of claims further appealed to an administrative law judge hearing, between 51% (for Part B physician/supplier appeals) and 72% (for Part A appeals) are reversed in favor of providers. Medicare Appeal Process: Statement Before the Subcommittee on Health of the House Committee on Ways and Means (Statement of Michael Hash, HCFA Deputy Administrator, 1998), $\frac{http://www.hcfa.gov/testmonv/1998/98_0423.htm.}{^{19}}$ See 42 U.S.C. § 1320a-7a(a)(5).

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with the threat of fraud investigation and suspension of payment,²⁰ all before the underlying issue is ever resolved in the statutorily-mandated appeal process.

Congress enacted provisions that may help alleviate this untenable situation in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554, enacted December 21, 2000. This provision amended the Medicare statute to provide a formal appeal processes for coverage policy decisions--both national coverage determinations (NCDs), and local coverage determinations (LCDs) (i.e., local medical review policies), and directed the Secretary of Health and Human Services to promulgate regulations implementing its provisions effective October 1, 2001.²¹ These new BIPA appeal provisions would allow aggrieved beneficiaries, but not providers, to appeal adverse coverage policies without having to secure a denied claim and exhaust the administrative procedures for claims determinations. This appeal process should be available to all providers who accept assignment of the beneficiary's claims.

Instead of conducting timely rulemaking or issuing temporary instructions implementing the provisions of BIPA, however, CMS (as the Secretary's delegate) has announced through a CMS Ruling that it does not intend to implement these new appeal provisions until it conducts full "notice and comment" rulemaking procedures to establish the mechanisms for handling those appeals.²² Nevertheless, CMS has continued to encourage the development and application of LMRPs by its contractors. I agree that notice and comment rulemaking should be pursued

²⁰ 42 U.S.C. §§ 1320a-7(a)(A) and (E). 21

See 42 U.S.C. § 132647 (a)(Y)(B) and (2)(B), CMS Ruling 01-1 (September 24, 2001), 66 Fed. Reg. 54253 (October 26, 2001). 22

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regarding these appeal provisions. The fact remains that despite the passage of 15 months since BIPA, CMS has not even issued a proposed rule. I submit that consistent with Congressional intent, at a minimum, a moratorium should be imposed on the denial of claims and assertion of liability based on either NCD or LMRP until such time as appeal rights required by BIPA Section 522 are fully implemented. Adverse determinations in the interim should be reversed.

Inadequate Provision for Participation in Covered Policy Decision Making

Even if notice and comment rulemaking is not appropriate for all coverage policy determinations, participation by affected parties is nevertheless essential under well-established tenets of administrative law. In order to participate in decision making, all parties need adequate notice of the proposed policy or the issues to be decided. While CMS has taken steps to address this issue through the publication of LMRPs and proposed LMRPs on the Internet, no regulatory authority specifies the effect of a failure to timely post such policies for review. In practice, some CMS contractors are better than others in providing their LMRPs and draft LMRPs to CMS for posting. The fact that a contractor has not provided the draft LMRP to CMS, or that CMS has not timely posted the draft LMRP, does not preclude the application of the LMRP in the review and denial of claims.

Even if we assume that posting on a web site should be considered sufficient notice, failure to post should mandate at least a delay in the effective date of such new policies. Furthermore, I would argue that mere posting is not sufficient notice; it is simply impractical to expect health care providers to check a website daily to ensure they are able to participate in the

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process. The Medicare Carriers Manual once required carriers to provide 30 days written notice to providers before implementing changes in coverage policy or documentation requirements. The Carriers Manual explained that: This provision recognizes that a physician who regularly furnishes "services . . . not always covered by Medicare needs to know the circumstances under which services will be covered and what documentation is necessary.ⁿ²³ While many Carriers Manual provisions related to claims processing were moved and redrafted in the new Program Integrity Manual, CMS Pub 83, this provision appears to have been eliminated.

More fundamentally, why should NCDs be exempt from APA notice and comment rulemaking?²⁴ Even if time is of the essence with regard to a particular decision, CMS could promulgate a final rule with comment period, allowing for revision of the rule based upon public comment. The existing state of the law in essence allows the Secretary to determine which determinations will be subject to full review and which will not simply by declaring a policy an NCD. Requiring Federal Register publication with comment following the current NCD development processes would enhance the legitimacy of NCDs, which are, after all, policies of general applicability (binding on ALJs, like properly promulgated regulations) which would normally have to be published as regulations pursuant to 42 U.S.C. § 1395hh. One solution might be to amend the Medicare statute to eliminate from the definition of a national coverage determination any decision that was <u>not</u> published as a final rule or final rule with comment period.

Medicare Carriers Manual, Part 3, CMS Pub. 14-3, § 7531 (superceeded).
 See 42 U.S.C. §§ 1395hh, 1395ff.

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In BIPA Section 522, Congress also undertook to make it easier for beneficiaries to request national coverage determinations regarding services that they need by requiring CMS to establish a process for handling such requests. Once again, however, the BIPA provisions do not go far enough. BIPA limits standing to beneficiaries, who are subject to the same resource limitations here as in connection with the BIPA appeals discussed above. Indeed, the right to request an NCD is also limited in specific technical ways that most beneficiaries will be unable to understand. CMS has yet to issue regulations regarding these provisions although the statute directed an effective date of October 1, 2001. Petitions for revising NCDs should be considered based upon the submission of new evidence affecting a prior decision. Given the rapid change that characterizes many segments of health care, the standards for requesting such revisions should not be set artificially high to avoid change in either direction (*i.e.*, expanding or restricting coverage). A process for addressing these difficult coverage questions directly is what has been lacking in program regulations since the inception of the program.

Unsupported Variations in Coverage Policy Among Contractors and Regions

Whatever historical justification may have existed in the past for permitting regional variation in Medicare policy, including medical necessity and coverage standards, it now appears that few, if any, situations justify deviation from national standards. The negotiated rulemaking used in establishing coverage and related policies for clinical laboratory tests demonstrates that it

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is possible to develop consistent national coverage policies across all CMS regions and contractor jurisdictions.²⁵

Nevertheless, although there has been some movement towards standardization in this area, inconsistent coverage policies continue to exist among CMS contractors and the potential exists for inconsistent interpretations exists among CMS regional offices. Indeed, different coverage policies are currently applied in carrier areas that are separated from other carrier areas by as little as a road. One example drawn from the Los Angeles area demonstrates the irrationality of these variations. Under current LMRPs, an MER scan of the lumbar spine is considered medically necessary for over 70 fewer conditions when furnished on the west side of the street dividing Los Angeles and San Bernardino counties than when furnished on the east side of the same street. There is no rational basis for such LMRP differences or the challenges they present for physicians and providers furnishing services near the borders of contractor service areas. (This example is even stranger because both counties are now in the jurisdiction of the same carrier.)

Circumvention of Appeal Rights Based on Alleged Fraud and Abuse

The government currently circumvents provider appeal rights in several ways. First, by electing to pursue fraud and abuse investigations prior to the denial of claims in question, either an ordinary claims processing or on reopening, the government deprives providers of the appeal rights provided by the statute and forces providers to choose between no appeal at all or taking

²⁵ See 66 Fed. Reg. 58788 (November 23, 2001).

its chances litigating a false claims case risking treble damages and Draconian per-claim penalties (at least \$5500 under the Civil False Claims Act). In essence, this approach seeks to impose sanctions for knowingly submitting improper claims before there has ever been a determination that the claims in question were not in fact proper and payable as billed.

The second way in which the government circumvents provider appeal rights is through the imposition of payment suspensions without due process. Medicare regulations currently allow a CMS contractor, with the concurrence of a CMS regional office, to suspend Medicare payment to a provider before ever determining that an over payment actually exists, before granting a hearing regarding the issue and in some cases before even notifying the provider that the suspension will be imposed.

When a contractor has made a formal determination that an overpayment exists and has notified the provider of that determination, the provider will ultimately get a hearing regarding the determination. The bigger problem is that CMS contractors are permitted to suspend payments based on "reliable evidence" that there may be a problem with certain claims or prior payments. Under these rules, any provider that seeks to continue what it believes to be a proper course of action, such as continuing to furnish services it believes to be medically reasonable and necessary, after it is put on notice that a CMS contractor disagrees would be subject to payment suspension under these rules. The fact that the provider may be appealing the contractor's determination or that the provider has a history of winning it's appeal's on similar determinations does not, under current Medicare regulations, prevent a contractor from imposing a payment suspension.

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Current OIG Recommendations Regarding Appeals Would Further Exacerbate Problems

The OIG has published two reports regarding the claims appeal process that make suggestions that appear likely to make the appeal process even more expensive and ultimately less fair for providers by undermining the independence of ALJs.²⁶ For example the OIG next suggests requiring "both Medicare contractors and ALJs to apply the same standards." If the OIG means to limit contractors to standards that are consistent with the statutes, regulations, and published national coverage determinations, I would agree. It appears, however, that the OIG is suggesting imposing LMRPs and other sub-regulatory guidance upon ALJs. Such a recommendation would effectively create a presumption that all LMRPs are valid -- a conclusion that is inconsistent both with the Congressional intent expressed in BIPA Section 522 and a proper understanding regarding the high level of reversal rates at the ALJ level. In the current system, the ALJ level of appeal is the first opportunity for a provider to test the contractor's interpretations and LMRPs against statutory and regulatory standards.

Even more troubling is the second OIG report²⁷ regarding the potential impact of BIPA Section 521 on the claims appeals process [not to be confused with the coverage policy appeal process established by BIPA, Section 522]. I generally agree that the timeframes set forth in Section 521 of BIPA may be unworkable, and may in fact impose hardship on providers, particularly those who seek to aggregate claims in order to pursue appeals in a more efficient

Medicare Administrative Appeals: ALJ Hearing Process, Report No. OEI-04-97-00160, U.S.
 Department of Health and Human Services, Office of the Inspector General (September 1999).
 Medicare Administrative Appeals: The Potential Impact of BIPA, Report No. OEI-04-01-00290, U.S. Department of Health and Human Services, Office of the Inspector General (January 2002).

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manner. I also agree with the OIG's suggestion that CMS should promulgate regulations regarding the appeal processes. I do not agree many of the OIG's suggestions, and I must take issue with the OIG's comment that "to a large degree, program integrity and speedy appeals are in conflict."28 OIG suggests that the ALJ process is somehow deficient because ALJ's "may not be aware that cases they are hearing are also under fraud investigation."²⁹ I submit that this is as it should be because whether a provider is under fraud investigation is completely irrelevant to the question before the ALJ - whether the specific claims in question were proper and payable. The OIG's concern regarding the impact of favorable ALJ decisions upon ongoing fraud and abuse investigations proves too much. The government should not be able to pursue a false claims case until there has been a final impartial determination with respect to the merits of provider's appeal regarding the claims in question.

Conclusion

William Roper, HCFA Administrator during the third decade of the Medicare program, reportedly said that, in its first decade, the Medicare program sought to improve access to health care for its beneficiaries; in the second decade, it focused on containing costs; and in the third, it was dedicated to maintaining quality.³⁰ Now, in its fourth decade, I believe it is time for the Medicare program to concentrate on the difficult fundamental issues surrounding coverage policy and determinations and assuring the legitimacy of the administrative process.

²⁸ Id. at 14. 29 Id. at 6.

³⁰

Medicare Procedures Symposium at 2 (attributed to Mr. Roper by Richard P. Kusserow, then Inspector General of the U.S. Department of Health and Human Services).