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SUBCOMMITTEE HEARING ON THE IMPACT OF CMS REGULATIONS AND PROGRAMS ON SMALL HEALTH CARE PROVIDERS

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UNITED STATES HOUSE OF REPRESENTATIVES

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CONTENTS

OPENING STATEMENTS

	Page
González, Hon. Charles	1
Westmoreland, Hon. Lynn	7
Fallin, Hon. Mary	3
Altmire, Hon. Jason	4

WITNESSES

PANEL I:

Hill, Mr. Timothy B., Director of the Office of Financial Management, Centers for Medicare & Medicaid Services - Accompanied by: Farris, Dr. James Randolph, Administrator, Consortium for Quality Improvement and Survey & Certification Operations, Centers for Medicare & Medicaid Services 5

PANEL II:

Dolan, Dr. William A., American Medical Association	15
Wiesner, Mr. Dennis, R.Ph., H.E.B. Grocery Company	17
Schweitz, Dr. Michael, The Coalition of State Rheumatology Organizations	19
Smith, Dr. Karen L., American Academy of Family Physicians	21

PANEL III:

Allen, Ms. Terry, South Texas Oncology and Hematology, P.A.	29
Schraad, Mr. Joseph A., Oklahoma Allergy and Asthma Clinic	31
Wolf, Ms. Rina, RedPath Integrated Pathology, Inc.	32
Tieken, Ms. Mary Helen, Texas Association of Home Care	34

APPENDIX

Prepared Statements:

González, Hon. Charles	43
Westmoreland, Hon. Lynn	45
Hill, Mr. Timothy B.	46
Centers for Medicare & Medicaid Services: Information for the Record	54
Dolan, Dr. William A.	56
Wiesner, Mr. Dennis	65
Schweitz, Dr. Michael	80
Smith, Dr. Karen L.	92
Allen, Ms. Terry	98
Schraad, Mr. Joseph A.	114
Wolf, Ms. Rina	116
Tieken, Ms. Mary Helen	124

SUBCOMMITTEE HEARING ON THE IMPACT OF CMS REGULATIONS AND PROGRAMS ON SMALL HEALTH CARE PROVIDERS

Wednesday, May 14, 2008

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

The Subcommittee met, pursuant to call, , at 2:10 p.m., in Room 1539, Longworth House Office Building, Hon. Charlie González [chairman of the Subcommittee] presiding.

Present: Representatives González, Altmire, Westmoreland, and Fallin.

OPENING STATEMENT OF CHAIRMAN GONZÁLEZ

Chairman GONZÁLEZ. I will call this hearing to order. Today we are going to be conducting a hearing to consider a rather important issue under the heading of ″The Impact of CMS Regulations and Programs on Small Health Care Providers.″

I want to start off by indicating that we have been awaiting the arrival of the ranking member, Mr. Westmoreland. He has been detained, but he will be here shortly. I thought I would get my opening statement out of the way and we would proceed.

Another observation is that we have a number of votes today and that means we will be interrupted. I am going to ask for everyone's patience. Everyone is going to get to testify. We will have Members up here. I am not sure if Mr. Westmoreland will be able to remain throughout the hearing, because I know he has other matters that are of real pressing importance regarding his district. I will proceed then with my opening statement.

Medicare and Medicaid are essential components of our nation's health care system. Many small health care providers are dependent on reimbursements from these programs. Changes to the programs can have profound economic effects on their businesses. With many small providers struggling to stay afloat, it seems a number of medical practices and pharmacies are merely one reimbursement cut away from being forced to close their doors.

As program costs have risen, Congress has taken steps to cut them. All too often, CMS implementation of these efforts to reduce costs has placed small health care providers on an unlevel playing field and threatened their continued viability. In some instances, CMS has adopted rules to implement cost cutting measures, which is understood. When agencies, though, make rules, the law requires

them to consider their impacts on small businesses and examine less burdensome alternatives.

The Small Business Committee has jurisdiction over this important law known as the Regulatory Flexibility Act. The committee has held several oversight hearings on CMS in the 110th Congress, and we have seen that the agency can do a better job of meeting its obligations to small firms.

When CMS implements regulations and programs unfairly, it hurts not just small providers, but also patients, and damages the entire health care system for all Americans. Several CMS programs are creating particular concern among small health care providers. For instance, the Recovery Audit Contractor program will be one of those. Because of the enormous scale of Medicare, it is inevitable that some errors in the payment process will occur. In some instances, providers may be underpaid by Medicare. In others, they may be overpaid.

With the aim of reducing the amount of Medicare's improper payments, Congress created the Recovery Audit Contractor program, known as RAC. A pilot program for RAC concluded in March of this year and now the program has become permanent.

While the law requires RACs to identify underpayments to providers, it is clear that contractors are almost exclusively focusing on correcting overpayments. For example, of the $371 million of improper payments identified by RACs in fiscal year 2007, over 96 percent were overpayments collected from providers. Less than 4 percent of those dollars were underpayments repaid to providers. It is hard to believe that this number represents the true proportion of underpayments.

The manner in which RACs are compensated is also troubling. RACs get a part of every dollar they bring in. This is the first time ever that Medicare has paid a contractor on a contingency fee basis. According to small providers, these contingency fees, coupled with a lack of proper oversight at CMS, have led to aggressive, and, in some cases, improper pursuit of recoveries and a disregard for the accuracy of the auditing process.

Another significant issue is one that impacts pharmacies nationwide. They are facing major hardships from CMS's implementation of the Deficit Reduction Act. The DRA directed CMS to recalculate the way it reimburses pharmacies for providing generic prescription drugs to Medicaid beneficiaries.

Last July, CMS released a final rule which could devastate pharmacies and Medicaid recipients. The new formula dramatically reduces reimbursements to pharmacies. GAO has determined that they will be paid back for only 64 percent of their costs of acquiring generic prescription drugs.

This rule will have a disparate impact on small retail pharmacies, an impact that CMS overlooked when it wrote the rule. Small retail pharmacies serve a higher proportion of Medicaid beneficiaries and get more of the revenue from prescription drugs. Implementation of this rule may force many of them out of business, reducing access to care for millions of Americans. It is clear that CMS needs to do a better job of considering the needs of small health care providers when it implements programs and regulations.

I look forward to today's testimony, and I thank the witnesses for coming here to share their stories.

Chairman GONZÁLEZ. At this time, I would be recognizing Mr. Westmorelandfor an opening statement, but since he has been detained, my preference will be that we then proceed.

I am happy, in the absence of Mr. Westmoreland, the ranking member, to defer to a fellow Member and colleague from Oklahoma, Ms. Fallin, for an opening statement.

OPENING STATEMENT OF MS. FALLIN

Ms. FALLIN. Thank you, Mr. Chairman. Hopefully Mr. Westmoreland will be here soon, but I also have an opening statement and will try to assist him as he is busy with his other committees too, but he should be here shortly.

I want to, first of all, thank all of our witnesses for joining us here today and taking time out of your busy schedules. Many of you have traveled from different areas of the United States to be here to join us. I thank you for doing that. I know I have a gentleman here from Oklahoma with the allergy clinic, Mr. Schraad, who is here to help us give some testimony from Edmond, Oklahoma. So thank you for joining us here today and giving us some knowledge, all of you witnesses giving us knowledge about CMS and working with this agency and how we can better improve our relationship between the Federal Government and the private sector as it relates to health care.

We are all here today to better understand how CMS regulations impact small businesses and health care, and there is no better way of learning about that than hearing from those on the ground directly affected and interacting with these regulations on a daily basis. Medicaid place a large role in this area, and even small changes within the system can reverberate rate throughout small businesses and health care providers and pharmacies, as we just heard the chairman talk about.

I do believe, as the chairman does, that we must seriously evaluate the health care system as it stands today and how the slight changes that we talk about can alter the landscape for the providers as well as the beneficiaries in the future.

I often hear providers in my district say that they are in a very precarious situation. They want to provide access to health care and the best type health care, pharmaceuticals, but yet at times, it is hard to have a viable business and sustain that business under the rules and regulations that are imposed upon them and that they have to operate in within the system.

Due to decreases in the Medicare fee payments, many providers in my district reduce the number of Medicare patients they see in order to effectively recoup the costs of the services they provide. In many instances, the providers are actually losing money on transactions because Medicare does not reimburse the full costs of the services rendered.

I have also heard from many of my doctors in my district that over the years, because of the amount of Federal regulations and rules that are put upon them, that they actually have to hire specific people just to work through all the rules and the insurance policies and try to figure out how to match those things up and

what they can do and can't do and what they will be reimbursed for and at what rate.

Under these circumstances, it is very difficult to see how anyone is expected to sustain a healthy business practice. Health care providers and beneficiaries in this country are suffering, and it is time that we get to the bottom of this.

So I am looking forward to the testimony, both from CMS, and I know that CMS has a very tough job and I appreciate their Federal work and even having to work with Congress too. So we appreciate both of you gentleman being here and we look forward to the other testimony.

Thank you.

Chairman GONZÁLEZ. Thank you very much. At this time, I know Mr. Altmire is present and he may not be here when we get to panel three and he would be introducing Ms. Rina Wolf. If Mr. Altmire has some opening remarks, I would be happy to defer to him at this time for that purpose.

OPENING STATEMENT OF MR. ALTMIRE

Mr. ALTMIRE. Thank you, Mr. Chairman. I would just say to be very brief that our witness from Pittsburgh is going to be Rina Wolf, and we look forward to hearing her. She is the vice president of Reimbursement and Regulatory Affairs for RedPath Integrated Pathology in Pittsburgh. They have a very good story to tell regarding the purpose of this hearing.

So I appreciate the opportunity to say a few words, and I will listen with interest to the testimony. Thank you.

Chairman GONZÁLEZ. Thank you very much, Mr. Altmire. To the witnesses that are present, let me explain the system. You will be given 5 minutes obviously to make your remarks. I know that is going to be a summary of your written statement, of course, which will be entered into the record in its entirety. So we would ask that it be summarized within those 5 minutes.

When the green light comes on, obviously, the time will start. When the yellow light comes on, I believe you will have 1 minute at that time. And then, of course, red, that means you have consumed all of the time. If you feel that you haven't had enough time to cover everything, believe me, during the question and answer period, at that time you can supplement any of your comments.

The first witness will be Mr. Timothy B. Hill. Mr. Hill is the Chief Financial Officer and Director of the Office of Financial Management for the Centers for Medicare and Medicaid Services. As CMS's senior financial management executive, he is accountable and responsible for planning, directing, analyzing and coordinating the agency's comprehensive financial management functions.

Mr. Hill, it is my understanding you will be assisted by Mr. James Farris, but that Mr. Farris will not be giving testimony, but is present here to answer any of those questions that fall within the purview of his expertise.

Mr. Farris, I apologize, it is Dr. James Farris, he is the Administrator to the Consortium For Quality Improvement and Survey and Certification Operations for CMS. In this capacity, he works with

all of the CMS regional office components that oversee quality improvement organizations and survey and certification operations throughout the country.

STATEMENT OF TIMOTHY HILL, CFO AND DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT, CENTERS FOR MEDICARE & MEDICAID SERVICES, ACCOMPANIED BY JAMES RANDOLPH FARRIS, ADMINISTRATOR, CONSORTIUM FOR QUALITY IMPROVEMENT AND SURVEY & CERTIFICATION OPERATIONS, CENTERS FOR MEDICARE & MEDICAID SERVICES

Chairman GONZÁLEZ. At this time you may proceed, Mr. Hill.

Mr. HILL. Thank you, Chairman González, distinguished members of the Subcommittee, thank you for inviting us here today to discuss the recovery audit contractor program and its effects on Medicare providers that are small businesses.

In January 2008, the Office of Management and Budget reported that Medicare is one of the top three Federal programs making improper payments, with an estimated $10.8 billion in improper payments made during fiscal year 2007. It is in this context that Congress directed HHS to conduct a 3-year demonstration program using recovery audit contractors (RACs) to detect and correct improper payments in the Medicare program.

Pursuant to the law, HHS began the demonstration in March of 2005. During the demonstration, the recovery audit contractors were tasked with the detecting of both overpayments and underpayments in the Medicare program and correcting those improper payments. I am pleased to report that as of its conclusion in March of 2008, the demonstration had corrected a total of more than $1 billion worth of improper payments in the Medicare program. Even before the demonstration had been completed, Congress recognized its potential by making the program permanent and mandating that HHS expand it nationwide by no later than January 1st, 2010.

During the demonstration and our planning for expansion, CMS has worked very closely with physician and other provider groups to make sure that they understood the demonstration program as well as to solicit input about how to make the program better. So, for example, we have standing monthly meetings with the American Medical Association and members of the affected State medical associations to discuss ongoing operational issues. We created programs for specific e-mail accounts for the demonstration that will continue during the program expansion as a method for addressing individual physician questions. After the companies, the permanent RACs, are selected later this spring, CMS and the new RACs will conduct extensive provider outreach, including visits, onsite visits with local medical organizations and representatives in each State. State medical associations are also currently partnering with CMS to prepare a bulletin that will inform the physicians about the expansion of the RAC program which will be sent to the entire membership of each state's association.

CMS has also utilized its standard methods of provider education and outreach, including e-mail list serve messages that are distributed widely among national and regional provider trade associations, open door forums, Medicare learning network articles, press

releases and various CMS and contractor Web sites with links to frequently asked questions and contact information for each RAC.

We believe that our ongoing outreach to physicians and other Medicare providers has had a significant impact on our ability to maximize the effectiveness of the program while minimizing its burden on providers and physicians.

Some of the specific changes we have made to the program were a direct result of the feedback we solicited from providers. So, for example, both a medical director and certified coding experts will be required to be employed by all the permanent RACs. Under the demonstration project, no medical director was required nor were coding experts required of the RAC contractors.

Additionally, during the demonstration, RACs were only required to pay back their contingency fees if they lost the first level of appeal, but not at subsequent levels of appeal. Permanent RACs must pay back their fees if they lose at any level of appeal.

In the demonstration, there was no maximum look-back date, meaning that RACs could review claims as old as four years. In the permanent program, RACs will not be able to look back for improper payments on claims paid before October 1, 2007.

CMS will require the permanent RACs to operate Web-based systems so that providers involved in an audit will have secure on-line access to information that explains the status of their claims and the RAC audit process. None of the RACs in the demonstration had this capability.

In the demonstration, CMS did not limit the number of medical records that could be requested by a RAC. In the national RAC program, CMS will establish a record limit that will vary by a biller's size to protect small providers from undue administrative burden.

Most importantly, I think, under the permanent RAC program, CMS will place a much greater emphasis on provider education and training. For example, RACs will be required to gain CMS approval before beginning medical necessity reviews of provider claims. CMS oversight will ensure that providers are not unduly burdened by RACs. Additionally, CMS will require the permanent RACs to identify and publish vulnerability analyses so that the provider community can better understand where mistakes are being made so they can correct these mistakes before an audit begins.

To sum up, let me emphasize CMS's commitment to our continued partnership with Medicare providers, particularly physicians who are small businesses, as we move forward on this new important program. Ultimately, we believe that the implementation of this program will support ongoing beneficiary access to care by ensuring the appropriate expenditure of taxpayer resources and supporting the financial integrity of the Medicare program.

Thank you for your time. Dr. Farris and I remain to answer any of your questions and would be happy to take them now.

Chairman GONZÁLEZ. Thank you very much, Mr. Hill.

[The prepared statement of Mr. Hill may be found in the Appendix on page 46.]

Chairman GONZÁLEZ. At this time the Chair is going to recognize the ranking member, Mr. Westmoreland, for some comments.

OPENING STATEMENT OF MR. WESTMORELAND

Mr. WESTMORELAND. Thank you, Mr. Chairman. I do want to thank Chairman González and his willingness as chairman of this Subcommittee to have these hearings, where we look at how small business is affected by government regulations. As a former small business owner, I am very aware of the regulations and the hurdles that government puts in front of industries and small business in particular.

Our health care system is the envy of the world due to the excellent patient care that we receive in this country. However, the same cannot be said about the treatment of our health care system and the treatment it receives from our government.

So I hope, Mr. Chairman, in this hearing, that we will hear some testimony from not only CMS, but from small business on how these burdensome regulations slow down not only maybe their production, but also their ability to provide health care for their employees.

I have a written statement here I would like to have unanimous consent to submit to the record.

Chairman GONZÁLEZ. Without objection.

Mr. WESTMORELAND. With that, I yield back the balance of my time.

Chairman GONZÁLEZ. Thank you very much. I have already explained, Mr. Westmoreland, to everyone that is here, that you may have to absent yourself due to a very pressing issue there in your district, and you better be there or you may not be joining us next Congress. So I think it is kind of important.

Mr. WESTMORELAND. I appreciate that. I am going to leave, if it is okay and go make another opening statement.

Chairman GONZÁLEZ. My pleasure. It is my understanding that substituting in place of the ranking member will be Ms. Fallin from Oklahoma.

It is the prerogative of the Chair, of course, to lead off with the questions. It is a good place to be, in many ways. But I have some preliminary questions, Mr. Hill. I understand that we had what would be a demonstration or the project in different States, and now it is going to be permanent and there are going to be some structural changes which may address some of the concerns that some of the physicians and health care providers have regarding professional staff that will be with the permanent RAC, and I know that is the term we use now.

But I do have a question, and that is how many physicians will each RAC be required to have on staff? I think you pointed out that there is going to be a medical director, and I understand that, as well as a coding expert. But we are talking with physicians. Because I have been told we have non-physicians, in essence, passing on a physician's judgment on what was medical necessity.

So how many doctors, how many MDs are we going to have required or mandated?

Mr. HILL. Right. The requirement for the permanent RAC program is that each recovery audit contractor have a medical director

who is a physician. The concept here isn't to enumerate the absolute number that has to be there, do they have to have one or do they have to have five, but the concept here is there is one medical director who is overseeing the judgment of the other clinicians, whether they are nurses or therapists or coding professionals, who are sort of making the judgments on claims whether or not they are going to get paid or on review or not, and it is that physician making the ultimate determination. If, in the example you used, the RAC is going to make a judgment to overturn a claim, the physician would be the one overseeing that process and making that judgment.

Chairman GONZÁLEZ. What do you think would be, and I guess it is a claim or a caseload of a medical director. When we say the permanent RAC will have a medical director who is a physician who is going to be overseeing the non-physicians and such, but realistically, the demands on someone's time, how many claims are we talking about? Is there a process that will require the review by the medical director, or is that going to be something that will be established within each independent and permanent RAC?

Mr. HILL. Right. I think it will be established within each permanent and independent RAC, but again, I think what we are talking about here are processes as much as workloads, which is to say it is not the notion here that the physician would look at each and every claim.

So, for example, you may have a series of claims dealing with one benefit category, one particular issue, and I think that the job of the medical director would be to ensure there are processes in place as the nurse reviewers or the therapists or whoever making judgments on the claims are making those judgments, they are making them consistently and in a way that the physician could sign off on that ultimate disposition. Not that they would look at each and every claim.

Chairman GONZÁLEZ. What evaluation did you have before we went into the permanent phase of how it operated, how the RAC system operated in those other States? I have some information that obviously has been provided to me, and it says that an independent contractor reviewed a sample of medical necessity decisions made by the California RAC and found an error rate of at least 40 percent, or up to 40 percent.

I am just wondering, did you ever conduct, did you ever have any kind of independent analysis of the work that was actually being done by these RACs in these selected States?

Mr. HILL. Absolutely. And that independent evaluation that you discussed there was something that I directed in California in particular, which was our sort of poster child for bad decision making on the part of the RACs. A lot of that, I would say most of that, had to do with a particular benefit area in patient rehab services in hospitals in California where the RAC's judgment on medical necessity ultimately didn't end up conforming with what CMS thought the right judgment would be.

And after we had heard from a series of folks, hospitals in California, some Members of the California delegation, about what was going on there, we sort of suspended that review, sent in an independent evaluation to make sure that the RACs were making—that

particular RAC was making correct decisions on those particular claims in California.

Now, that was specific to those sets of issues. It is also the case that because of that we have built into the process an independent evaluation of every RAC's reviews. So, say the RAC does 100 claims. We are going to take a sample of those claims and independently are going to review those and say did they make the right decisions on that review that they did on a sample. That will help us detect whether or not we need to do corrective action with the RAC or whether they are going in the right direction. But it is giving us a little more comfort that they are making the right decisions on an ongoing basis.

Chairman GONZÁLEZ. So that is going to be built in in the permanent RAC arrangement where you actually will have some oversight, again, taking a sample of those, let's say, medical necessity challenges and claims and such.

Mr. HILL. Correct. And actually on the medical necessity issue, even more important, because what I have just described is what happens after the RAC has made a decision. So it has already had the impact on a physician or a hospital. More important than that, I think, is we have put in place a process what we sort of euphemistically call in CMS a new issue review process.

You can think about it this way: If an RAC wants to open up a new set of reviews on a particular issue having to do with medical necessity in a particular state, before they can begin that review in earnest, in other words, before they can start asking for a lot of medical records from a lot of different providers, they need to come into CMS and they need to talk to me as the CFO and they need to talk to the physicians who do our coverage policy and the people who do our payment policies who really write all the policies and explain how they are going to do that review, the rules that they are using to do that review, and we need to sign off and agree that what they are doing comports with the policies that we have got in place, precisely so we don't get in the situation like we did in California where the RAC was reviewing rehab claims in a way that ultimately we didn't agree with.

I think that, on the front end, puts a level of oversight and discipline in the process that we don't have now, and, quite frankly, we don't have for any of the other sorts of review activities we have in Medicare. That would be unique to the RACs. I think it will provide for me, anyway, a much greater level of comfort and oversight for the RAC processes.

Chairman GONZÁLEZ. I don't mean to misinterpret what you are doing, and I think it is done in good faith, but I also believe that you see some real potential for things going haywire or not as we would prefer that it perform.

One thing that concerns me is this contingency fee arrangement, which I understand that concept, but I have never seen something like this, to be honest with you. Let me get this straight.

If the RAC finds that a claim should be denied, a medical necessity claim, a denial, it is that first step, are they reimbursed at that point? In other words, are they entitled to their contingency fee at what stage? At the initial finding?

Mr. HILL. They are only entitled to the fee when the overpayment amount has been recouped by Medicare. So to the extent that they have identified a claim, a medical necessity claim that should be overturned and recouped by Medicare, to the extent that Medicare recoups that amount, the RAC is repaid.

If, for example, a provider, say it is a significant amount and a hospital, this is typically the case in hospitals or a home health agency, as I said, they would like to pay that amount over time, they would like to have an extended repayment plan, the RAC only gets a portion of each payment. They don't get the full amount right away. They get the percentage as Medicare gets its amount.

On the back end, to the extent a provider appeals that determination, the way the Medicare process works now is typically the amount is collected when the appeal happens. To the extent the provider appeals and wins, in other words, that appeal is overturned, the RAC has to pay that money back. They don't get to keep that money. That is how it works.

Chairman GONZÁLEZ. And I have another question. I am going to reserve that and give myself a little additional time after I allow my colleagues to have a question here.

At this time, the Chair will recognize Ms. Fallin.

Ms. FALLIN. Thank you, Mr. Chairman. I thank you once again for your testimony. I have a couple of questions.

If a physician appeals a claim and it goes to an appeals judge, what percentage of those claims are overturned by the appeals judge? Do you have an estimate on that?

Mr. HILL. I do. I actually have the numbers. If you think about it in three buckets, you have got the total amount that has been denied by the RAC. Of that total amount, roughly 4.5 percent ultimately get overturned on appeal. Of that total amount, the number that are appealed is roughly 13 to 15 percent. So you get 100 claims, 13 to 15 of those get appealed, and of those, roughly 30 percent get overturned. So it is ultimately an overturn rate of about 4.5 percent. And that compares—it actually compares favorably, or not favorably, however we want to think about it, with the appeals rates that we see with our normal FI and carrier operations who also do this sort of work.

Ms. FALLIN. We are talking about some issue. What is the appeal rate for the FI and the appeals carriers?

Mr. HILL. Those rates are about the same.

Ms. FALLIN. They are about the same.

Mr. HILL. Right. The initial—so the 13 percent is probably a little lower, right? So fewer of the denials are appealed. But of those denials appealed, more are overturned for the FIs and the carriers. It is closer to a 50 percent overturn rate.

Ms. FALLIN. Do you have any classifications of claims that are automatically denied on the first time they are sent?

Mr. HILL. I do, but for the FIs and the carriers, the way we do that is normally through the systems process, that is Noble. I don't know that here. I can get back to you on that for the record.

Ms. FALLIN. My physicians frequently tell me that, that they will submit a claim and it is just automatically denied. I just wonder why we do that sometimes in Federal Government.

Mr. HILL. Well, there are certain circumstances where we have what we characterize as correct coding on it, so they look at the claim and make a judgment as to—the system makes a judgment as to whether or not that procedure matches up with the particular diagnosis code. You know, sort of the procedure for fixing a broken arm wouldn't match unnecessarily with a diagnosis of pneumonia. So those might get denied.

Others are what we call medically unbelievable edits. Certain amounts of procedures that are done on a particular day, the system would look at that and say that is medically sort of unrealistic that that would happen, and those would get denied on their face. So I am not going to say there aren't certain circumstances that they would be believable. In those cases, they get appealed and get overturned.

Ms. FALLIN. Do you know of any particular illnesses that are denied on the first claim?

Mr. HILL. Illnesses? No. Other than things that would not have been normally covered for Medicare. But I can't think of any illnesses that would be denied on the first blush.

Ms. FALLIN. What do you think is the root cause for the improper payments by the CMS contractors?

Mr. HILL. I think there are roughly four categories of improper payments that we see. We see improper payments that are the result of medical necessity. Those are the hardest ones. Those are the ones where we are going in there and we are saying the physician made a judgment, admitted somebody into a hospital or facility and does a particular thing to a particular person that perhaps could have been in a different setting or should not have been done.

Roughly a third are what we characterize as coding. You know, they just coded it incorrectly. The person needed a service. They got the service. Somebody just put down the wrong code for that service.

And roughly a third are what we would characterize as no documentation or insufficient documentation. So something was provided, but the information that we got back from the facility, there is not enough information in the record that we got back from the facility to support whether or not it should have been provided. So it is those three.

I think sort of why do they occur, some of it is Medicare, and medicine is very complicated, and sometimes the rules are tough to follow, and so that is an obligation for CMS to do a better job on provider education and outreach.

Sometimes it is people trying to game the system. As much as we don't like to admit it, there are people who try to game the system. And sometimes they are just straight out mistakes.

Ms. FALLIN. In light of that, do you think that proliferation of the contractors helps or hinders the medical service provider's ability to deliver care to their patients?

Mr. HILL. Ultimately, it is CMS' position that it is going to help. I understand the issues around RACs and sort of what the provider community in particular believes or sort of perceives as some of the issues.

My judgment has always been as CFO that, you know, a physician or a supplier or a home health agency should have competence

in the process they are in. They may not like the outcome, right? They may not like it that a claim was denied or perhaps something was covered or shouldn't have been covered or was. They may not like the outcome. But they should walk away from the process saying CMS was fair, they were predictable, we knew what was going to happen in the process.

That is what we are striving to do with all our integrity efforts and, with the RACs in particular, we learned a lot in the demo. I am not going to say that I achieved that vision in the demo all the time, but we strove to, and I think as we roll this out nationally that is what we are seeking to achieve.

Ms. FALLIN. Thank you, Mr. Chairman.

Chairman GONZÁLEZ. Thank you very much, Ms. Fallin. I am going to follow up with a couple of questions, one that is going to be on prescription drugs, generics. I referred to it in my opening statement. GAO conducted a study and my information is that it appears that they would say that a pharmacy may well be only reimbursed at somewhere around 64 percent.

In my district, I have Caremark, and I think both Dr. Farris and yourself know what Caremark represents. But I also have the Ortiz Pharmacy there in the west side of San Antonio, which is a poorer side. I have visited both and they are totally different operations, I assure you.

But I do know that the Medicaid population in San Antonio is going to depend on Ortiz before it depends on other. And I guess I am somewhat concerned. I don't understand the average manufacturer price. But the GAO report is very disturbing. How do you reconcile that? Do you agree with the findings? Is there anything that you are going to be doing? We are going to have testimony later from the private sector, but what is your understanding of that situation today?

Mr. HILL. Well, a couple of things. First, I know that as we promulgated the rules and as we talked about AWP, we are carrying out what we believe is the intent and sort of what needed to happen as a result of the DRA.

I think with respect to the details and sort of whether or not CMS believes that the GAO report was correct or incorrect or the impact, I would sort of defer that for the record. Some of that gets sort of complicated. There are people who work in the Center for Medicaid and State Operations who are the real experts, who are not here. I want to get you a fair answer, and the right answer, and not sort of just sort of dance around with it. With your indulgence, I would like to defer that for the record.

Chairman GONZÁLEZ. We will follow up probably with a written question. Of course, members of the Subcommittee will be given time to submit written questions and we would appreciate a prompt reply.

The last question I have for you, of course, we come back to RAC, which I understand that you are simply saying we are following exactly what you and other Members of Congress told us to do. Well, we understand that, but what we expect is that you are going to have some sort of a fair process that is not just going to be efficient and effective, but obviously fair to the health care providers in this country.

There has to be an incentive, obviously, and if it is a contingency fee, then it is those overpayments. Maybe I don't understand, but they are also supposed to be looking for underpayments. Common sense and human nature tell me that you may not have the same motivation or inspiration, and I could be wrong on that, to put as much effort in finding the underpayments.

How do you address that particular side of the equation? And, secondly, what is the incentive to identify under payments?

Mr. HILL. The incentive to identify underpayments is exactly the same as the incentive to identify overpayments. The contingency fee, the proprietary fee that has been negotiated with the RACs, is the same as a percentage of the overpayment as it is on the underpayment. So if they find a $100 overpayment and they got a 10 percent fee, they are getting 10 bucks. If they find a $100 underpayment and they get a 10 percent fee, it is 10 bucks. The incentives are the same.

I take this next step lightly sort of dealing with the chairman of the Small Business Subcommittee, but what we have done on a random basis for 10 years now, 11 years now, having nothing at all to do with the RACs, is a random assessment under the Improper Payments Act of where Medicare makes improper payments. A completely random sample. It is not focused on overpayments, it is not focused on underpayments. We just take a strict sample. Over 10 years, we have been doing that.

For the 10 years we have been doing that, we do find that there are not a lot of underpayments. The vast majority of the improper payments, in the percentages you identified, 5 to 10 percent, being only the underpayments. We don't see a lot of underpayments as we look at those records and we go back and make a redetermination.

Now, whether that is—I don't know how to explain that, whether or not the overpayments are the result of people trying to game or the underpayments—not having underpayments is the result of physicians or other just feeling like they don't want to bill for more, for whatever reason. But we haven't seen over time a remarkable amount of underpayments as we looked at our improper payments across the program.

Chairman GONZÁLEZ. The last question is probably the toughest one for anyone that represents an agency or department here, but under the leadership of Chairwoman Velázquez, who takes this responsibility very, very seriously, under the jurisdiction of this Committee comes the Regulatory Flexibility Act. And what we always ask heads of departments, organizations, cabinet members, it doesn't matter, we always say, what do you do as you promulgate these regulations and such to take into consideration the mandate and the responsibility with which you are charged under the Regulatory Flexibility Act.

One, it is applicable, I believe, and if you disagree, you would say, Charlie, we are an exception to the rule or something. But what do you do? Because it seems that has always been the hardest question for everyone to answer when we pose it.

Mr. HILL. Right. Well, I don't know what this is going to say, but I am not quite sure it is that hard to answer, so maybe it will be

the wrong answer. But I am going to try. There are two aspects of this for us.

On the demo side, there is the basic analytic due diligence function for us, right? So we knew we were doing a demo. We knew it was going to have a impact on a number of providers. There was not going to be any regulations associated with it. So the piece of the Regulatory Flexibility Act that talks about the assessments that you need to do as you do regulations wasn't going to apply.

But we did reach out quite aggressively with the Small Business Administration to help them understand what we are doing, sort of lay out our plans so they understood what we are doing. Not that they were going to sign off or sort of say it was the greatest thing since sliced bread one way or another, but we did at least want to do that due diligence.

So for us, that is the two-pronged piece. There is the Ombudsman Office at SBA that we work with as they get comments in from providers and we proactively work with them to tell them what we are doing. And as we roll the demo out nationally, that is a group that we will work with quite closely so that they understand the impact of what we are doing on the RACs.

Not just on the RACs. Whether it is regulations having to do with home health agencies or DME or whatever, we work very closely with that group to be sure we are in compliance where we need to be with the Regulatory Flexibility Act.

Chairman GONZÁLEZ. Thank you very much. The Chair is going to recognize Ms. Fallin.

Ms. FALLIN. Thank you, Mr. Chairman. I have one last question I am just trying to get a feel of. Under the statute for Recovery Audit Contractor, that they can review a payment in a particular fiscal year or up to the four preceding fiscal years as I understand it, is that right?

Mr. HILL. Under the Demonstration Act, that is correct.

Ms. FALLIN. Under the Demonstration Act. Okay. Is it then conceivable that the Recovery Audit Contractor could reexamine a payment to a hospital or a physician that was ordered by a Federal Court, including the possibility of even the United States Supreme Court, that they could reexamine that, and does CMS have any guidelines for your Recovery Audit Contractor from reviewing the decisions of the Federal Court or Supreme Court?

Mr. HILL. That is a very interesting question. I think the short answer is I never say never, right? I mean, it is absolutely entirely plausible that a claim could get reviewed and that claim could be the result of some sort of judicial action, either a stipulation or a mandate that something occur.

I mean, off the top of my head, you know, under the Medicare statute, a judge stipulating that something or demanding that something is medically necessary, that is not something I have seen come up before. I mean, I have seen where a particular, whether it is a provider or a jurisdiction, be it a State or local jurisdiction, is required to provide a set of services to a set of individuals, but not that every service has to provided and covered by Medicare. We still have to reach those coverage decisions.

So, I mean, if there is more information there or if there is something else I can do to sort of delve into that, I would be happy to.

It is a very interesting question, and I suspect it will lead to all sorts of odd answers.

Ms. FALLIN. Okay. All right. Thank you very much.

Chairman GONZÁLEZ. Thank you very much, Ms. Fallin. And Mr. Hill, Dr. Farris, thank you very much for your testimony. We are going to go to the next panel. You may receive written questions from members of the Subcommittee. Also I anticipate that you may have to leave, but we will have representatives from CMS that will remain throughout the hearing. It is always very important to the witnesses to know that someone from the government is there and listening to their specific testimony.

Mr. HILL. We will be here. Thank you very much.

Chairman GONZÁLEZ. Thank you. You may be excused.

The Chair is going to call panel 2. We will have staff set up the particular order.

I welcome the second panel of witnesses and thank you for your patience. I know it took a little longer with CMS, but it is always important when we have somebody here that can answer some of the questions that I know you have had and hopefully were reflected in some of the questions posed by the members.

I will indicate now that Ms. Fallin may also have to excuse herself. We try to do everything in about 2-1/2 days when we are here, and you are finding yourself in one of the busiest. At this time what I will be doing is I will be recognizing the witnesses individually, and I will introduce them as they are about to testify.

Chairman GONZÁLEZ. The first witness is Dr. William A. Dolan. Dr. William A. Dolan was elected to the American Medical Association Board of Trustees in June 2007. He is an orthopedic surgeon from Rochester, New York, and has served on the AMA Council on Medical Service since 2002 before becoming Chair this year. The American Medical Association helps doctors help patients by uniting physicians nationwide to work on the most important professional and public health issues facing our country.

Again, I will remind everybody, you have 5 minutes, and, believe me, you will have plenty of time to expand on anything during the question and answer.

Dr. Dolan, you may proceed.

STATEMENT OF DR. WILLIAM DOLAN, MEMBER, BOARD OF TRUSTEES AMERICAN MEDICAL ASSOCIATION

Dr. DOLAN. Thank you, Mr. Chair, and acting ranking member, Ms. Fallin, and members of the Subcommittee. My name is Bill Dolan. I am a member of the Board of Trustees of the AMA and a practicing orthopedic surgeon in Rochester, New York. I want to thank you for inviting us to testify here today on the impact of the CMS regulations and programs of the small health practitioners.

Chairman GONZÁLEZ. Excuse me, Doctor. I don't think the mike is on. If you can hit that button. I can hear you fine, but they can't in the back.

Dr. DOLAN. Approximately 75 percent of physician practices are composed of fewer than eight physicians. For the majority of these small physician practices, including mine, burdensome regulations can take valuable time away from patient care. We believe that

this is particularly true with regard to the Recovery Audit Contractor, or the RAC program, and the ICD-10 implementation.

Now, as you pointed out, the RAC program employs contractors to analyze and audit physicians' reimbursement claims for billing errors. The pilot program, which began in 2005 and will begin nationwide this year, has been extremely burdensome on the affected physicians and does nothing to educate them about common billing mistakes. Instead, the program embraces the ″bounty hunter″ technique that provides the RACs with incentives to deny claims.

While we strongly oppose the RAC program, we believe there are things that CMS can do prior to the national rollout that would improve it. Specifically, CMS should consult with the AMA on RAC physician communications. In addition, they should make RAC monthly financial reports public and maintain an accessible list of commonly audited procedures.

CMS, in addition, should preclude RACs from reviewing claims for the past 12 months. The failure to do so will result in RACs reviewing claims still under review by carriers and other fiscal intermediaries.

RACs should not be permitted to review billing issues arising from evaluation and management services or medical necessity determinations, as they are extremely individualized and extensive clinical review is necessary.

CMS should limit the number of records requested from individual physicians. I know of one neurologist from California who had a request for 50 of his patients' charts.

CMS should also raise the minimum claim level from $10 to at least $25.

Finally, CMS should encourage the pursuit of underpayments, as you spoke about, as well as the overpayments, by requiring RACs to accept case files from providers for underpayment reviews and including as an underpayment those situations where a physician mistakenly neglects to report a delivered service.

The AMA also concerns itself with the rollout of the ICD-10, the 10th version of the international classification of disease is used in outpatient and inpatient settings. While the AMA recognizes the important action of updating the current coding system, ICD-9, we believe that due to the complexity and the cost of this extensive transition, a plan and timeline must be developed prior to a national rollout. Any transition must take into account the fact that physicians are already struggling to implement the HIPAA electronic transaction standard and also the transition to the national provider identifier number.

Given the costs and complexities involved with the move to ICD-10, the AMA suggests that the HIPAA electronic standards be upgraded to version 50-10 prior to the national rollout as the current standard, 40-10 is totally incompatible with the ICD-10. In addition, the ICD-10 coding system should be pilot studied and tested so that problems with it can be identified and resolved in advance of a national rollout. Physicians, their staffs, their coders and other national stakeholders will need adequate education and training very early in the transition process.

Due to the significant resources, administrative complexities and advanced planning required to retool and replace our systems and

processes which currently depend upon ICD-9 logic, HHS should work collaboratively with the health care industry stakeholders to develop a realistic transition process and timeline.

The AMA looks forward to working closely with the Small Business Committee to ensure that physician practices, especially the smaller practices like my own, are able to manage the RAC audit process and prepare for the ICD-9 rollout and transition without compromising health care to our patients.

Thank you.

[The prepared statement of Dr. Dolan may be found in the Appendix on page 56.]

Chairman GONZÁLEZ. Thank you very much, Doctor.

Chairman GONZÁLEZ. The next witness is Dennis Wiesner. Mr. Wiesner is the Senior Director for Privacy, Regulatory, Government, and Industry Affairs for H.E.B., a grocery company in San Antonio. Beginning in 1905, H.E.B. Grocery Company is now one of the largest independently owned food retailers, with stores throughout Texas and Mexico.

When I make a comment that I have got Caremark in San Antonio as well as the Ortiz, somewhere in the middle I have grocery stores like H.E.B.

Welcome, Mr. Wiesner. You may proceed.

STATEMENT OF MR. DENNIS WIESNER, SENIOR DIRECTOR FOR PRIVACY, REGULATORY, GOVERNMENT, AND INDUSTRY AFFAIRS, THE H.E.B. GROCERY COMPANY, SAN ANTONIO, TEXAS

Mr. WIESNER. Thank you, Chairman González.

Chairman González and members of the Small Business Committee, I am Dennis Wiesner, a registered pharmacist, and I am senior director for Privacy, Regulatory, Government, and Industry Affairs for H.E.B. Grocery Company, headquartered in San Antonio, Texas. I am testifying today on behalf of the National Association of Chain Drug Stores. Over half of the NACDS membership operates 20 or fewer stores.

We appreciate this Committee's support for pharmacies, particularly the leadership of Chairman González, Chairwoman Velázquez, Ranking Member Chabot, and others on the Medicaid AMP issue.

As you may be aware, 20 percent of the Medicaid population is located in rural areas of the country, and in Texas, many of our stores are located in rural towns. For Medicaid beneficiaries, we are often the most accessible supplier of prescription medications, health information and critical health care services. In particular, my company offers immunizations in all of our locations. Pharmacies are the face of neighborhood health care.

It is with this in mind that I express my concern regarding the devastating cuts to Medicaid pharmacy reimbursement called for by the Deficit Reduction Act of 2005 and the CMS implementing regulations commonly referred to as the AMP rule.

For many pharmacies, the AMP cuts to Medicare reimbursement place our businesses at risk and threatens patients access to medication. Many pharmacists will not survive the AMP cuts because they will be paid less for generic drugs than it costs to purchase

them. Many pharmacies may have to cut back services or shorten their operating hours, and it has been estimated that as many as 12,000 pharmacies across the country could close their doors.

If patients lose access to vital medications it could also lead to more emergency room visits and expensive catastrophic care. Failure to take medications as prescribed is estimated to cost $177 billion annually.

The AMP rule is fundamentally flawed in many ways, but in particular, it fails to provide a thorough analysis of the economic impact that this rule would have on small pharmacy businesses as required under the Regulatory Flexibility Act.

In light of numerous statutory violations, a Federal judge has blocked implementation over the AMP cuts. However, only Congress can prevent these cuts with a permanent legislative fix. That is why it is essential that Congress pass the Fair Medicaid Drug Payment Act, H.R. 3700 and Senate bill 1951. I urge all Members of the Committee to cosponsor this important bill.

I would like to focus the rest of my statement on the Medicare program and the impact of related CMS regulations on beneficiary access to drugs, medical supplies and services.

When enacting the Medicare Modernization Act, Congress recognized the value and trust patients place in their local pharmacist and the need to preserve those relationships, many of which go beyond the simple filling of a prescription. Thus Congress included playing field provision to ensure that patients can obtain their Part D benefits from any retail pharmacy of their choice.

However, CMS' implementation and its guidance on how plans should follow this provision are inconsistent with congressional intent.

As a result, Medicare plans are steering patients to mail order houses and discouraging 90 day supplies at retail by offering lower reimbursement rates or by charging higher copays for the patients. These practices deny patients a choice in their health care provider.

Another area of concern involves new program requirements and competitive bidding under the Medicare Part B for durable medical equipment and supplies which will also harm patients' access to their local community pharmacist, the most readily accessible health care provider in the community. On this issue, NACDS proposes the following recommendations, on which I elaborate in my written statement.

First, State licensed retail pharmacies should be exempt from the accreditation requirement. State licensed pharmacies are licensed by their respective state board of pharmacy and abide by strict State and Federal laws, including those related to health care, fraud and abuse.

Next, diabetes testing supplies sold at retail pharmacies should not be subject to competitive bidding. Expansion of the program to include diabetic supplies sold at retail pharmacies could harm patients' access to those products and create a fragmented care in the management of diabetes.

Last, CMS should not create national or regional competitive bidding areas for mail order items. The mail order program is likely to compromise on the quality of products and services, pose tre-

mendous navigational obstacles to the low income and minority beneficiaries, and could force patients to either forego diabetes testing or do it in an improper and limited manner. And this, of course, could have devastating effects.

On behalf of my company, H.E.B., and NACDS, Mr. Chairman, thank you again for the opportunity to testify today before the Committee. I welcome any questions you may have.

Chairman GONZÁLEZ. Thank you very much, Mr. Wiesner. We will get back no doubt.

[The prepared statement of Mr. Wiesner may be found in the Appendix on page 65.]

Chairman GONZÁLEZ. The next witness is Dr. Michael Schweitz. The doctor is a practicing rheumatologist and vice president of the Coalition of State Rheumatology Organizations. The doctor is here to testify on behalf of the Alliance of Specialty Medicine, a coalition of 13 national medical specialty societies representing more than 200,000 physicians.

You may proceed with your testimony.

STATEMENT OF DR. MICHAEL SCHWEITZ, VICE PRESIDENT, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS, WEST PALM BEACH, FLORIDA

Dr. SCHWEITZ. Good afternoon Mr. Chairman and members of the Subcommittee. I am Dr. Michael Schweitz, a practicing rheumatologist from West Palm Beach Florida. I would like to discuss the experience of physicians and my own personal experience impacted by one aspect of CMS regulations on small health care providers, namely the CMS demonstration project referred to as the Recovery Audit Contractor program, or RAC.

The implementation of the demonstration has created unfair and expensive administrative burdens for physician practices, which are, after all, small businesses with limited capacity for dealing with arbitrary, ill-informed and often very confusing policies of those contractors. Some of these problems are detailed in our written documents and I will summarize some of them for you.

Number one: Recovery and review of old and previously adjudicated claims. In Florida, the RAC contractor, HGI, demanded multiple physician refund payments throughout the State for claims that had previously been reviewed and adjudicated by the Florida Medicare carrier.

Two: Errors by RAC's misstating or misapplication of codes. Records were requested or refunds demanded involving hundreds of thousands of dollars from oncologists in Florida after the RAC erroneously misstated the codes for IV hydration, which is necessary during chemotherapy.

Three: Refund requests exceeding time limits. California urologists were asked by the RAC to refund payments on the basis of least costly alternative policy for drugs used to treat prostate cancer. The RAC was discovered to be misapplying CMS written policy by exceeding time limits for reviewing claims.

Four: RACs have also taken on the role of interpreting clinical guidelines governing utilization for procedures, such as inpatient

versus outpatient procedures for hysterectomies and the implantation of cardiac devices.

Five: RACs have also applied new regulations retroactively to previously performed procedures. In Florida, hundreds of physicians were asked for refunds or records pertaining to spinal joint injections to relieve pain based on a 2003 commentary in The Federal Register, when the actual CMS policy had not been developed, distributed or published until September of 2007.

Hundreds of practices were forced to hire consultants or counsel and divert clinical and administrative staff in order to retrieve, review and submit records to comply, and even some had payments withheld, creating significant cash flow problems for that practice. One practice, in fact, had the funds withheld before the demand letter was received.

The RAC's decisions, if successfully reversed on appeal, do not resolve secondary carrier withholds or demands that are triggered by CMS notifications. This creates an exceptional additional burden on these practices to interact with dozens of carriers in order to reconcile hundreds of claims.

Our recommendations are outlined in our written testimony, but I will summarize some. These include, number one: As stated, changing the bounty hunter payment mechanism that seems to embolden RAC behavior.

Two, precluding the RAC from reviewing work from the current year. It is redundant. There are already contractors who are doing that at the same time.

Three, shortening the look-back period to 12 months from months 12 to 24. This should be a sufficient time.

Four, and most importantly, CMS should remove medical necessity reviews from the RAC statement of work. We do not think that these reviews are appropriate for the RAC program and believe that they exceed the authority imparted to the RAC by Congress. These reviews should be conducted by clinicians with the relevant experience and expertise to make rationale judgments. RACs do not appear to have used appropriately qualified staff for their reviews. If CMS intends to significantly reduce error rates in its transactions, physicians should expect no less from the RAC.

For these reasons, we support H.R. 4105, the Medicare Recovery Audit Contractor Act of 2007, or any other similar legislation that proposes a much-needed moratorium on RAC activities and expansion until the serious flaws are adequately evaluated and addressed and demonstrably corrected.

Thank you, Chairman González.

[The prepared statement of Dr. Schweitz may be found in the Appendix on page 80.]

Chairman GONZÁLEZ. Thank you very much.

The next witness is Dr. Karen Smith. Dr. Smith is the Board Chair to the American Academy of Family Physicians. She also practices family medicine in her own clinic in Raeford, North Carolina. The American Academy of Family Physicians is the National Association of Family Doctors. It is one of the largest national medical associations, with more than its 93,000 members in all 50 States, and also Puerto Rico, the Virgin Islands and Guam.

You may proceed with your testimony, Dr. Smith.

STATEMENT OF DR. KAREN SMITH, BOARD CHAIR, AMERICAN ACADEMY OF FAMILY PHYSICIANS

Dr. SMITH. Good afternoon, Chairman González and members of the Committee. I am Dr. Karen Smith, a family physician and owner of a solo private practice in Raeford, North Carolina.

On Monday morning, October 24, 2005, two representatives from AdvanceMed presented to my office with badges identifying themselves as authorized subcontractors for CIGNA Medicare and requested 72 charts for review of clinical documentation of services rendered from July 1, 2004, through July 30, 2005. My staff extracted the requested information from the electronic record system, and I personally provided the walking tour of the building, including inspection of State and Federal licenses for medical business operations. The care of my patients was disrupted in our open access rural family practice, as patients, pharmaceutical vendors and other visitors of the practice observed the unannounced review.

Five months later, on March 16, 2006, I received notification that 72 claims with 154 services submitted were reviewed and 91 of the 154 disallowed for payment. The actual amount paid to the practice for the services questioned was $1,551.11. This overpayment amount, when extrapolated to a sampling frame size of 2,935 patients, resulted in an overpayment calculation of $48,245. However, my practice management system noted I only had 1,287 CIGNA Medicare patients in the practice at that time. This discrepancy was never acknowledged nor was it corrected in the final calculations.

The reasons given for denial included incomplete or no documentation, services incorrectly coded, services not covered by Medicare, lack of documentation for drugs administered, services not medically necessary in the judgment of the reviewer, who was not a physician.

When my staff and I reviewed this summary, we noticed that several items of documentation the reviewer cited as being nonexistent were indeed present in our electronic medical record system. I notified AdvanceMed of this discrepancy and requested instructions for sending this information. They responded that this information could be submitted only in an appeal.

This answer was communicated in such an intimidating and aggressive manner, prompting me to call a well-known independent auditor. I participated in several of her coding workshops and quickly recognized additional professional assistance was going to be needed. At my request, the auditor immediately contacted an attorney who also called AdvanceMed, only to receive the same answer.

The appeal process was initiated and then delayed due to AdvanceMed sending letters to the wrong medical office which neither I nor my counsel ever received. Documentation was finally accepted by CMS and forwarded to Q-2 administrators hired by CMS to review the file and make an independent decision.

The outcome from the CMS review was partially favorable in that it decreased the overpayment amount from more than $48,000

to $18,158, a $30,000 error. But it was still based upon an incorrect and inflated number of Medicare patients in my small practice.

Our attorney reviewed additional options, including an administrative law hearing for services performed, but required additional appeal presentation. The practice, my family and myself were at a point of stress never imagined. We were exhausted and emotionally distressed after countless hours and days of preparation and review during our third year in business. Thus, we decided to halt further appeals and review. We were financially drained and feeling the pressure to make payroll, pay mortgage, as well as other expenses.

A loan was acquired from my personal home equity and a check sent to CMS to satisfy the obligation. Ninety days later I received notification from the U.S. Attorney's Office for a possible levy of assets due to nonpayment of the CMS recoupment. After providing documentation two times, it was clarified that the payment had not been applied to our debt.

I established a technologically advanced primary care practice in one the poorest counties in North Carolina. This is a practice that adheres to the highest standards of care and participates in quality-based projects and a goal of decreasing medical errors, eliminating redundancy and State-of-art communications with the hospitals located in the region.

The guilty until proven innocent audit we endured used sampling and extrapolation calculations which are not properly verified for validity. In addition to the disruption to patient care and possible reputation damage by the surprise and abrupt visit of badge-bearing authorities, the process quickly exhausted our financial reserves.

It defies common business sense to run a highly qualified medical practice using records in a financial environment where Medicare does not recognize the true total costs for caring for individual patients with many medical problems. The escalating costs of health care cannot be subsidies for moneys taken out of the businesses of small physician practices. We have the compassion and the desire to remain in operation, but will not be able to endure in a world of uncontrolled costs and diminished payment.

Thank you for allowing me to testify.

[The prepared statement of Dr. Smith may be found in the Appendix on page 92.]

Chairman GONZÁLEZ. Dr. Smith, thank you very much. Quite a compelling experience I would say. It wasn't a story, it was reality.

We are going to have votes in a few minutes, but I think, since I don't have any other members that are present, and please do not interpret that as not having an interest. Believe me, we are just pulled in every which way. If I wasn't chairman, I probably would have been here and then I would have been at another hearing.

All of your testimony, of course, is being recorded. Your statements are part of the record. The questions that we have here, probably the most important people will be our staff members. Chairwoman Velázquez is not one to conduct a hearing or allow us to conduct Subcommittee hearings without looking at taking some sort of affirmative action on these things. She is very proactive. So, believe me, this is incredibly important and informative.

My first question, Dr. Dolan, you have recommended that the minimum should be increased from, let's say a $10 overpayment to $25. I guess it is a two-part question. What is the basis for that? And simply, if the threshold is really low, obviously you have multiple claims being challenged and overpayments and such. I understand that. Is it worth it, even at $25, for the physician to go through all the trouble to basically contest it? That is the first question.

The other thing is if you don't contest and you just simply pay, are you establishing some sort of record in that big computer in the sky or whatever, that Dr. Dolan, because you just didn't want to contest all these low ones or even cumulatively, it was just not worth the expense? Is there some fear on the part of a physician that somehow they are having some sort of a record out there for someone to look at, and it obviously would not be a good reflection that you had 1,000 claims, maybe they are all $10 or whatever, but nevertheless there is no distinction. Is that a fear?

Let's just go back to you want to increase it from $10 to $25, and what would be the basis for that?

Dr. DOLAN. I personally would want to increase it to $100. At $10, the physician will lose money, just listen to the story next door here, will lose money in even trying to replicate the records. Remember, we do not get paid like the hospitals get paid for replicating the records, nor the postage nor anything else. So you will lose quite a bit of money. Even if you have to do one record, it is not worth it.

It is like us seeing Medicaid patients. It is not worth us to charge. We do it for free. The same with $25. With all the work you have to do, it is probably not worth paying a full time equivalent to go back, find the record, $15-an-hour payment, to file and then copy all those things and then get the postage and send it off, filling out all the forms. It is not worth it.

We know of no such dragon in the sky who is watching over this. There may be. But if you are just dealing with several items, unlike the multiple requests by the doctor, I would just blow it away. It is not worth my time. It is not worth my secretary's time. It is not worth the patient's inconvenience. So I would do that.

Now, PPAC, which is the Physicians Advisory Counsel to CMS, has recommended $25. That is where the $25 came in. But, personally, I would go higher than that, because that is when you are really going to fight, when it gets to be $100. That is where that number comes in. It is an arbitrary number, and I will have to say that.

Chairman GONZÁLEZ. The fear, of course, is if you are on a contingency basis and you go for all this low hanging fruit, but the real reason is you simply know it is not going to be contested and cumulatively you can make a lot of money, to be honest with you, because obviously the other side, it is just not a financially viable proposition for them.

I will instruct Committee staff if they will remind me to follow up as to how CMS keeps these statistics and whether there is any adverse effect on someone. In other words, if there is a future let's say investigation or whatever it is, they go back and they go, my gosh, look at all these claims, not looking at the numbers or any-

thing like that. So is a physician or health care provider placed in jeopardy by simply making that determination of not to oppose or to appeal or so on.

I think that is a real concern. At the end of the day, you are still a business. Your life span and profession always say that, but, nevertheless, they are business considerations.

Then, Mr. Wiesner, let me ask, I am trying to figure this thing out on the average manufacturer's price and how it plays out and the different type of pharmacists that we have out there. I think I have already described, I think I have all three there obviously in my own district.

But you heard Mr. Hill from CMS, and he seemed to say, not in reference to RAC, but what we are talking with here, that it seems to be more of a work in progress still. Do you sense that? Do you feel that you still have some input, that something can still be done? Or is this a bygone conclusion and you are going to be facing this. And then the potential impact on someone like H.E.B. And what I refer to as my supermarket pharmacies?

Mr. WIESNER. Correct. I don't believe at this particular point we have that much more input that is going to change the direction that we are going. Obviously, I did refer to the fact that we have a temporary injunction so it is not in effect at this point in time. But at some point, there will need to be a benchmark to help determine the adequate cost basis for generic products, and at this moment, AMP is a flawed definition of how that is achieved.

It is intended to be really the average price paid by a community retail pharmacy. But included in the information that is gathered is prices from a large number of other facilities. They could include clinics, they could include the mail order operations, for example, and in each of those instances we are not on a level playing field with those. I could elaborate, but that would take a little while to do that.

So what we actually have is kind of a misnomer. It says average manufacturer price. The real reality, it is the lowest price that is reported. It is not an averaged weighted price across all these various classes of trade. So it would be the lowest price that would come in. And in many cases, as you reported earlier, the GAO report, it has already been determined and confirmed that 60 to 65 percent of the time, the average community retail pharmacy would not be able to purchase the product at the price that it is going to be set at.

Chairman GONZÁLEZ. It is a fair statement though, if you are looking, in essence it is going to be the lowest price. And it is not a level playing field, for many reasons. A mail order house obviously don't have the facility, the physical structure, the employees and such, which creates jobs and everything else in my district, by the way, and everybody else's district, and the traditional pharmacist there. But, nevertheless, you all would all come under this general umbrella at arriving at that price. Everybody is basically under it or in the same situation.

Mr. WIESNER. That is correct. We would all be underneath that same umbrella. What that is going to really create is for individual pharmacies to make some very tough decisions if nothing is changed. They will each have to look at their own financial situa-

tion, and the ones that would be most at risk, more than any, would be pharmacies located in rural settings that have a high percentage of Medicaid recipients.

It is important that the Medicaid recipients have providers across-the-board for access, and if they have to make decisions such as not participating in the program, there still needs to be avenues for the Medicaid recipient to receive their prescriptions. So that will then push that out into the community and further overburden the rest of the pharmacy community.

Chairman GONZÁLEZ. I appreciate it. It is so important for us as Members of the Congress to understand how the real world works out there and the different competitors in the same enterprise. So it is, when you are explaining to me the difference between, let's say mail order, and you pointed that out, I think it is an important distinction.

Dr. Schweitz, your testimony obviously was very interesting and also very compelling. I do want to obviously be fair to CMS and some of the concerns you had.

I just want to know if you believe they are going to be adequately addressed? We know it is a pilot project. We know it is in certain States. Mr. Hill indicated in his testimony lessons were learned. They are going to improve on that particular system.

Chairman GONZÁLEZ. I just want to know if it provides you and addresses your concerns. From his testimony, he says, for example, they will now have both a medical director and certified coding experts will be required to be employed at all permanent RACs. That is an improvement. Does it go far enough?

Dr. SCHWEITZ. That addresses the issue of medical necessity reviews to some degree, but I think your question to the CMS representative was right on the mark. What kind of volume are we talking about and how is one medical director going to address all of those necessity reviews from all of those different specialties?

I would like my necessity reviews to be done by someone who has expertise in my field to make a judgment on what I am doing. I really don't know how a general medical practitioner or general medical director can have the expertise to make those determinations in all the different fields there are in those kinds of volumes. So I have reservations about that part of it.

Chairman GONZÁLEZ. I think Mr. Hill was, again, very candid and I think those decisions on how that process will operate within that particular RAC is really going to be up to that medical director, what he or she will actually be seeing. I don't think that it is going to be every doggone claim. That is the most obvious observation that we could be making.

In Florida, I forget the name of the outfit that you dealt with. I don't know if—

Dr. SCHWEITZ. Health Data Insights. HDI.

Chairman GONZÁLEZ. HDI. Do you have an idea how much of an area they were provided? I should have asked Mr. Hill this. I am still not sure how many RACs we had out there during this process. Let's say in the State of Florida, which is—

Dr. SCHWEITZ. There were only three States that were part of the demonstration project initially, Florida, California and New York,

and I believe there is one contractor in each State. We only dealt with one.

Chairman GONZÁLEZ. And now I see everybody shaking their heads in the audience. I think they are all in agreement with you. I am just wondering if when we expand this to all 50 States—and anybody else, I am really—again if that is what we are going to do, it is going to be an overwhelming challenge I would suspect. I am not saying that CMS is not attempting to do the best they can. I am just saying now that we are going to have 50 States, how many RACs are we going to—permanent RACs, that is what we refer to them now. Nothing is really permanent permanent, as you know, and that is why we have legislation. You could also have lawsuits and so on. But I am hoping we have a collaborative and come up some answers that address your main concerns because obviously CMS is acting at the direction of Congress. It is just the manner in which they are executing the policy and that is what we are trying to arrive at.

Dr. Smith, I guess—I wanted to ask you when they paid this visit and it was unannounced, you talked about people just coming in. Your employees, your patients, and you have somebody who comes obviously in an authoritative manner. I don't think they flash badges or whatever it is, but in essence and that actually occurred. You did not have any warning. There wasn't any discussion—"we need to meet with you, this is what we are going to do and we are coming by tomorrow."

I am not saying they give you 30 days notice. I understand how the real world works. If they think someone is doing something they don't want to give you any time to do anything if they believe that you are a wrongdoer. Not that that is what was happening in your case. But I understand that is the way the government works. But nevertheless they came in; right? And at some point it just isn't profitable to continue to resist; is that correct?

Dr. SMITH. Yes, that would be correct. And exactly as you described, they appeared at the front window and they did flash badges which placed us on notice immediately, which is why we responded immediately and prepared this information.

Chairman GONZÁLEZ. The other thing that was disturbing in your particular circumstance, which is different circumstances than what we have been talking about prospectively, what we have already had in place and what goes on, is this sampling when you extrapolate. I understand that concept, too. I just don't think it is applicable in many instances.

And that is what they basically do. They find one or two cases and say, well, you have 50 recipients, therefore we are just going to go and figure that each and every one of those then should reflect this overcharge of whatever it is; is that correct?

Dr. SMITH. Yes, that is the sampling frame size. And in our situation, the sampling frame size was grossly incorrect. We ran our numbers before taking the flight yesterday and as of yesterday we had 1,487 Medicare patients. At the time of this audit it was still noted that we had 2,935 patients. As of this date we have never acquired that many patients and it was extrapolated against that number.

Chairman GONZÁLEZ. So the base number was wrong. The other thing, too, I think you indicated some payment was tendered or whatever. Obviously it wasn't applied. I think we all run into that in some respects.

But for you, I mean, you are getting a letter, obviously—and I don't remember if it was an Assistant U.S. Attorney or someone in a legal capacity—which technically they could just shut you down; is that correct? How were you able to remedy that situation?

Dr. SMITH. Fortunately, by that time we had maintained copies of each piece of correspondence sent out from the office. And so he immediately asked me to fax those to him. We faxed it over. He called back to verify the information. We also had a copy of the check that was written and also showed on the back where it had been cashed, and we sent that to them. And we thought the matter was resolved.

And literally 3 to 4 weeks later the same letter comes again and we sent back the same information, this time with the certified mail receipt showing where we sent it and we sent a copy to CMS so they were aware of what the problem was.

Chairman GONZÁLEZ. I want to thank you for your testimony. One last question on the ICD-10. Dr. Dolan, I think you made some reference to it. Based on your testimony, this is being rolled out but we really have not had a pilot project. We haven't had any kind of a test out there, any rollout. I know what we did with RAC, but we don't have anything similar regarding what we are going to be doing with coding and such.

And I was reading the staff's memorandum on this—and I want to commend staff for doing such a good job because this is quite complicated in many ways unless you are a physician or you work in CMS—but it is an incredible expansion of the code. The numbers that you have out there actually to apply and to use—and I forget the exact number and I could find the memorandum, but what you are saying is they are just going to roll this thing out. You are going to have to adopt it, whether you can reconcile it with what you have in an existing framework or procedure. Is that correct?

Dr. DOLAN. That is correct. The current plan of CMS is to roll this out. The current terminology base, ICD-9, is not compatible with ICD-10. All right? That is the 4010 software.

Chairman GONZÁLEZ. Okay.

Dr. DOLAN. Now, ICD-10 has 10 times the number of diagnoses, procedures, et cetera. Since ICD-9 was started in 1970 and they never got the bugs out of it for 20 years, ICD-10 has 10 times the diagnoses numbers and procedures. And on top of that, one, ICD-9 is a numeric base. ICD-10 will be an alpha numeric base with at least three, sometimes four digits following the main number.

So this is going to be very complex. And to get a software that will be compatible with this is possible, but first you have to apply the software to the new ICD-10, and then have at least a 2-year pilot project to make sure it works. And once we know it works, then teach everybody about it before you put it into effect. This should take 4 to 6 weeks—4 to 6 years at least before you can get a good enough shot.

Now, we don't deny that ICD-10 will be good. But you have to think of the thousands, hundreds of thousands of nurses, coders,

doctors, who don't know a thing about this and they are going to thrust this big complex system on top of them and it is going to be Y2K all over again. So I just really would want you to understand the complexity of this matter and the problems that we are going to run into.

Chairman GONZÁLEZ. And I know it was pointed out in simple terms, ICD-10 has 200,000 codes.

Dr. DOLAN. Correct.

Chairman GONZÁLEZ. And that alone—then you are telling me about the incompatibility of software and of course the conversion and what that is going to take and so on. It seems like a prudent thing—and I will educate myself on this as well as in talking with other members of other committees that have jurisdiction over this particular issue to address exactly what you are describing here. Because it seems like if it is just rolled out and dumped in everybody's laps, I am not even sure it is a practical matter. And I am sure we have software vendors and everybody out there that can tell you that they can get their hands around it and can handle it, but I am not sure of that.

Again, I just want to thank the witnesses for your testimony. And, again hopefully we can come to some sort of consensus in a collaborative effort. As I have always said, short of lawsuits and short of major legislation which is always hard to pass, in a regulatory scheme we are going to be more nimble and we can react more quickly, and that is what the Regulatory Flexibility Act was all about.

Let's do that but make sure we are getting the input. And I am not real sure on some of this if CMS has met its duty under the Regulatory Flexibility Act. And again we want to work with them, of course, and see if we can find something that meets the needs of CMS, the mandates of Congress, but at the end of this, doesn't in any way imperil the care that our citizens under the programs receive.

Again thank you very much. And I am going to ask the next panel to come and have a seat. We are going to get as much done as we can before the next votes, which should have already happened, but I can get introductions.

Thank you very much. Again, you have been the most patient because you are the last panel. And we will be interrupted, but I am going to again ask for your patience. And I hope you are not missing any flights or anything. Your testimony is very, very important as I heard from the previous witnesses.

What I am going to attempt to do, because I have got about 10 minutes but that will allow me to go through the testimony of one or two witnesses, and I don't want you to hurry. You have your full 5 minutes. Your testimony is as important as all the others, if not more important on some of the practical aspects.

The first witness on Panel 3 will be Ms. Terry Allen. Terry Allen is the Director of Reimbursement for the South Texas Oncology and Hematology in San Antonio, Texas. South Texas Oncology and Hematology offers a full range of treatment options for patients facing cancer treatment. And you may proceed at this time, Ms. Allen.

STATEMENT OF MS. TERRY ALLEN, DIRECTOR OF REIMBURSEMENT, SOUTH TEXAS ONCOLOGY AND HEMATOLOGY, P.A., SAN ANTONIO, TEXAS

Ms. ALLEN. When I was asked to speak to the committee today regarding the Medicare regulations, Lynn Kuhn asked me to speak from a business office perspective because I get to deal with them from across the board, from admissions talking to patients, from the compliance standpoint for billing, auditing, and looking at business applications going forward.

One of our largest challenges in cancer care is the emerging technologies and the amazing advancements that have come along. With that are some capital investment ventures that come out. One of our hardest things with looking at capital ventures and expanding our services is tied to emerging technologies.

We offer radiation therapy services. An emerging technology over the last several years has been stereotactic radiosurgery. Stereotactic radiosurgery is for lesions, tumors, and other radiation therapy needed services. It has been FDA cleared for the entire body. This service to start out is 4 to $5 million. As a small business we are looking at a patient population, radiation therapy and that the service can cover the entire body. So you are fixing to make a business decision based on that information.

Next comes the G-codes. How are we going to bill for it and pay for it? CMS has outlined some G-codes for stereotactic radiosurgery. Unfortunately, only for the hospital, not for outpatient. In working through the coalition and various organizations, those codes were opened up for the outpatient setting local carrier price. So we said that is great. So we called and said we would like to purchase the system. We are looking at the G-codes, it is carrier priced. Can we have the price that you are setting for this payment?

No. Buy the equipment. Submit your claims individually and we will determine the payment on a case-by-case basis. We escalated the calls, we sent letters, we still are not at that platform. The inconsistency of the regulations being applied is difficult for us to manage.

Six other States have published what the States are going to pay for the G-codes, so it is a daunting task for a small business to look at making a substantial investment to better the patients to keep at an outpatient setting without having to duplicate the services in a hospital setting, but we are stuck here.

The emerging technologies is really an interesting gambit for us to look at and it is part of our ongoing viability as reimbursement is cut for drugs and ongoing services throughout the system.

And that leads me to probably one of the other Federal regulations that seems to be going through a significant change for cancer patients, and I would briefly like to touch on erythropoietin stimulating agents. Unlike an emerging technology, that is a technology that has been around for a long time. It is a drug that is a support drug and helps us continue to give chemotherapy treatments.

CMS has recently limited, outside the FDA guidelines, how we can administer that drug to our patients. We are abiding by that. Patients are having to delay chemotherapy treatments. We can define a direct correlation to reduced prescriptions for chemotherapy.

And one of the hallmarks of good cancer care is maintaining on-schedule correct dosing for your patients.

So ESAs are very troubling. The patients don't understand it. They feel better with the product. They know that they are able to tolerate the treatment and advance more quickly.

The negative impact to the patients is many of our patients are saying we would like to pay for it out of pocket. So we are filling out the appropriate paperwork and talking with them. And many of our patients are going there. The other thing they are asking us, are the other payers requesting the same guidelines? No, they are not. CMS has taken a bold step and it is the only payer that is limiting the guidelines for the use of ESAs for chemotherapy-induced anemia.

Unfortunately, a lot of our patients are now looking to the Medicare Advantage Plan. From an administrative burdensome standpoint the Medicare Advantage Plan has been a major stumbling block for our practice. Patients are signing up. They are having salesmen come to their offices and homes and telling them that it is just like Medicare and it is going to pay all of your same benefits.

What they don't understand, they are no longer part of Medicare Part B program. They are now part of Medicare Part C, and they have just forfeited their dual eligibility rights. If they don't purchase a product that again covers them for the Medigap information, they are not going to be covered and 20 percent of chemotherapy is a substantial dollar amount. They cannot afford it.

Even more troubling, if they are dual eligible to Medicaid, Medicaid will not make the 20 percent coinsurance payment because it is no longer Medicare Part B. We worked with a nationally recognized carrier, Humana, for 6 months trying to resolve these issues. Texas Medicaid sent us a letter back saying it is not Part B, it is Part C and we don't cover it. We were stunned. Out patients were stunned. So they are disenrolling as quickly as they were enrolling.

Thank you for your time.

[The prepared statement of Ms. Allen may be found in the Appendix on page 98.]

Chairman GONZÁLEZ. Thank you, Ms. Allen. And obviously I am fairly familiar with the situation there in San Antonio and thanks for your effort, for the education that you have provided me for the past few years, along with your colleagues.

The next witness is Mr. Joseph A Schraad. Joseph A. Schraad is the Chief Operating Office of Oklahoma Allergy and Asthma Clinic. And we need you in San Antonio and D.C. The Oklahoma Health Center is the epicenter of research, health care education, and technology for the community. It consists of 30 member organizations ranging from cutting agent biotechnology companies to government education, patient care, and community-supported institutions. And you may proceed with your testimony.

STATEMENT OF MR. JOSEPH A. SCHRAAD, MHA, CHIEF EXECUTIVE OFFICER, OKLAHOMA ALLERGY AND ASTHMA CLINIC, OKLAHOMA CITY, OKLAHOMA

Mr. SCHRAAD. Mr. Chairman and members of the subcommittee, thank you very much for your time to allow me to come out here.

One of the challenges that we are faced with, I am sure across the Nation but specifically in Oklahoma, is the number of providers that will take Medicare. In Oklahoma, the Oklahoma Allergy and Asthma Clinic as well as the Allergy Clinic in Tulsa are the only two allergy clinics in Oklahoma that takes Medicare. That is staggering whenever you look at the rural areas. We get patients from Kansas, western side of Oklahoma, as well as New Mexico coming to visit us because there is no one else to take Medicare.

With the challenge of reimbursements and overhead, we have to find unique challenges that will allow us to see these patients and at the same time cover our overhead. With the onset or the potential of Medicare reducing their fee schedule, coupled with the fact that we are looking at implementing electronic health records as mandated by Medicare, we are having several challenges.

When I met with the board about 2 months ago over the impact of these two situations, the first question was what would happen if we just did not see Medicare? And that was a situation that I did not want to address. Because I think we need to see Medicare, we need to continue seeing Medicare, and we just need to work a little smarter and making sure that our patient population is taken care of it.

With the Medicare reimbursements fluctuating, a lot of the commercial insurance carriers also fluctuate their payments based on what Medicare does. If Medicare drops their payments by 3 percent, 5 percent, 10 percent, they decrease theirs as well. If Medicare increases it, the commercial carriers increases theirs as well.

I am in the process now to determine if Medicare drops their reimbursement by 5 percent, what kind of ripple effect will that have across the board with other commercial insurance, and it is staggering of how much we are going to be losing as far as revenue.

One of the other issues with the Medicare is encouraging people, all the practitioners, to take Medicare. And as we have the challenge of having less reimbursement and more mandates, there is less and less providers signing on for Medicare.

I have talked with some of my constituents in Oklahoma, some of the CEOs and administrators, and asked them what they were going to do. And they said they were going to basically—if Medicare drops their reimbursements they are just going to drop Medicare. They said they cannot survive, because we—a few years ago I had two sole practitioners seeing Medicare and Medicaid trying to build a practice. They had one staff member, and they gave up. They went on back to teaching at a university, because it failed because of the reimbursements that they were trying to do, plus the dollars that they were expending trying to deal with Medicare.

And at Oklahoma Allergy and Asthma Clinic I have two members solely devoted to Medicare. All the other insurance carriers, I only have four. That is a big impact on how we see patients and some of the challenges that we are faced with.

[The prepared statement of Mr. Schraad may be found in the Appendix on page 114.]

Chairman GONZÁLEZ. I appreciate your testimony. We are going to stand in recess until this series of votes. It could be 30 minutes. I appreciate—I do have some questions. Now we are getting into the real practical application of what is going on out there, even outside of what we have had with RAC and of course the codes and such.

So again we will stand in recess until after this last series of votes, and I will be back.

[Recess.]

Chairman GONZÁLEZ. The Chair calls back into order the hearing. And at this time we are going to have Rina Wolf. And Mr. Altmire more or less already introduced you, but I am going to the formal introduction.

Rina Wolf is Vice President of RedPath Integrated Pathology, Incorporated in Pittsburgh, Pennsylvania. RedPath provides advanced molecular support for difficult oncology cases. They serve pathologists, clinicians and patients by resolving diagnostic dilemmas. And you may proceed with your testimony, Ms. Wolf.

STATEMENT OF MS. RINA WOLF, VICE PRESIDENT, REDPATH INTEGRATED PATHOLOGY, INC., PITTSBURGH, PENNSYLVANIA

Ms. WOLF. Thank you, Chairman González and other distinguished members of the committee. Good afternoon and thank you for inviting me here today to share with you my experience and challenges with Medicare regulations that are not keeping pace with and hampering the evolution of medical technology and personalized medicine in the United States.

RedPath Integrated Pathology is a genomics-based cancer diagnostics company located in Pittsburgh, Pennsylvania. RedPath operates as a fully accredited laboratory, providing complex testing services that help oncologists and pathologists to resolve indeterminate cancer diagnoses and shape cancer treatment plans.

Our test, PathFinderTG, is based upon a powerful proprietary technology platform that was under development for 15 years prior to commercialization. It is clinically validated with strong peer review and support and is used by clinicians in major cancer centers, including many of the major national comprehensive cancer network cancer centers (NCCN) in the United States.

PathFinderTG allows earlier and more informed diagnosis of cancers, such as pancreatic cancer, a cancer that has historically been very difficult to diagnose and is very aggressive. When suspected but not definitively diagnosed, physicians typically have two options: Watch and wait to see whether or not cancer actually develops over time, or remove major portions of the patient's pancreas to definitively limit the spread of cancer.

Neither option is without serious consequence. Because of the aggressive nature of this cancer, waiting and therefore delaying treatment can have fatal results. However, removing major portions of the patient's pancreas out of an abundance of caution also has grave implications, including significant surgical morbidity, as well

as long-term consequences such as leaving the patient with insulin dependent diabetes.

By providing a definitive diagnosis, PathFinderTG provides information that can help to preserve the patient's quality of life, while assisting physicians in selecting an appropriate, timely and cost-effective treatment plan.

RedPath is part of a small, but growing, industry that is translating knowledge gained from the Human Genome Project into clinical practice by providing treatments that are tailored to individual patients based on their DNA and the specific molecular character of their disease. By understanding the molecular nature of disease, new technologies increasingly allow clinicians and patients to pick individually appropriate treatment options, rather than basing treatment choices on broad assessments of what works best for a population.

RedPath also is one of several new technologically-based companies providing job growth for southwestern Pennsylvania as its economy shifts from manufacturing and service to a life science and robotics industry. In just 4 years we have grown to 51 employees, and as is the case with most life sciences companies, our workforce is highly educated and well compensated. We are not just providing jobs, but better quality jobs to our region.

As you can imagine, ours is a highly regulated industry, and rightly so. Poor quality is not an option. Lives hang in the balance. It is important, in fact necessary, that Federal and State authorities and nongovernmental accreditation organizations provide rigorous oversight of our research, methodologies, processes and outcomes. However, it is likewise necessary that all regulatory regimes keep pace with this rapidly evolving world.

Medicare date of service regulations generally provide that any test furnished within 14 days after the patient's discharge from a hospital is deemed to have been performed on the day the specimen was collected; for example, when the blood was drawn or tissue biopsied. This makes no sense, given that the PathFinderTG and other specialized laboratory tests are typically performed and reported to the treating physician after the patient has left the hospital.

Hospitals are encouraging physicians to delay ordering these tests until after the 14 days. Imagine, if you will, that you or someone you love is faced with a suspicion of pancreatic cancer. After the biopsy it can take 2 to 3 days to get the initial pathology. Then, if PathFinder is indicated, the hospital would decide to hold the test for 14 days. RedPath's PathFinder takes 5 days. It can conceivably be 3 to 4 weeks before you have an answer, with tremendous anxiety and potentially negative impact on the outcome.

CMS almost certainly did not intend for Medicare's date of service rule to restrict access to specialized in vitro diagnostic tests, as it does. Nonetheless, the rule remains in place.

We appreciate the agency's willingness to meet with us, which they have, and review these serious issues, and we remain hopeful that CMS will propose a new remedy for this problem. I applaud this subcommittee for studying and focusing attention on this important area and implore CMS to remove this impediment to the promise of personalized medicine.

Again, thank you for inviting me here today and for listening to my statement. I would be delighted it take questions.

[The prepared statement of Ms. Wolf may be found in the Appendix on page 116.]

Chairman GONZÁLEZ. The next witness is Mary Helen Tieken. Mary Helen Tieken is the President-Elect of the Texas Association for Home Care in Floresville, Texas. With over 1,100 members, the Texas Association for Home Care is a nonprofit organization aimed at improving acute, sub-acute, rehabilitative and long-term care.

You may proceed with your testimony.

STATEMENT OF MS. MARY HELEN TIEKEN, RN, BSN, PRESIDENT-ELECT, TEXAS ASSOCIATION OF HOME CARE, FLORESVILLE, TEXAS

Ms. TIEKEN. Thank you very much, Chairman González, distinguished members of the committee. Thank you very much for allowing us to be here today to discuss our issues that have to do with CMS regulations and programs on small health care providers, particularly those of us in home health and hospice.

I am a registered nurse and the owner and administrator of Nurses in Touch, Inc., a Medicare-certified home health and hospice company. Currently we serve about 280 patients. I have a 16-county service area that we cover, and we have employed 185 people.

I am also here today as the President-Elect of the Texas Association for Home Care. It is a nonprofit trade association, and we have 1,200 agencies in that group that provide home health, hospice and personal assistance services in Texas.

Because of the time constraints, you have my written testimony, but I want to go over the five burning issues that we have.

The first issue deals with employee staffing. We need flexibility to use contracted staff to meet the unique needs of our patients and to accommodate a fluctuating caseload. This is especially true for small home health agencies who serve primarily rural areas, like mine. This is an issue because current CMS rules limit our ability to use contracted staff.

As an example of this, if a majority of my nursing staff became ill with the flu and could not conduct their patient visits, I would not have the flexibility to use a staffing agency. Yet hospitals are allowed to use this contracted staff. We believe CMS should allow the same flexibility.

Second, in regards to telehealth and telemonitoring, CMS does not recognize the technology and visit costs as reimbursable under the current Medicare home health benefit, even though CMS encourages the use. Telehealth and telemonitoring methods are used by agencies to monitor patient care without the nurse being present in the home. These monitors can assist vital signs, weight and other valuable parameters that alert the home health nurse to potential health problems and possibly averting a visit to the emergency room or even hospitalization. And if CMS moves to a pay-for-performance model, those of us unable to invest in these technologies to the degree that larger agencies can will certainly will be at a disadvantage.

Third, gas prices. They have had an immediate impact on home health and hospice care. Ladies and gentlemen, we drive to see our patients. We don't walk down hallways to see them. Last year, my staff drove 700,000 miles to see our patients, and it is not unusual to have one of our nurses drive as many as 100 miles in a single day.

We are concerned that the rising prices have deterred nurses and therapists from even working for home health and hospice agencies. Larger agencies can purchase fleets of cars for their employees, something that is not possible for small agencies like mine to do. With no end in sight to rising gas prices, we would like CMS to take into account increases in gasoline prices when determining our reimbursement amounts.

Our fourth issue has to do with who is allowed to sign orders for care. Currently, CMS rules require physician certification on home health plans of care, and that means that for home health, nurse practitioners and physician assistants are not allowed to sign plans of care, even though they are allowed to do so in other health care settings, and, ironically, CMS did allow them to sign these orders on hospice patients. So the question would be, why not home health? Not only would allowing them to do so expedite patient care, it would also reduce our administrative costs and allow us to bill more timely for the services we have provided.

Congress should enact legislation to instruct CMS to allow nurse practitioners and physician assistants to certify and make changes to home health plans of care.

Fifth, regarding contingency plans for claim payment delays, CMS should be required to have a contingency plan in place and these plans should be accessible for all Medicare providers, especially when there are changes in reimbursement systems that impact claims payment.

In conclusion, Chairman González and distinguished members of the committee, I want to thank you for allowing me to be here to testify today. I would be happy to answer any questions.

[The prepared statement of Ms. Tieken may be found in the Appendix on page 124.]

Chairman GONZÁLEZ. Thank you very much, and we will have questions. I will go ahead and proceed and ask a couple myself.

Ms. Allen, you all, you can tell I am from Texas with the ″you all,″ but you have educated me as well as other specialists in oncology on the present setting in which cancer patients receive their treatment. In what I refer to as the old days or previous days it was a hospital setting. That is no longer true.

There is one area of concern the past couple of years, more than 2 years, and I just want to know what is the status, and that basically was where the oncologist or the cancer treatment facility was actually being reimbursed for the drugs that were being utilized at something less than the actual cost to you. Can you elaborate on that?

Ms. ALLEN. That continues to be an ongoing problem. The Medicare Advantage Plan has certainly not helped that. The 20 percent, if we don't collect 100 percent of the allowed charge, the 80 plus the 20, we are not covering the cost of the drug. It certainly doesn't

begin to address the pharmacist and registered nurse and everything along with it. So that 20 percent for us to chase has become more vital just to our survival at this point.

With Medicare Advantage coming on board and with the reimbursement for drugs continuing to decrease, I have had to add three additional staff members to access foundation programs for coinsurance, which helps with some drug-specific conditions, but certainly doesn't cover the entire 20 percent. I think that is a total of about $115,000 that we have expended, and that is just to try to maintain the revenue. We are not gaining anything there but an additional cost.

We are putting in additional systems to try and streamline our practices and to be more cost-effective, but at some point you have to hire more people to chase dollars that are harder to find. It is still a huge issue for a practice.

Chairman GONZÁLEZ. So it continues. I know we have been trying to get their attention and I know we have some meetings set up for CMS not to basically recognize what have been the past practices that actually were encouraged by them by regulation and switching over a regulation. And I think that is one of the reasons we are here today. So, again, thank you for your testimony.

I would like to go to Mr. Schraad. This is interesting, I guess. What happens? I mean, first of all you are telling me because of the regulation, because of the unnecessary and maybe burdensome regulatory scheme that we have, we have fewer and fewer health care providers that are available to you to utilize. I think that is the gist of your testimony. That is the greatest impact. We have many other side issues. But first, how about just availability and accessibility, which is going to be major, and we are always reminded of that by the different physicians.

I also want to ask, what is the practical aspect, if something is challenged and we keep talking about denial and so on, what happens to the payments that are pending or prospectively while something is being examined for potential denial, which already there has been a preliminary finding that they are going to deny it or there is a problem. We have had examples cited by different witnesses.

But what is the practical implication let's say to you as far as billing and such?

Mr. SCHRAAD. The impact is quite large. We have to—basically on our company we are on a cash basis. So if we don't have the revenue coming in, the actual payment coming in, we just sit on it, and that is less revenue coming in per month. But we look at all revenue by the month. Sometimes we don't get payment for 10 or 11 months, depending on what the denial was. So if we don't have it, we don't have it to spend either.

So that is just one of the challenges that the staff are working on every day, and it is an everyday occurrence. This is nothing new, it has been going on for years and years and years. But at the Oklahoma Allergy and Asthma Clinic, we have two devoted individuals who work very well and very close with CMS to streamline this, and some things are rectified very quickly and some things take several months.

Chairman GONZÁLEZ. I appreciate it. I apologize for the hoopla over there. Those are not Members of Congress, I assure you. We are never that happy.

Ms. FALLIN. They were cheering on their answers.

Chairman GONZÁLEZ. It could be the answers. Let me go on to Ms. Wolf. There was something that was very interesting, and you lay it out. The end effect of this 14-day rule of when a test is ordered, it relates back to the time that it is actually ordered, which may be in the hospital setting, then who is the responsible person, even though it may be even at that point it is referred to someone else who makes that determination. It still kind of goes back in time, and there is a lot of liability issues there people that are assuming.

But this is the paragraph, and I know you touched on it. But I just have to really get this in the record. ″In light of these and other administrative and financial disincentives, hospitals are encouraging physicians to delay ordering the test until after the 14 days.″

Ms. WOLF. That is correct.

Chairman GONZÁLEZ. If you can get a little closer to the mike.

Ms. WOLF. That is correct. Because otherwise the hospital will have to assume financial responsibility either by billing Part B, if the specimen was collected during an outpatient encounter, and that is very difficult because many of these tests are billed using what they call miscellaneous codes, which don't have coverage and coverage amounts with MACs other than their home MAC, which would create a policy. Or if the specimen was collected during an in-patient encounter, it has to be absorbed by the hospital as part of their DRG payment, which certainly are not developed to take into consideration these expensive new technologies.

Chairman GONZÁLEZ. But it is amazing that it impacts a decision of a physician in a certain setting because of the relating back aspect of it. I mean, I can't imagine—I am not saying that a physician would delay anything that would be of greatest importance where time is of the essence, but sometimes we are not real sure. You know, we catch things, we don't believe they are a problem at that point in time, but sometimes a delay, no doubt—I know I would not want my test delayed because of the 14-day relating back, that is the way I am going to refer to it, the relating back.

You say CMS is listening. There is dialogue, there is discussion?

Ms. WOLF. There is dialogue, but this dialogue has been going on for quite a while and we cannot seem to get resolution on this issue. And as you so rightly point out, it is typically not the hospital itself that is making the decision that this test needs to be ordered. It is a clinician as a follow-up to the hospital encounter, and the results of this test and the others that are impacted by this rule are used strictly for patient management decisions that are made that are unrelated to the encounter where that specimen was collected.

Chairman GONZÁLEZ. Thank you very much for your testimony. I would like to follow up on that discussion of the 14-day rule. I understand there may be some logic to it, but, again, the practical application, the theory is good and then the practice is never.

Ms. Tieken, let me ask you a question. Obviously with additional operating costs, gasoline is one of them, and we have many Members that are here today and especially on the floor that are always championing the rural aspects of health care. Your operation, you have 700,000 miles to see home health and hospice patients.

Ms. TIEKEN. Yes, sir.

Chairman GONZÁLEZ. There is no way you can build in that additional cost. Is Medicare, CMS, is anyone willing to say, gee, because of the nature of your practice, of the health care that you provide, which entails going to and obviously transportation, that is not factored in?

Ms. TIEKEN. No, sir, it isn't. Under our current reimbursement system, we are reimbursed on an episodic payment, which means that there is a configuration of information that goes in to Medicare. The conglomerate is a number that comes up, and that is how we are paid, based on the diagnosis code and some other numbers that go in, and that for that patient is all we get. It is a one number deal for us. None of our costs like that, none of our costs are separately considered in terms of reimbursement. In the old days when we had cost reimbursement, yes, those figures were looked at, but not today.

Chairman GONZÁLEZ. All right.

Ms. TIEKEN. So those are absorbed into any amounts that we get back for reimbursement purposes.

Chairman GONZÁLEZ. But it is such a relevant factor depending on the setting of the health care provider, and it has to be addressed one way or another.

Thank you very much. At this time the Chair is going to recognize Ms. Fallin for her questions.

Ms. FALLIN. Thank you, Mr. Chairman. I apologize. I had to step out for a couple other scheduled meetings and things. But I appreciate all of your coming up, and I appreciate my gentleman from my district coming to testify with the allergy clinic. I am sorry I missed your comments, but I do have them in my book and looked them over before you came. Thank you very much for being here. We appreciate your coming.

I had a couple of questions, and maybe all of you deal with Medicare payments, if you can address this for me. I asked CMS earlier today if there were any particular classifications of procedures that they automatically denied, because I hear that from my physicians at times, that they can file for reimbursement for procedures, it is denied the first time, and then they have to go through this long process of waiting for them to be looked at again and going through the appeals process.

But he said that CMS doesn't really just deny specific procedures, at least that is what I thought he said, but if they are coded wrong or if they think there is an excess of procedures done in one day that may not make sense, then they may deny them automatically.

So I guess my question is what percentage of your Medicare submissions for payment are denied? Is there a particular percentage that you see in your businesses? If you could answer that one first of all?

Ms. ALLEN. We see probably about 5 percent of our claims are denied. Being in oncology, we deal with a lot of not classified codes, which historically require additional information because they are just kind of generic codes at this point.

The biggest part for oncology, especially with the advent of the genome project and more specific diagnostic testing, is that we actually get a cocktail back from that testing that says this patient's DNA appears like it is going to work best with this combination of drugs. Fabulous. We are going to cut to the chase and get there. The problem is that the combination of drugs that come back may not be FDA cleared for the cancer type that has been identified.

We have Federal regulation on our side to a certain extent that we can go ahead and create the necessary medical documentation, document it, work through that, but then we wait typically at least a year for payment. We go through the denial process. Because we have to tell CMS I am billing you off label and I know that I am billing it off label so we are not creating a fraudulent incident.

So we inform them of that in this information. We go through a first level of appeal. It is routinely denied straight up. Nobody even looks at it. We get to a second level of appeal. Even if there is overwhelming documentation that we have met the Federal criteria for the use of anticancer drugs off label, it is historically denied again.

You take it to an ALJ. At that point you are probably at a year out. I pulled my last ALJ, the service was for June 7, 2006. I won at July 7, 2007.

We are not talking about a $10 payment. These cancer payments are, depending on the drug, can be $20,000 for each visit. That is a lot of money for a practice to loan out for 12 to 18 months. But it is the right thing to do medically.

So I think that is the precipice that physicians are at. The medical decision has been made, but can they financially afford to give the care. They do have access. We look towards foundations to help ensure that we don't have to write a check for the drugs and we look to the drug companies for that information. But the patients have to financially qualify.

So I think the technology has certainly outpaced the reimbursement, but that is the routine denial that our practice sees, is truly the technology pacing and looking for additional guidance.

I believe that Medicare is on the right track. They have expanded the credible journals that will be accepted. It used to be a very narrow list. The list is now longer. But still it is an extraordinary investment in time. I think what is difficult and a learning curve that we learned at our practice is what you submit at your first level of appeal is what you have to submit at the administrative law judge panel. You can't add anything. So you know the first one is going to be kicked out so you may not put as much effort because you are trying to get through the process. But once you forfeit payment on the first one, the administrative law judge says so sorry, why didn't you give it to the first two? You lose it. So you figure out you have to do the up front investment at the very beginning.

Ms. FALLIN. Mr. Schraad, do you have a comment?

Mr. SCHRAAD. I have a couple. What is interesting is one of our patients is on therapy which was given skin testing or shots to help

them out with their allergies. But when a patient comes in and sees a physician and gets a shot the same day, they reject the shot. So what we do is do a modifier 25 and they pay it. So my first question is, why? What is the difference between a modifier 25 or not? Just submitting it with this other patient and the patient got the shot, so why are they rejecting it?

Going back to your question, how many of ours are rejected initially, I would be afraid to look. Because I mean we have two people full-time doing Medicare, dealing with Medicare patients—I am sorry, with the issues with the Medicare patients we see.

Another one that is interesting, if a Medicare patient comes in and they get skin testing and there is a couple of sets, I am trying to recall the name of them, I want to say sublingual and interdermal, one of them Medicare only pays for 20 skin tests. The other one they pay for 70. But what I got notified just recently, which you have to laugh about it, if we submit or do 21 skin tests, Medicare rejects the entire thing. It doesn't pay for anything. But if we do 18, they will pay for 18. If we do 20, they will pay for 20, which I thought that was kind of interesting, and that is where some of our challenges are in play.

Ms. FALLIN. If I can ask you one more question too about the length of time for processing these claims. I thought I heard some of you say it that takes up to 10 months at times or a year for some of the processing of claims, especially once they have been denied.

Mr. SCHRAAD. Right now, we are in May, and we are still working on the claims that were rejected in January. Some of them we cleaned out were done in November and December.

Ms. FALLIN. If they are not rejected, what is the length of time to get reimbursed on Medicare?

Ms. ALLEN. Nineteen days probably. It is a quick turnaround for clean claims.

Mr. SCHRAAD. It is quick. Clean claims, yes.

Ms. FALLIN. If everything was electronic, what do you think your time payment would be? If everyone used electronics?

Ms. ALLEN. CMS, they are going to hold the claim for 14 days, because we time how we bill. They hold it for 14 days, it goes to the banking floor for 2 days. You allow 1 day for transmission. So the best you are going to have is probably 17 days. And we typically see 19.

Ms. FALLIN. If I could ask Nurse Tieken a couple of quick questions, I think our bell is ringing for voting, in your testimony you mentioned something about the State operations manual. How many pages are in that State operations manual?

Ms. TIEKEN. My goodness. I don't really know the count, but I can tell you it is that thick.

Ms. FALLIN. How do you keep up with all the changes made?

Ms. TIEKEN. That is an ongoing—if you do not pay attention to that manual and don't keep up with the updates, you are behind. It is a daily chore for me. I am a small administrator in terms of numbers, so it is me. I am the one responsible for keeping up with that. Some larger agencies have more staff that they can devote that time to. So it is a burdensome task for us, but it is absolutely imperative that we keep up with it. So I do it by e-mail and just

staying on line with them and watching any of the information that comes out.

Ms. FALLIN. Do you ever find that there are any of the rules or regulations that might be more burdensome than they are helpful, and if there are, could you identify them and send them to us?

Ms. TIEKEN. Oh, yes, ma'am. Yes, ma'am. Yes. It is unfortunate, and, you know, I would say that we want to work with CMS. We don't want to fight with anybody. We want to take care of patients and we want to do that the most efficient, effective way that we can. Because the bottom line is who is out there may be your mother or your father or your sister at some point, and we want the best people out there taking care of patients, not being burdened with a lot of bureaucracy and paperwork that bogs us down frequently.

Ms. FALLIN. I missed part of your testimony, but you do telemedicine?

Ms. TIEKEN. Personally we make phone calls to patients, but we do not have the monitors that I spoke about. Those monitors cost anywhere from $1,200 to maybe $2,500, depending on the elaborateness of that particular unit. It is a little bit out of range for my size agency.

Ms. FALLIN. Maybe one of you can answer this, but is telemedicine reimbursable for Medicare?

Ms. TIEKEN. It is not for home health.

Ms. FALLIN. I know in rural Oklahoma that telemedicine is a very good asset to be able to deliver access to care and especially specialty practitioners who might not get out into the rural areas, and I am just curious if that is reimbursable?

Ms. TIEKEN. At this point it is not. CMS encourages it, and even the quality improvement organizations that CMS designated to help agencies and other facilities become more efficient and work towards quality care, they have all encouraged the use of it. It is the cost factor that is prohibitive right now.

Ms. FALLIN. Thank you, Mr. Chairman.

Chairman GONZÁLEZ. Thank you very much. The Chair is going to recognize Mr. Altmire.

Mr. ALTMIRE. I want to thank all of you for being here. This is not easy to do, to prepare your testimony and travel here and wait out these votes and wait to be on the second or third panel. This is something that this committee realizes that you have gone to extraordinary effort to be here today and provide us with this testimony, and I want you to know that we really appreciate your time here today.

In the interest of time, because we do have a vote coming up, I just wanted to ask a question of Ms. Wolf. We have heard a lot about the promise of personalized medicine. For those who might not be as familiar, and especially for the record, for the committee, can you tell us more about personalized medicine and what it means for the future of health care?

Ms. WOLF. Certainly. Traditionally, the efficacy of medical diagnostics and therapeutics has been proven suitable for broad patient groups. Norms were developed based on groups rather than specific patients. The reality we are finding out, however, is that diagnostics and treatments that work for some patients don't work for all and may even be harmful to some.

The mapping of the human genome now provides us the potential to look at an individual patient or even that patient's specific tumor, the molecular information, to personalize diagnosis and treatment. In the past we would look at cancer and make treatment decisions based on the organ. Now we can look at gene expression profiling for breast cancer or liver cancer, for example, and identify the most appropriate and specific treatments.

So just to review, personalized medicine gives us the ability to detect diseases at an earlier stage where effective treatment may be possible and enable the selection, as my panel member referenced, of optimal therapy, reduce trial and error prescribing, which can be dangerous and highly expensive, reduce adverse drug reactions and increase patient compliance with their therapy because they believe they are getting the right therapy.

Mr. ALTMIRE. Very quickly, to conclude, how many companies and services are similarly affected?

Ms. WOLF. Now there are probably less than a dozen. These are not the routine tests that you would see done every day on blood and tissue. These tests are developed by small independent laboratories. They are proprietary tests that are only done at these laboratories. They are typically the only ones in the whole country that do them. And we do anticipate more tests being developed that are like this if CMS clears the way and allows us to be successful.

Mr. ALTMIRE. Thank you. Thank you all very much.

Chairman GONZÁLEZ. Thank you, Mr. Altmire.

First, I want to thank all the witnesses. I think Mr. Altmire described our appreciation adequately, but I just want to express my own personal thanks. I want to thank staff for putting all this together. I don't think we ever say thanks. But they prepare the memorandum, they provide us with your testimony and they coordinate getting you here. I know that is a tough job.

What we are trying to avoid is that we don't want a health care professional to go out there having to sue the Federal Government to stop them implementing regulations. We want a streamlined system that promotes good practices and pays you fairly and compensates you as you should be.

We really aren't that interested in having to go through the legislative process if we can work it through our regulatory scheme of things, and that is if CMS listens carefully and makes sure it takes into consideration the impact, the consequences of their regulations. That is hopefully what we are doing here today. Hopefully we have those lines of communication.

We understand that sometimes that lawsuit that people file is necessary and surely that legislative intervention at times is the only way. But please understand we are trying to do this collaboratively. We appreciate your input.

I will ask unanimous consent that members will have 5 days to submit statements and supporting documents for the record. I thank my colleagues for their participation, and without objection, that will be ordered.

This hearing is now adjourned.

[Whereupon, at 4:55 p.m., the subcommittee was adjourned.]

CHARLES A. GONZALEZ, TEXAS
CHAIRMAN

LYNN A. WESTMORELAND, GEORGIA
RANKING MINORITY MEMBER

Congress of the United States
U.S. House of Representatives
Committee on Small Business
Subcommittee on Regulations, Health Care and Trade
2361 Rayburn House Office Building
Washington, DC 20515-6315

STATEMENT
Of the Honorable Charles A. Gonzalez, Chairman
United States House of Representatives, Committee on Small Business
Subcommittee on Regulations, Health Care and Trade:
"The Impact of CMS Regulations and Programs on Small Health Care Providers"
Wednesday, May 14, 2008, at 2:00 pm

Medicare and Medicaid are essential components of our nation's healthcare system. Many small health care providers are dependent on reimbursements from these programs. Changes to the programs can have profound economic effects on their businesses. With many small providers struggling to stay afloat, it seems a number of medical practices and pharmacies are merely one reimbursement cut away from being forced to close their doors.

As program costs have risen, Congress has taken steps to cut them. All too often, CMS implementation of these efforts to reduce costs has placed small health care providers on an unlevel playing field and threatened their continued viability.

In some instances CMS has adopted rules to implement cost cutting measures. When agencies make rules, the law requires them to consider their impacts on small businesses and examine less burdensome alternatives.

The Small Business Committee has jurisdiction over this important law known as the Regulatory Flexibility Act. The Committee has held several oversight hearings on CMS in the 110th Congress, and we have seen that the agency can do a better job of meeting its obligations to small firms.

When CMS implements regulations and programs unfairly, it hurts not just small providers, but also patients, and damages the entire health care system for all Americans.

Several CMS programs are creating particular concern among small health care providers.

The Recovery Audit Contractor program is one of them. Because of the enormous scale of Medicare, it is inevitable that some errors in the payment process will occur. In some instances providers may be underpaid by Medicare, in others they may be overpaid.

With the aim of reducing the amount of Medicare's improper payments, Congress created the Recovery Audit Contractor Program—known as RAC. A pilot program for RAC concluded in March of this year and now the program has become permanent.

While the law requires RACs to identify underpayments to providers, it is clear that contractors are almost exclusively focusing on correcting overpayments. For example, of the $371 million of improper payments identified by RACs in FY 2007, over 96 percent were overpayments collected from providers. Less than four percent of those dollars were underpayments repaid to providers. It is hard to believe that this number represents the true proportion of underpayments.

The manner in which RACs are compensated is also troubling. RACs get a part of every dollar they bring in. This is the first time ever that Medicare has paid a contractor on a contingency fee basis.

According to small providers, these contingency fees, coupled with a lack of proper oversight at CMS, have led to aggressive and—in some cases—improper pursuit of recoveries; and a disregard for the accuracy of the auditing process.
Another significant issue is one that impacts pharmacies nationwide. They are facing major hardships from CMS's implementation of the Deficit Reduction Act. The DRA directed CMS to recalculate the way it reimburses pharmacies for providing generic prescription drugs to Medicaid beneficiaries.

Last July, CMS released a final rule which could devastate pharmacies and Medicaid recipients. The new formula dramatically reduces reimbursements to pharmacies. GAO has determined they will be paid back for only 64% of their costs of acquiring generic prescription drugs.

This rule will have a disparate impact on small retail pharmacies—an impact that CMS overlooked when it wrote the rule. Small retail pharmacies serve a higher proportion of Medicaid beneficiaries and get more of their revenue from prescription drugs. Implementation of this rule may force many of them out of business, reducing access to care for millions of Americans.

It is clear that CMS needs to do a better job of considering the needs of small health care providers when it implements programs and regulations.

I look forward to today's testimony and thank the witnesses for coming here to share their stories.

U.S. House of Representatives
SMALL BUSINESS COMMITTEE
Subcommittee on Regulation, Health Care and Trade

Wednesday,
May 14, 2008

Opening Statement of Ranking Member Lynn A. Westmoreland

The Impact of CMS Regulations and Programs on Small Health Care Providers

Thank you, Mr. Chairman, for holding this hearing today. I would also like to thank all of the witnesses for their participation.

As a former small business owner, I am very aware of the hurdles that our government places before industries in this country. Our health care system is the envy of the world due to the excellent care patients receive. However, the same cannot be said of the treatment our health care system receives from the government.

The maze-like system of rules and regulations created by the Centers for Medicare and Medicaid Services (CMS) has imposed enough paperwork on the health care system to make the Internal Revenue Service blush. I am sure every one of us here today have realized just how valuable our time is whenever we are stuck behind a mountain of paperwork. Personally, I would rather my health care providers be working on the newest ways to keep me healthy, rather than worrying if they crossed every "T" and dotted every "I."

There is also real concern with the ever growing number of contractors responsible for managing CMS. Contractors are determining costs, maintaining records, making payments, and assisting providers and patients. With so many contractors handling so many different things, it is easy to see how fast things get out of control. What's the obvious solution: Hire more contractors to audit the other contractors' work. As ridiculous as it sounds, this is the current structure, and without corrective measures, things will only get worse.

As is often the case, when the system is flawed, the product is flawed. I think we can all agree that the CMS program is not operating as well as we would like. Medicare alone represents roughly 13 percent of the federal budget at a cost of $389.9 billion. With a price tag that high, it is vital that we work towards creating a more manageable system.

I welcome these distinguished panels, and thank you all for your willingness to testify.

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STATEMENT OF

TIMOTHY B. HILL
DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

THE IMPACT OF CMS REGULATIONS AND PROGRAMS ON SMALL HEALTH CARE PROVIDERS

BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE
SUBCOMMITEE ON REGULATIONS, HEALTH CARE, AND TRADE

May 14, 2008

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of
Timothy B. Hill
Director, Office of Financial Management
Centers for Medicare & Medicaid Services
Before the
House Small Business Committee
Subcommittee on Regulations, Healthcare and Trade
Hearing on
"The Impact of CMS Regulations and Programs on Small Health Care Providers"

May 14, 2008

Chairman Gonzalez, Mr. Westmoreland, and distinguished members of the Subcommittee, thank you for inviting me here today to discuss the Recovery Audit Contractor (RAC) program and how it affects Medicare providers that are small businesses.

The Centers for Medicare & Medicaid Services (CMS) is committed to being effective and accountable stewards of the public resources entrusted to us. CMS is dedicated to managing our programs in a fiscally responsible manner to ensure our resources are used wisely and efficiently. As part of that effort, we are actively engaged with the Congress and the provider community to ensure accurate and appropriate reimbursement payments to all Medicare providers. Given the size and scope of the Medicare program, now and in the future, it is critical that CMS maintain a commitment to fiscal integrity as the Agency moves from a passive payer to an active purchaser of high-quality, efficient, and cost-effective care.

Identifying Improper Payments

The Department of Health & Human Services (HHS) has been measuring improper payments in the Medicare program since 1996 and was a model for the Improper Payment Information Act (IPIA), enacted in 2002, which requires all Federal agencies to annually review their programs and activities to identify those susceptible to significant improper payments. In January of 2008, the Office of Management and Budget reported

that Medicare is one of the top three Federal programs making improper payments, with an estimated $10.8 billion in improper payments made in Fiscal Year (FY) 2007.

To fulfill IPIA's statutory requirement and safeguard the fiscal integrity of the Medicare program, CMS has developed a variety of tools to reduce payment errors in the Medicare program and to ensure the proper use of taxpayer dollars. These tools include policy development, provider education, claims review processes, and recovery processes when improper payments are identified. RACs are not tasked with identifying civil or criminal fraudulent payments.

CMS' efforts to reduce improper payments have been successful, even though we know that more work remains. Since 1996, CMS has reduced the Medicare fee-for-service error rate from 13.8 percent to 3.9 percent.

RAC Demonstration Summary

It is in the context of significant Medicare payments errors that Congress passed Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), directing HHS to conduct a three-year demonstration program using RACs to detect and correct improper payments, primarily from coding errors, in Parts A and B of the Medicare program.

The Act required the demonstration to be conducted in at least two of the states with the highest Medicare utilization rates. California, New York, and Florida were chosen for the initial demonstration program, as they represent three of the largest Medicare utilization states, and contracts for RACs were selected using a competitive bid process. It is worth noting that one of the three claim review RACs that CMS selected to conduct the demonstration is a small business.

The demonstration program was conducted from March of 2005 through March of 2008, expanding beyond the three initial States of California, New York, and Florida to include Arizona, Massachusetts, and South Carolina in July of 2007, although no claims were

ultimately reviewed in Arizona. During the demonstration, the contractors were tasked with detecting underpayments and overpayments in the Medicare program and correcting those improper payments, by either collecting the overpayments or paying back providers who were underpaid.

The demonstration corrected a total of more than $1 billion in improper payments during its three-year run. This amount includes both overpayments collected from providers and underpayments refunded to providers. The RAC demonstration program has cost only 20 cents for every dollar collected. In addition to uncovering substantial savings, the RAC program has also provided information to CMS and the Medicare claims processing contractors that can be used to further protect the Medicare Trust Funds by preventing future improper payments.

While this $1 billion in improper payments are significant, it is worth noting that they were identified from a universe of $317 billion in Medicare payments that were available for review by the RACs during the demonstration. This amounts to a 0.3 percent error rate, significantly lower than the national Medicare fee-for-service error rate of 3.9 percent.

Of the $980 million collected by the RACs, only $12.8 million, or 1 percent, were overpayments that had been made to physicians. In fact, the vast majority of overpayments (more than 84 percent) were collected from inpatient hospitals. The remaining 15 percent were collected from outpatient hospitals, skilled nursing facilities, durable medical equipment (DME) suppliers, ambulance suppliers, clinical laboratories, and other providers. Over half of the overpayments to physicians were due to billing for an incorrect number of units. (For example, billing for six vials of a drug when the physician only administered one vial of the medication to the patient.)

It is important to note that if a provider disagrees with a RAC's overpayment determination, he or she can appeal the decision through the normal Medicare appeals process.

Transition to Permanent RACs

Because the demonstration program has been successful in identifying and correcting improper payments, Congress, in Section 302 of the Tax Relief and Health Care Act of 2006 (TRHCA), required HHS to make the RAC program permanent and expand it nationwide by no later than January 1, 2010. The results of the demonstration program are currently under review, and a comprehensive report will be issued to inform on optimal approaches for expanding the RAC program consistent with Section 302 of TRHCA. The evaluation of the demonstration has focused on some valuable lessons that were learned throughout the course of the demonstration project, and as a result of the feedback and experience of the demonstration, CMS has already made some important improvements and protections that will be in place when the permanent RAC program begins.

For example, both a Medical Director and certified coding experts will be required to be employed by all permanent RACs. In the demonstration project, no Medical Director was required, and coding experts were optional. Additionally, during the demonstration, RACs were only required to pay back their contingency fees if they lost a first-level appeal, but not at subsequent levels. Permanent RACs must pay back their fees if they lose at any level of appeal. Permanent RACs will also be able to review claims in the current fiscal year, whereas, the demonstration program RACs were not able to review current claims. In the demonstration, there was no maximum look-back date. In the permanent program, RACs will be able to look back for improper payments for up to three years, though no earlier than claims paid before October 1, 2007. CMS will require the permanent RACs to operate web-based systems so that providers who are involved in an audit will have secure online access to information that explains the status of their claims in the RAC audit process. None of the RACs in the demonstration had this capability. In the demonstration CMS did not set a limit on the number of medical records that could be requested by a RAC. In the national RAC program, CMS will establish a record limit that will vary by a biller's size to protect small providers from undue administrative burden.

Most importantly, under the permanent and nationwide RAC program, CMS will place a much greater emphasis on provider education and training as part of the RAC program. For example, CMS will require RACs to seek CMS approval before beginning medical necessity reviews of provider claims. These reviews sometimes involve "grey" areas of Medicare policy and CMS oversight will ensure that providers are not unduly burdened or second-guessed by the RACs. Additionally, CMS will require the permanent RACs to identify and publish vulnerability analyses so that the provider community can better understand where mistakes are being made so they can correct those errors before an audit would begin.

CMS hopes to have selections of the national RAC contractors made later this spring so that claim review can begin this calendar year.

Provider Outreach

As CMS moves towards a phased-in, nationwide implementation of the RAC program, CMS is committed to ensuring that Medicare physicians and other providers have sufficient information on how the program will work and what changes, if any, providers can expect.

Under the demonstration program, CMS worked very hard to take into account the concerns of individual physicians. CMS specifically excluded from review physician claims for evaluation and management services precisely because of the considerable confusion that can be associated with review of these physician services.

CMS also worked very closely with physician and other provider groups to ensure that they understood how the demonstration program was progressing. This included monthly meetings with the American Medical Association (AMA) and members of the affected State medical associations to discuss specific issues that arose during the course of the demonstration. Many of these discussions were helpful for making improvements to the demonstration as it was happening. For example, the AMA helped draft a physician-friendly medical record demand letter which was piloted in one state during the

demonstration. CMS representatives also attended on-site meetings with local medical societies in New York and Florida.

When specialty-specific issues arose, CMS held meetings with representatives from the affected specialty societies to address their concerns. In addition, an e-mail account was set up specifically for RAC inquiries, and CMS was thus able to answer questions from physicians, which generally consisted of individualized concerns. Similarly, CMS met regularly with the Practicing Physicians Advisory Council to update this HHS advisory group on the status of the demonstration and to seek their input and suggestions for program improvement.

In addition to the information found on the Physician Regulatory Issues Team (PRIT) website and e-mail address, which aim to eliminate unnecessary regulatory burdens on physicians, 26 PRIT outreach events in the last year have featured RAC provider education presentations, and the director of PRIT authored a RAC article that was distributed to physician trade associations to be used for their own publications.

The RAC-specific e-mail account previously mentioned will continue to operate during the program expansion as a method for addressing individual physician questions. The CMS staff who oversee the RAC contracts have worked diligently to resolve physician concerns and the discussions with the AMA and State medical associations helped CMS draft a Request For Proposal (RFP) for the permanent RACs which ensures that these new RACs will be more physician friendly. The RFP for the new RACs, for instance, requires that the RAC employ an M.D. or D.O. as a Contractor Medical Director (CMD). Providers rely heavily on their local carrier medical directors, so having a doctor in this role at the RAC will be helpful and reinforce the importance of the RAC program.

CMS staff and physicians running the RAC program continue to lead the communication efforts with the AMA and State medical associations as CMS prepares to launch the permanent RAC program. After the companies that will be the permanent RACs are

selected, CMS and the new RACs will conduct extensive provider outreach, including visits with local medical provider organizations and representatives in each State.

Even now, CMS continues to hold monthly conference calls with the AMA and State medical associations to address areas of future concern. The State medical associations are also currently partnering with CMS to prepare a bulletin that will inform physicians about the expansion of the RAC program, which will be sent to the entire membership of each State's association.

CMS is also utilizing its standard methods of provider outreach and education, including listserv e-mail messages that are distributed widely among national and regional provider trade associations, Open Door Forums, *Medicare Learning Network (MLN) Matters* articles, press releases, Provider Partnership Programs, Regional Office outreach activities, and publication of the RAC website address, which includes links to Frequently Asked Questions and contact information for each RAC. These multifaceted initiatives demonstrate the Agency's ongoing commitment to educate providers about upcoming changes in the Medicare program.

Conclusion

The RAC demonstration program has proven to be successful in identifying past improper Medicare payments and recognizing ways to prevent them in the future. Moreover, the demonstration program has provided helpful feedback for CMS as the Agency prepares to implement the expansion of the RAC program, as authorized by Congress. CMS views the RAC program as a complement to its existing program integrity activities and a valuable new tool for ensuring the integrity of Medicare provider payments. We believe that the implementation of the permanent RAC program will support ongoing beneficiary access to care by ensuring the appropriate expenditure of taxpayer resources and supporting the financial integrity of the Medicare program. Thank you for your time and I would be happy to answer your questions.

HOUSE COMMITTEE ON SMALL BUSINESS
HEARING ON
"SUB REGS, HC, AND TRADE—RAC"

MAY 14, 2008

These are the answers for the record to be inserted into the transcript for this hearing:

Ms. FALLIN: Do you have any classifications of claims that are automatically denied on the first time they are sent?

INSERT: Page 26, line 568

Mr. Hill: I do, but for the FIs and the carriers, the way we do that is normally through the Medicare claims processing systems. The Medicare claims processing system contains many edits that identify and deny claims before they are paid. These automated prepayment edits are only installed when clear policy exists to support automated adjudication. In fact, during the Recovery Audit Contractor (RAC) demonstration, the FIs, carriers, other contractors and CMS Claims Processing System staff, who develop edits for the Medicare claims systems participated in monthly calls with the RACs. During these calls the RACs provided information regarding RAC identified vulnerabilities. Additional information regarding prepayment claims processing edits can be found at the following web addresses:

1. National Correct Coding Initiative (NCCI):
http://www.cms.hhs.gov/NationalCorrectCodInitEd/01_overview.asp#TopOfPage

2. Medically Unbelievable Edits (MUE):
http://www.cms.hhs.gov/NationalCorrectCodInitEd/08_MUE.asp#TopOfPage

3. Medicare Claims Review Program (MR, NCCI Edits, MUEs, CERT and RAC:
http://www.cms.hhs.gov/MLNProducts/downloads/MCRP_Booklet.pdf

Lead In

Mr. GONZALEZ: ***Thank you very much, Ms. Fallin. I am going to follow up with a couple of questions, one that is going to be on prescription drugs, generics. I referred to it in my opening statement. GAO conducted a study and my information is that it appears that they would say that a pharmacy may well be only reimbursed at somewhere around 64 percent.***

In my district, I have Caremark, and I think both Dr. Farris and yourself know what Caremark represents. But I also have the Ortiz Pharmacy there in the west side of San Antonio, which is a poorer side. I have visited both and they are totally different operations, I assure you.

Mr. GONZALEZ: But I do know that the Medicaid population in San Antonio is going to depend on Ortiz before it depends on the other. And I guess I am somewhat concerned. I don't understand the average manufacturer price. But the GAO report is very disturbing. How do you reconcile that? Do you agree with the findings? Is there anything that you are going to be doing? We are going to have testimony later from the private sector, but what is your understanding of that situation today?

INSERT: Page 30, line 679

Mr. Hill: As you are aware, the Deficit Reduction Act of 2005 (DRA) modified several key provisions of the Medicaid drug pricing statute. Many of the changes were a result of several reports conducted by the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG), which demonstrated Medicaid reimbursements to pharmacies for generic drugs as being much higher than what pharmacies were actually paying for the drugs. The DRA changes are intended to make transparent accurate pricing data to assure that the Federal government and State Medicaid program are paying appropriately for multiple source drugs.

The DRA clarified and revised the definition and calculation of the average manufacturer price (AMP) to now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The DRA provided that the AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. The DRA also made significant changes to the Federal Upper Limit (FUL), which is an aggregate upper limit with respect to the amount that the Federal government will pay for certain drugs. The DRA changed the FUL from 150 percent of the published price for the least costly therapeutically equivalent drug to 250 percent of the AMP for the least costly therapeutic equivalent.

Statement

of the

American Medical Association

to the

Committee on Small Business
Subcommittee on Regulations, Health Care and Trade
United States House of Representatives

RE: The Impact of the Centers for Medicare and Medicaid Services (CMS) Regulations and Programs on Small Health Care Providers

Presented by: William A. Dolan, MD

May 14, 2008

Division of Legislative Counsel
202-789-7426

Statement

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Re: The Impact of the Centers for Medicare and Medicaid Services (CMS) Regulations and Programs on Small Health Care Providers

Presented by: William A. Dolan, MD

May 14, 2008

The American Medical Association (AMA) appreciates the opportunity to present testimony to the Committee on Small Business Subcommittee on Regulations, Health Care and Trade on the impact of the Centers for Medicare and Medicaid Services (CMS) regulations and programs on small health care providers. We commend Chairman Gonzalez, Ranking Member Westmoreland, and Members of the Subcommittee for your leadership in recognizing the effect of often-burdensome regulations on small physician practices.

Approximately 53 percent of physician practices are comprised of fewer than three physicians and 75 percent of physician practices are comprised of fewer than eight physicians. For the majority of these small physician practices, burdensome regulations can take valuable time away from patient care. We believe that in some circumstances the worthy goals of CMS regulations could be better served through less onerous means. Specifically, we have significant concerns with the Recovery Audit Contractor (RAC) program and the transition to ICD-10.

THE RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM

The RAC Demonstration Program was instituted under Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). It mandated pilot projects that employed RACs to analyze and audit physician reimbursement claims and rewarded them for identifying billing errors made by physicians and other providers. The program began in 2005 and was initially implemented in Florida, New York, and California and subsequently expanded to include Massachusetts, South Carolina, and

Arizona. The RAC pilot (hereinafter the Demonstration) terminated in March of this year. Under Section 302 of the Tax Relief and Health Care Act of 2006, however, the program was made permanent and will be expanded nationwide beginning later this year. The AMA is pleased that throughout the program, we were able to work in cooperation with CMS on several issues of concern to the physician community. We continue, however, to harbor significant concerns with the burdensome and punitive nature of the program.

We firmly believe that the best way to reduce common billing and coding mistakes is through targeted education and outreach, rather than onerous audits performed by outside contractors provided with incentives to deny claims. RACs are not compensated by CMS. Instead, they receive a share of the funds recovered from alleged overpayments, otherwise known as "contingency fees." At best, this type of compensation system provides an incentive to RACs to deny aggressively "borderline" claims. At worst, it effectively forces physicians, whose time is better spent caring for patients than reviewing old documents and pursuing appeals, to simply yield to unproven RAC claims. We believe that RACs should be paid a contractual amount unrelated to collections. Any collections should go to educating physicians about common billing errors and supporting desperately needed health care services for America's seniors and disabled in the Medicare program rather than the RACs' bottom line.

In addition, given the burden on physicians associated with a RAC review, the ends do not appear to justify the means. Some physicians have seen upwards of 50 RAC audits over the course of a few weeks, overwhelming them and requiring many to either close their offices or devote significant staff resources to gathering the requested medical records. And although little data has been released by CMS concerning the average alleged overpayments RACs collected from physicians, the 2006 data suggests that the average was as little as $135 per provider in Florida and $216 per provider in California. These collections are nominal compared to the time and effort required to process them. Moreover, it must be taken into account that during the Demonstration there was an emphasis on identifying overpayments rather than underpayments, and that many physicians did not to challenge RAC claims due to the nominal amount of the claim, the burden of the appeal, or general confusion about the process.

Challenging or appealing RAC claims requires physicians to reallocate valuable resources to provide data that could be several years old. The RACs typically require physicians to collect and send myriad documents, including physician orders and progress notes, diagnostic test results, history, operative reports, and certificates of medical necessity, even when the requested documentation is housed or archived in a multitude of different locations or facilities.

In addition to costing countless patient hours, this program is redundant. Other audit processes such as the Comprehensive Error Rate Testing Program (CERT), employment of fiscal intermediaries (FIs), carriers, Medicare administrative contractors (MACs), and Quality Improvement Organizations (QIOs) already oversee Medicare payments. Rather

than add another Medicare contractor to the system, we believe current contractors could address any gaps in the review process.

As stated above, the AMA believes that the RAC program is seriously flawed. The Demonstration was incredibly laborious and failed to address the need to educate and communicate with physicians in order to avoid billing mistakes. For this reason, the AMA supports the passage of H.R. 4105, the "Medicare Recovery Audit Contractor Program Moratorium Act," which would impose a one-year moratorium on the RAC program. This legislation, sponsored by Representative Lois Capps (D-CA), would allow policy makers needed time to re-evaluate the program and would allow CMS to focus its efforts on education and outreach.

Given, however, that the planned expansion of the RAC program is currently set to proceed, we sincerely hope that CMS will make every effort to continue to work with the AMA to mitigate the burdens and confusion that expansion of the program will undoubtedly bring. In addition, CMS should resolve outstanding issues, discussed below, prior to the nationwide rollout of the RAC program.

AMA/CMS Coordination

The AMA has been working closely with CMS on the RAC program implementation in an effort to mitigate the harmful effects we believe the program will have on the nations' physicians. We are pleased with CMS' cooperation to date and look forward to continuing to work with them. There are numerous issues related to the rollout of the RAC program that we believe would be best implemented with coordinated effort and input from the AMA.

Specifically, we understand that CMS plans to use RAC validation contractors to measure the accuracy of RAC claim determinations and to ensure that the RACs are not denying Medicare claims that were properly paid. Given the AMA's coding expertise, we believe it is particularly important that we be involved with the validation contractors. We would like CMS to use the AMA as a resource should CMS and/or the validation contractors require Current Procedural Terminologies (CPT) coding clarification, as confusion with coding resulted in inappropriate recoupments during the Demonstration.

In addition, we would like CMS to involve the AMA in matters relating to physician communication. We would appreciate CMS sharing any proposed letters associated with RAC audits with the AMA for feedback. Specifically, we understand that CMS will be developing standardized demand letters, which the RACs will be required to use. The AMA is pleased that CMS recognized the need for standardized language in the overpayment letters for the expanded program. If developed correctly, this should decrease physician confusion by more clearly and accurately explaining the audit and appeals process. We look forward to providing meaningful input on these letters and we hope that CMS will utilize language developed as part of earlier coordinated efforts.

We are satisfied with CMS' plans to increase reporting requirements for RACs. We support this increased oversight and believe that the monthly financial reports outlining all work accomplished by the RACs should be available to the public as they contain crucial data (i.e., overpayments and underpayments collected and number of medical records requested) that is of significant interest to the physician community. During the Demonstration, this data was very difficult to obtain and was not provided in a timely manner.

While CMS has consistently noted that RACs will not be involved in proactive provider education, the agency has committed to ensuring provider education for those areas identified as vulnerable to errors. It is vital that CMS follow through on this commitment through meetings, conference calls, and written guidance. Furthermore, CMS should clarify which of its contractors is responsible for education and outreach and ensure that such education and contractor practices are consistent. We strongly encourage CMS to share any information related to provider outreach and education with the AMA in a timely fashion so that we can remain informed and help alert physicians to contractor educational efforts. CMS should also make available online, in an easily understandable format, an up-to-date list of procedures that have been the subject of audits as this will promote transparency and assist in physician education. And CMS should evaluate whether it is appropriate to make systems changes to improve payment accuracy upfront, reducing the need for retrospective audits.

RAC Program Concerns

While we appreciate CMS' willingness to work with the AMA thus far, we believe there are several problems with the current proposed program. Most immediately, we do not think that the RACs should be permitted to review claims from the previous 12 months. If the RACs are intended to catch improper payments missed by the carriers and Fiscal Intermediaries (FIs), RACs beginning work this year run the risk of reviewing claims that are still under review by such carriers and FIs. Therefore, we believe that CMS should preclude RACs from reviewing any claims within the past 12 months and only authorize reviews for claims processed in the past 12 - 24 months. Prohibiting RAC reviews for the first fiscal year gives the carriers and FIs the opportunity to educate physicians when billing errors are detected, adequately explain to the physician how to correct future errors, and monitor the physician's billing practices for a period of time before taking recoupment action.

We are also concerned that CMS decided to allow RACs to review Evaluation & Management (E&M) services. We do not believe that E&M services are appropriate for RAC review as the broad parameters for reporting E&M codes do not lend themselves to basic review. The various levels of E&M services pertain to wide variations in skill, effort, time, responsibility, and medical knowledge, applied to the prevention or diagnosis and treatment of illness or injury, and the promotion of optimal health. A review of E&M codes requires that all factors including mixed diagnoses, variations in age, and decision-making, be taken into consideration and carefully evaluated. Similarly, we believe CMS should remove medical necessity determinations from the RACs purview. We do not believe that medical necessity determinations are appropriate for the

RAC program. Medical necessity determinations are highly subjective and require extensive clinical review. They are not "mistakes," that can be identified using automated software. Rather, they are individualized clinical assessments of compliance with Medicare coverage policy. Medical necessity reviews should involve a comprehensive assessment of the medical record by a physician of the same specialty, licensed in the same state who reviews the physician's orders, the patient's history, execution of the patient's plan of care, and other details to determine whether the care provided satisfied Medicare coverage criteria. If this type of review is only performed at the appellate level, countless patient care hours and already dwindling practice resources will already have been wasted. Should medical necessity reviews be included in the expanded program, however, they should be limited to no more than one year past the date of the original determination.

The RAC Demonstration has shown how incredibly burdensome a RAC audit can be for a physician, particularly a single practitioner or small group practice. Many physicians have had to close their offices for a day or more to retrieve requested records. Thus, we appreciate that CMS is considering raising the minimum claim amount and limiting the number of medical records requested. The minimum claim amount should be $25 rather than $10. $10 is simply too low and will likely result in many physicians simply paying the alleged overpayment rather than expending the time and resources required for an appeal. In addition, CMS should require that physicians are reimbursed for the copying expenses associated with documents produced in response to overpayment claims.

In the hopes of ensuring that the program causes as little anxiety and confusion as possible, we believe CMS should shorten the timeframe within which RACs must respond to physician inquiries. Currently, CMS requires RACs to respond to written correspondence from audited physicians within 30 days. We believe that this timeframe is unnecessarily long. For physicians contacted about a RAC audit, there are immediate questions and concerns. These physicians are entitled to a prompt response. CMS should require RACs to respond to written physician inquiries within 15 days and to respond to physician phone inquiries within 48 hours.

Furthermore, CMS should clarify the appeals process under the RAC program. The appeals process for the RAC program is supposed to mimic the Medicare appeals process. However, CMS has yet to publish a final rule related to Section 935 of the MMA, calling for a limitation on recoupment, which halts the recoupment process once a physician properly appeals. Consistent with Congressional intent, the limitation on recoupment should be triggered at the first level of appeal. Although CMS has begun to implement this policy, it has not been finalized and is being applied inconsistently. Thus, we strongly encourage CMS to clarify and finalize the Medicare appeals regulations, ensuring the policy is applied at the first level of appeal, as they will greatly affect all physicians who are subjected to a RAC audit.

Though statutory language and the demonstration Statement of Work that govern the RAC program provide the RAC with authority to pursue underpayments as well as overpayments, underpayments were not pursued vigorously during the Demonstration. CMS must provide the oversight necessary to ensure that inaccurate payments are

pursued by RAC contractors in an equitable manner. Specifically, CMS should reverse their decision not to include, for the purposes of underpayments, situations where a physician mistakenly neglects to report a service they delivered. If a physician has delivered appropriate care to a patient, they should be reimbursed for the care. Services omitted from claims should be treated as underpayments. Additionally, CMS should require that RACs accept case files from providers for an underpayment case review. At the very least, CMS must permit national, state, local, and specialty medical societies to share information with CMS and the RACs about underpayments. Finally, CMS should include underpayments in its online list of incorrect billing issues.

Physicians strive for payment accuracy and are committed to continuing to work with CMS and its contractors to ensure the validity of physician payments. We believe that the best way to promote these worthy goals is through education. Given that expansion of the program appears imminent, however, we hope that CMS will address our concerns and resolve these issues prior to nationwide rollout of the program. The AMA is dedicated to working with CMS and we look forward to ongoing efforts to address our concerns and improve the RAC program.

ICD-10

Physicians value the transformative power that the adoption of new technology promises for patient care, including advances in the electronic transmission of claims and other transactions. The International Classification of Diseases, Ninth Revision, Clinical Modification, (ICD-9-CM) is used for diagnosis coding in both the inpatient and outpatient settings, as well as for procedure coding in the inpatient setting pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which called for using standardized transactions and code sets.

While the AMA recognizes the importance of updating the current coding scheme, ICD-9, with ICD-10, we realize that the transition process will be a complex and costly undertaking. As physicians experienced with the transition to the HIPAA standard electronic transactions environment, an effort that continues even 12 years after the passage of HIPAA, we believe a well-defined and executed transition plan is critical to ensuring the success of a migration of this magnitude. The drawn-out, costly process that the health care industry experienced with electronic transactions could be avoided if an appropriate transition plan to move to ICD-10 is fully developed through a consensus process that involves multiple stakeholders, including physicians.

The transition to the ICD-10 system will increase the number of possible codes ten fold. Physicians, and other stakeholders, including health plans and payers, clearinghouses, and software vendors, need adequate time to successfully plan the move to a new diagnostic coding system. In addition to incurring significant costs for implementing a new coding system, physician practices will also face additional challenges transforming their practices, including upgrades or replacements of practice management and billing systems and software, adjustments to current operational protocols, and staff education and training costs. Private and public payers will also have to upgrade or replace their

own payment processing and data management systems to accommodate the significant body of data generated by this extensive transition. Therefore, the AMA recommends pursuing a realistic transition time period to ICD-10 to ensure that the delivery of health care, claims and payment processing, and acquisition of critical health information technologies are not adversely impacted due to this substantial coding migration.

It is important to keep in mind that physicians are currently struggling to implement existing HIPAA requirements, including the ongoing transition to the National Provider Identifier. Also, physicians must comply with Medicare and other public and private payer mandates while facing shrinking payer revenues, that have failed to keep pace with the cost of practices, and even steeper Medicare payment cuts. Unlike other professionals and businesses, physicians are limited in their ability to pass on the costs or practice investments in the form of higher charges for their services. These costs are especially difficult to absorb for small physician practices. The costs that will be incurred due to system upgrades or replacements are more demanding for smaller practices that face greater technological, operational, and financial challenges.

On April 1, 2008, the AMA, along with multiple specialty groups, the BlueCross BlueShield Association, as well as other key health care stakeholders sent a letter to the Department of Health and Human Services (HHS) recommending the following process and timeline for moving to the ICD-10:

Adoption, Testing, and Verification of Version 5010 of HIPAA Electronic Transactions Standard Prior to Moving to ICD-10

The current HIPAA electronic transactions standard version 4010 is not compatible with ICD-10. Moreover, version 5010 significantly differs from 4010. As the National Committee on Vital and Health Statistics (NCVHS), an advisory body to the HHS on health data, statistics and national health information policy, recommended in their September 26, 2007, letter to HHS Secretary Leavitt, implementation of ICD-10 should not take place simultaneously with the adoption of the version 5010.

Implementation of a Comprehensive Pilot Testing of ICD-10 Prior to National Roll-Out

HHS should pilot test ICD-10 in order to identify potential issues and problems early on, allow time to develop solutions, and gather feedback from pilot participants that will assist in the national transition process.

Incorporation of Adequate Time in the Transition Process and Timeline to Train Coders

A transition from ICD-9 to ICD-10 will require an appropriate supply of coders. Training coders for ICD-10 will require the development of a new curriculum, publication of curriculum materials, and most importantly, adequate workforce training

to support the providers and billers under ICD-10; a system with approximately 10 times more codes than are in ICD-9.

Pursuit of an Aggressive Outreach Strategy to Covered Entities and Vendors

An important lesson from the transition to version 4010 and the current transition to the NPI is the essential need to begin educating the covered entities and vendors—especially the smallest practices and software vendors—as early and as often as possible.

Given the significant resources, administrative complexities, and advance planning that are required to retool or replace systems and processes that depend on ICD-9 logic, the AMA recommends that HHS work collaboratively with all health care industry stakeholders, especially physicians, in order to develop an effective transition plan to use ICD-10.

CONCLUSION

We appreciate the opportunity to provide input on the RAC program and the critical transition to ICD-10. The AMA looks forward to working closely with the Small Business Committee to ensure that physician practices, especially smaller practices, are able to manage the RAC audit process and prepare for the ICD-10 transition without compromising the delivery of health care.

Testimony of:

Dennis Wiesner, R.Ph.
Senior Director
Privacy, Regulatory, Government and Industry Affairs
Pharmacy Managed Care

H-E-B Grocery Company
San Antonio, Texas

On:

The Impact of CMS Regulations and Programs on Small Health Care Providers

To:

U.S. House of Representatives
Committee on Small Business
Subcommittee on Regulations, Health Care and Trade

Wednesday, May 14, 2008

National Association of Chain Drug Stores (NACDS)
413 North Lee Street
Alexandria, VA 22314
703-549-3001
www.nacds.org

INTRODUCTION

Members of the Committee, thank you for allowing the National Association of Chain Drug Stores (NACDS) the opportunity to participate in today's hearing to discuss the impact of CMS regulations and programs on Medicaid and Medicare beneficiary access to retail pharmacies. NACDS represents approximately 200 companies operating retail pharmacies in virtually every community in the country. The size of those companies ranges greatly. NACDS represents national companies with thousands of retail pharmacies as well as local chains that operate as few as four pharmacies.

Regardless of their size, all NACDS members are deeply concerned about the following: (i) the impact of unfair Medicaid cuts for pharmacy services, (ii) program inefficiencies and unfair treatment of retail pharmacy under Medicare Part D, and (iii) threats posed by program requirements under the Medicare Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) program, including competitive bidding. We outline below our concerns and suggestions for fair treatment of pharmacy under both the Medicaid and Medicare programs.

MEDICAID REIMBURSEMENT CUTS THREATEN ACCESS TO PHARMACY CARE FOR MEDICAID BENEFICIARIES

The Deficit Reduction Act of 2005 (DRA) required significant cuts to Medicaid pharmacy reimbursement for generic drugs. These cuts, as implemented by the Centers for Medicare and Medicaid Services (CMS), will result in pharmacies being reimbursed below the costs of acquiring many common generic drugs and cause upwards of 12,000 pharmacies to close nationwide.

The DRA and subsequent CMS regulations implementing the law set the maximum payment for generic drugs – known as the Federal Upper Limit (FUL) - using a calculation based on the lowest reported average manufacturer price (AMP), or the average price that manufacturers sell drugs to wholesalers for resale by retail pharmacies. The FUL places a cap on Medicaid reimbursement of the cost of generic drugs and does not include the cost of dispensing the drug. The AMP data on which generic drug FULs, and pharmacy reimbursement, are to be based will not include the markup that retail pharmacies normally pay to wholesalers. This is a significant change from previous practice, under which FULs were based on the lowest published list price (expressed as average wholesale price, AWP, or wholesale acquisition cost, WAC). In addition, FULs will be established when as few as two versions of a particular generic drug exist rather than three, as had previously been the case.

The DRA cuts to Medicaid reimbursement -- and the final rule to implement those cuts, place many retail pharmacies at risk of being forced to eliminate service to Medicaid recipients or close altogether. Many pharmacies that serve Medicaid patients will not survive the AMP cuts due to payments lower than their purchase price for generic drugs. Both the General Accountability Office and the HHS Office of Inspector General confirmed that the AMP system would reimburse pharmacies below their acquisition

costs for many common generic drugs. This could result in as many as 12,000 pharmacies going out of business, which represents about 20 percent of all pharmacies in the country according to expert testimony of Stephen Schondelmeyer of Prime Institute. That could devastate the prescription drug delivery system in this country, not just for Medicaid patients, but for millions of others and potentially increase other patient health care costs due to access limitations.

The final rule on AMP that CMS issued in July 2007 is unlawful because it exceeds statutory authority for calculating the reimbursement cap, or FULs, for generic drugs. The DRA defines AMP as "the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." However, the rule includes sales in that average price that do not belong in the calculation of AMP because they are not prices paid to manufacturers by wholesalers for drugs distributed to the retail class of trade. Improperly included sales to patients, physicians, surgical centers, dialysis centers, mental health centers, home health providers, home infusion providers, clinics, hospital outpatient pharmacies or a hospital affiliated entity, pharmacy benefit managers, mail order pharmacies, and sales at nominal price to "any entity" were included in the AMP rule as sales for drugs that are distributed to the retail pharmacy class of trade. In fact, not only are these sales for drugs that are never distributed to the retail class of trade, many of these purchasing entities are able to purchase drugs at a lower cost than retail pharmacy, which would result in a lower AMP used to calculate a lower reimbursement cap on generic drugs for Medicaid pharmacies. In addition, the AMP rule would publish the resulting flawed AMP data on a public website which could further harm retail pharmacies, not only affecting Medicaid reimbursement to pharmacies but reimbursement from other third party payers as well.

The AMP rule also misses the mark in that it fails to provide a thorough analysis of the economic impact that the rule would have on small pharmacy businesses, as required under the Regulatory Flexibility Act. A rule that would so drastically cut reimbursement to Medicaid pharmacies without a thorough economic impact analysis is irresponsible at best. With so much at stake - Medicaid beneficiaries' access to prescription medicine and pharmacy services and the livelihood of the community pharmacists dedicated to keeping them well - more emphasis should have been placed on the impact of this rule before it was published.

In December 2007, a federal court issued a temporary injunction to halt CMS' implementation of the Agency's final rule as result of a lawsuit filed by NACDS and the National Community Pharmacists Association (NCPA). The court order prohibits CMS from using the AMP data to calculate FULs pending resolution of the lawsuit. It also prohibits the publishing of AMP data by CMS or the distribution of the data to the States.

Although the preliminary injunction granted a delay in the implementation of this devastating rule, regardless of the decisions of the court, the DRA statutory cuts will eventually be implemented. Retail pharmacy and Medicaid beneficiaries need Congress to intervene to prevent these cuts to pharmacy reimbursement that remain a threat to patient access to drugs. A long-term remedy would require an act of Congress to change

the statute upon which CMS has based the AMP rule. Legislation to make the needed changes to protect access to prescription drugs and services and provide for fair reimbursement to pharmacies has to happen this year. We urge Congress to act quickly to enact legislation to revise the DRA provisions that threaten patient access to drugs and to protect the vital role that pharmacies play in our nation's health care system.

SUGGESTIONS TO RESOLVE PROGRAM INEFFICIENCIES AND UNFAIR TREATMENT OF RETAIL PHARMACIES IN MEDICARE PART D

NACDS members are the primary providers of pharmacy services to beneficiaries under the Medicare Part D program. While the Medicare prescription drug program has helped millions of Americans obtain their medications, the program is still plagued by some design and administrative problems that often create access difficulties for beneficiaries. First, beneficiaries are often unable to obtain their medications in time due to the enrollment lag that occurs after they enroll or switch into their new drug plans. Second, Medicare beneficiaries are often denied access to extended supplies of medications from their local community pharmacies because CMS has failed to implement this provision consistent with the Medicare statute and Congressional intent. Finally, Part D plans do not provide pharmacies with adequate disclosure of terms for reimbursement when pharmacies sign network pharmacy contracts. We ask the Committee to consider our recommendations to make the Medicare Part D program more successful for patients.

Establish a rolling-enrollment period for more effective Medicare Part D.

Like other parts of Medicare, seniors generally become eligible for the prescription drug benefit under Medicare Part D when they reach the age of 65. Others who were of requisite age but did not elect Part D coverage in the previous year(s) may decide to join a Part D plan at any time in the current year. As a result, many seniors become eligible for Medicare Part D on a daily basis and accordingly sign up to enroll in a Medicare Part D plan. Once beneficiaries apply to enroll in a plan, their applications must be processed by the plans, sent to CMS for confirmation, entered into the Part D plans' systems and then entered into the pharmacy systems before the beneficiaries can obtain their prescription drugs.

When a Medicaid recipient becomes eligible for Medicare, they are assigned to a Part D Plan but they are not required to remain in the plan. These "dual-eligible" beneficiaries (those eligible for Medicare and Medicaid) may switch plans every month. As a result, each time a dual-eligible beneficiary switches to a new plan, the same application process is repeated and must be completed before their benefits can begin.

Further, many beneficiaries enroll or switch into new plans during the annual coordinated election period, which occurs between November 15 and December 31 of each year. Again, their applications must be processed by the plans, sent to CMS for confirmation and entered into the plans' and pharmacies' systems.

For all of these beneficiaries, Part D benefits generally begin on the first day of the month following the month in which they enroll in or switch to their new plan. Under the current system, beneficiaries can technically expect to access their Part D benefit on the first day of the month, no matter how late in the previous month they joined or switched to a new plan. In reality, however, CMS and the plan cannot process the application, confirm eligibility, and provide information to the True Out-of-Pocket (TrOOP) facilitators in time for the benefits to become available on the first of the month if a beneficiary enrolls in or switches into a new plan on the last few days of the previous month. This lag in enrollment causes tremendous frustrations for providers and places beneficiaries in unnecessary danger of not being able to obtain their medications.

As patients visit their pharmacy, many will find that their enrollment information is not yet available on the pharmacy's system and will be unable to obtain their drugs. In such cases, pharmacies spend significant amounts of resources and time tracking eligibility, including calling plans' help desks to determine whether the beneficiary is eligible. If the beneficiary does not know what plan they signed up for (which is a common occurrence with dual-eligibles who have been assigned a plan) and a subsequent query on the pharmacy's computer system does not provide some indicia of coverage, the pharmacy is placed in an even more unworkable situation and faced with a tough decision – it can either fill the script and absorb the cost or turn the patient away.[1] Both situations are unacceptable and dangerous for patients.

The crux of the problem is that there is not enough time under the current system for processing to occur within a few days such that beneficiaries who sign up late in the month can obtain their medications at the beginning of the next month. Processing of Medicare enrollment can take two weeks or more in some cases. Often, plans do not forward necessary information about an applicant to CMS in a timely manner, which compounds the problem. While we commend CMS for reducing the overall time it takes to process Part D enrollment applications, the problem continues for late enrollees or those who switch plans.

Recommendation: Congress should establish a minimum amount of time between the time when a beneficiary enrolls in a Part D plan and the time they can start using their plan at the pharmacy to obtain their medications. Such a "rolling-enrollment" system would assure that important beneficiary and billing information are processed by both CMS and plans and entered into the pharmacy's computer system so patients can obtain their medications on time. Rather than provide false expectation that a beneficiary can obtain benefits on the first of the month no matter how late they enroll, this proposal will encourage beneficiaries to sign up early for their Part D benefits. CMS should also

[1] While CMS does allow pharmacies to enroll certain dual-eligible or low income subsidy individuals through the point-of-sale facilitated enrollment process, the system requires pharmacies to verify eligibility by examining documents provided by the beneficiaries. All too often, beneficiaries are unable to provide such documents as Medicaid ID card, Medicaid award letter, low income notice and others for pharmacies to verify coverage.

require plans to forward beneficiaries' applications to CMS for confirmation of coverage in a timely manner. These improvements will help ensure that beneficiaries can obtain their medications on time without any interruption to their medication therapy and will reduce frustration and stress for both pharmacists and beneficiaries.

Allow beneficiaries to obtain extended supply of drugs from any community retail pharmacy of their choice.

When beneficiaries obtain their medications from community retail pharmacies, they receive tremendous benefits that are not found anywhere else. For example, patients benefit from immediate access to counseling from a state-licensed pharmacist when they obtain their medications from retail pharmacies. During their face-to-face professional counseling, pharmacists can address not only any special needs concerning the prescribed medication but identify other health conditions and issues early so as to improve the health outcomes of their patients. As pharmacists often have long-term relationships with their patients, they are aware of the patients' unique conditions and needs and can address those concerns appropriately. These types of benefits are not available when patients order their medications through the mail.

Congress recognized these unique benefits when it passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003.[2] The MMA requires that beneficiaries have access to pharmacy services from any retail community pharmacy of their choice. Congress was concerned that Part D plans may attempt to push patients to utilize mail-order facilities for services, including access to extended supply of drugs.[3] Therefore, the MMA specifically stated that beneficiaries shall be able to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. This provision provided Medicare Part D beneficiaries with an option as to how they wish to receive their pharmacy services.

Despite the clear language in the MMA requiring a level playing field between retail and mail-order pharmacies, CMS' implementation of this important provision and its guidance documents on how plans should follow the level playing field requirement are inconsistent with statute and Congressional intent. As a result, plans are effectively denying patients' access to an extended supply of drugs, i.e. a 90-day supply, from their community pharmacies.

CMS' guidance indicates that Part D plans are "expected" to allow a retail pharmacy to offer an extended supply of drugs to any plan beneficiary at the same price,

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[2] 149 CONG. REC. S15743 (Nov. 24, 2003) [hereinafter *Hearing*] (during floor debate Sen. Enzi noting that, seniors trust their local pharmacists and should be allowed to keep those relationships in place).

[3] *Id.* (Sen. Enzi stated that, the level playing field provision was intended to prohibit plans from "implementing restrictions that would steer consumers to mail-order pharmacies." Chairman Grassley "expect[ed] that the Secretary of Health and Human Services would disapprove of any plan that would impose a differential charge that was intended primarily to steer Medicare beneficiaries to mail-order pharmacies versus retail pharmacies.")

reimbursement rate (including dispensing fee, if any) and cost sharing as the plan's mail-order pharmacy. CMS' guidance then goes on to state that the plan "may" allow retail pharmacies to dispense an extended supply of drugs for a higher contracted rate than the mail-order rate (called the alternative retail/mail-order rate). However, any difference in charge between the two rates would be paid by the beneficiary (or the pharmacy, as long as it was cost neutral to the plan). This interpretation by CMS erroneously suggests that plans have the discretion as to whether they allow pharmacies to dispense a 90-day supply at the higher non-mail-order rate even when a beneficiary is willing to pay the difference.

CMS' interpretation is contrary to the intent of the MMA, which requires that the beneficiaries have a choice of obtaining their covered Part D drugs either through mail or through their retail pharmacy, paying any difference in charge to obtain the drugs through the retail pharmacy. This presumes the pharmacy is willing to participate at the alternative rate and plans are required to offer this option to pharmacies. CMS' own regulation also states that the plan *must* permit its Part D enrollees to receive benefits, such as a 90-day supply, at any of its network pharmacies that are retail pharmacies.[4] Accordingly, plans do not have the discretion to exclude pharmacies from dispensing a 90-day supply if they do not accept the mail-order rate.

Nonetheless, based on CMS' guidance, plans often deny pharmacies the ability to dispense extended supply of drugs if they do not accept the mail-order rate. These plans feel that they are only required to offer the mail-order rate to retail pharmacies but not the alternative retail/mail-order rate. If retail pharmacies do not accept the mail-order rate, then the plan "may" offer the alternative rate, but the plans indicate that they do not believe that they are obligated to do so.

In some cases, however, plans may allow retail pharmacies to dispense an extended supply of drugs for a higher contracted rate than the mail-order rate, but require patients to pay much higher co-pays for a 90-day supply at a retail pharmacy than the co-pays required for mail-order. Often, these co-pay differences are designed to discourage the use of retail pharmacy as they do not reflect the cost to the plan of allowing the retail pharmacy to dispense a 90-day supply. These practices are contrary to Congressional intent and unjustifiably push patients to mail-order.[5]

Often, Part D plans make mail-order pharmacies their preferred pharmacy for extended supply of drugs. A retail pharmacy is not allowed to participate as a preferred pharmacy unless it will also provide an extended supply of drugs through mail-order. Even when a retail pharmacy may be willing to accept the preferred mail-order pharmacy's rate, the plan will require the retail pharmacy to participate at the non-preferred rate, which usually requires patients to pay higher co-pays and thereby encourages the plan's mail-

[4] 42 C.F.R § 423.120 (2008) (emphasis added).
[5] *Hearing*, *supra* note 2, at S15743 (Sen. Enzi and Chairman Grassley both remarked that differences in charge between mail order and retail be reasonable. Sen. Enzi further noting that, he would be concerned if differences in charges were used to steer patients to mail order).

order business. These policies deny fair choice to seniors and ultimately drive prescriptions to mail-order.

Recommendation: Absent a clear direction requiring CMS to follow Congressional intent to allow any community retail pharmacy the ability to dispense extended supply of drugs, plans will continue to rely on CMS' misinterpretation of the level playing field provision as a license to deny patients a choice in their own health care. We urge Congress to take strong action to clarify that plans must provide beneficiaries with access to an extended days supply at any community retail pharmacy of their choice.

Require disclosure of generic drug reimbursement rate and update of reimbursement benchmarks.

Pharmacies are required to sign network pharmacy contracts with Medicare Part D plans to dispense drugs to Part D beneficiaries in their network. Often, these contracts are lacking in critical reimbursement information that should be provided to pharmacies at the time of the contract offer. Specifically, Part D plans' network contracts with pharmacies often reference Maximum Allowable Cost (MAC) lists or prices for reimbursement of generic drugs. The MAC is the maximum amount of reimbursement a network pharmacy could receive for dispensing generic drugs that are listed on the MAC list. While plans' contracts with pharmacies reference MAC lists or prices, pharmacies are not provided such list or pricing during contract negotiations, thereby requiring pharmacies to sign network pharmacy contracts without adequate disclosure of the reimbursement they will receive from plans for the generic drugs they dispense. Additionally, plans retain the right to change the MAC price at "their discretion" without notification.

Some Part D plans also do not regularly update their pricing benchmarks (e.g., Average Wholesale Price, AWP, or Wholesale Acquisition Cost, WAC) to appropriately account for pharmacies' increased costs of purchasing drugs. These benchmarks are provided by an independent third party on a frequent basis (in some cases, daily) to reflect the prices of these drugs on the market. Even though current, updated benchmarks are available, plans do not update their reimbursement to pharmacies to accurately reflect the prices pharmacies pay to purchase these drugs. The reimbursements pharmacies receive are often based on outdated pricing databases, which results in pharmacies being underpaid for the prescriptions they dispense and creates a severe cash-flow problem for pharmacies. Given that pharmacies are expected to pay current "real-time" prices to manufacturers and wholesalers for their drugs, reimbursement by Part D plans to pharmacies should also be based on up-to-date pricing information.

Recommendation: We urge Congress to create a fair contracting environment under Part D by requiring plans to disclose generic drug reimbursement rates at the time of contract. Plans should also be required to update their reimbursement to pharmacies reflecting the date of the pricing change as reimbursement benchmarks are updated. Absent a legislative requirement for fairness and upfront disclosure during Part D contract process, plans will continue to deprive pharmacies of important reimbursement terms and updates.

Ensuring that pharmacies are reimbursed appropriately is critical in ensuring their continued ability to provide services under Medicare Part D.

THREATS POSED BY NEW REQUIREMENTS UNDER THE MEDICARE PART B DMEPOS PROGRAM, INCLUDING COMPETITIVE BIDDING

Medicare patients obtain coverage for DMEPOS through the Medicare Part B program. Durable medical equipment includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs, and oxygen equipment and supplies. Many Medicare beneficiaries obtain these supplies from their local pharmacies. In fact, a recent study conducted by HealthPolicy R&D found that nearly two-thirds of older diabetic patients obtain their diabetes test strips from their retail-based community pharmacies.[6] Retail pharmacies are the largest providers of DMEPOS services to Medicare patients and are in a unique position to assist patients with their care and treatment and to monitor disease trends and therapy outcomes. In many cases, a pharmacist is the most readily accessible health care provider in the community for the Medicare beneficiary. One-on-one patient-pharmacist consultations can often provide the first opportunity to identify chronic illnesses and changes in patient conditions, and these consultations often result in early detection, referral, and treatment. In addition to helping to preserve the patient's health, early detection and treatment provides tremendous savings for the Medicare program. For many of these patients, the pharmacist serves as a gatekeeper assisting them and their caregivers in their health care management needs. Continued participation of community retail pharmacies in serving Medicare patients should therefore be an important consideration in the Medicare program.

Some aspects of the DMEPOS program, including accreditation, the competitive acquisition program and the surety bond rule proposed by CMS will prevent pharmacies from effectively serving their Medicare patients. CMS' requirement for DMEPOS supplier accreditation creates significant administrative and financial burdens for small pharmacies. Further, any expansion of the competitive acquisition (hereafter "competitive bidding") program for DMEPOS to include diabetes supplies sold at retail or CMS' plan to establish national or regional competitive bidding areas for mail-order diabetes testing supplies could limit participation by small pharmacies and reduce diabetic patients' access to life-saving supplies and services. Finally, CMS' proposal to require a $65,000 surety bond from state-licensed pharmacies will present tremendous cost to pharmacies without any enhancement to the integrity of the Medicare program. We offer our thoughts to help the Committee address these issues to help ensure that beneficiaries have access to high quality products and services from their pharmacies.

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[6] HealthPolicy R&D, *Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring.* Washington, DC, January 2006.

State-licensed pharmacies should be exempt from the accreditation requirement.

The MMA requires DMEPOS suppliers to be accredited to sell covered items to Medicare patients and to participate in the competitive bidding program.[7] The goal of this requirement is to reduce fraud, waste and abuse in the Medicare program. While we agree with CMS on the importance of eliminating fraud, waste and abuse from the Medicare program, we do not believe that requiring accreditation of state-licensed pharmacies will accomplish this goal. CMS has at its disposal a variety of tools to ensure provider integrity in the Medicare program, which CMS could pursue instead of the onerous accreditation requirement. Accreditation of state-licensed pharmacies is an unnecessary requirement that could threaten patients' access to DMEPOS supplies from their most accessible health care provider.

We are concerned that requiring accreditation of pharmacies could result in reducing the number of pharmacies that are available to supply DMEPOS to Medicare beneficiaries. The costs associated with the accreditation process, which can amount to several thousand dollars and hundreds of man-hours for each pharmacy, creates a tremendous financial barrier for pharmacies that provide DMEPOS items to their patients. Pharmacies already struggle to minimize operational expenses to remain competitive in the marketplace, and are skeptical of the accreditation process because even if they undergo the accreditation process, they have no guarantees that they will ultimately be allowed to participate in the DMEPOS program. Combine this requirement with the proposed reimbursement cuts in Medicaid and other state programs and pharmacies are forced to closely examine their expenses.

Accreditation of state-licensed pharmacies is unnecessary due to the comprehensive licensure requirements for pharmacies and pharmacists. Pharmacies are licensed by the board of pharmacy of their respective states to provide services to patients. As part of their licensing process, pharmacies submit to rigorous requirements for their operations and compliance with federal and state laws. Further, state pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the operation of that pharmacy in compliance with appropriate laws and regulation. Today's pharmacists are highly educated, licensed experts in the use of medications and medical devices who advise patients and health care providers. These pharmacists are ideally situated to provide Medicare patients using diabetes supplies and other DME items with appropriate counseling and information on the proper use of these items. These qualifications clearly distinguish pharmacies and pharmacists from other unlicensed and unregulated suppliers.

While we believe that accreditation should not be required of pharmacies, we understand the mandate on CMS to implement the accreditation requirement under the MMA.

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[7] CMS has announced that *all* suppliers must be accredited by September 30, 2009 to maintain billing privileges under Medicare Part B. Those participating in the competitive bidding program are required to be accredited even sooner.

Nevertheless, CMS' recent implementation of the accreditation requirement through different deadline dates for suppliers with less than 25 locations has resulted in inequitable and unfair treatment of smaller suppliers. On December 19, 2007, CMS announced that existing DMEPOS suppliers enrolled in the Medicare program must obtain and submit an approved accreditation to the National Supplier Clearinghouse (NSC) by September 30, 2009. New DMEPOS suppliers who are enrolled for the first time before March 1, 2008 must obtain and submit an approved accreditation to the NSC by January 1, 2009. However, new DMEPOS suppliers with less than 25 locations submitting an enrollment application to the NSC on or after March 1, 2008 are required to be accredited prior to submitting their Medicare enrollment application.

The accelerated accreditation requirement for existing chain suppliers with less than 25 locations that open new stores on or after March 1, 2008 is arbitrary and unfair. The tiered accreditation deadline based on number of locations creates differential treatment for suppliers. Because CMS has conditioned the Medicare supplier numbers for new locations of an existing supplier on accreditation of the entire chain, the accelerated accreditation deadline also creates a back-log for accrediting organizations. Although CMS provided additional time, until September 30, 2009, for new and existing locations of chain suppliers that have 25 or more enrolled locations to become accredited, CMS retained the unfair tiered approach for suppliers that do not meet the 25 location threshold. While we appreciate the extension provided to suppliers with 25 or more locations, CMS should treat all *existing* chain suppliers with the same degree of fairness and create a single accreditation deadline.

Recommendation: To reduce the difficulties posed by the accreditation requirement on pharmacy providers and to ensure patients' continued access to DMEPOS items, we urge Congress to specifically exempt state-licensed pharmacies from the accreditation requirement. We also urge Congress to ensure careful oversight of CMS' administration of this and other elements of the DMEPOS program to ensure fair treatment of small providers.

Diabetes testing supplies sold at retail pharmacies should not be subject to competitive bidding.

The DMEPOS competitive bidding program was mandated by the MMA. The program is currently limited to 10 metropolitan statistical areas (MSAs) during the initial round and includes bidding for ten categories of medical equipment and supplies. CMS has also recently announced the second round of the program, which expands the program to an additional 70 MSAs. While CMS has excluded diabetes supplies sold at retail from both rounds of competitive bidding, we urge Congress to require CMS to continue this exemption in the future.

Currently, Medicare beneficiaries can obtain their diabetic glucose monitors and testing supplies from any retail pharmacy that participates in the Medicare program, allowing beneficiaries to obtain all of their covered equipment, supplies, and prescription drugs for managing their diabetes from the same qualified pharmacist. As mentioned earlier, the

majority of older diabetic patients rely on their retail pharmacies for their diabetic supplies. Evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for diabetic patients. Through programs such as the "Asheville Project," the pharmacy setting has been shown to provide a successful platform for initiatives to improve adherence to testing and treatment regimens for patients with diabetes.[8] Other private and public health care programs have also placed the pharmacist in a central role in the management of diabetes and other chronic diseases. It would be ill-advised to risk disrupting these pharmacist-patient relationships while further experience is being gained in the effectiveness of community-based pharmacies in promoting adherence to blood glucose treatment and monitoring regimens.

Unlike other DME supplies, CMS did not evaluate the effects of competitive bidding of diabetes supplies during the competitive bidding demonstration projects. Thus, expansion of the competitive bidding program to diabetes supplies sold at retail pharmacies will create significant confusion and frustration to diabetic patients and their providers. At a time when Medicare is attempting to move away from fragmented care, competitive bidding is likely to interfere with patient access and could adversely affect diabetes management.

Further, the study conducted by HealthPolicy R&D examined issues related to competitive bidding of diabetic products and associated services under Medicare Part B and noted the following:

- Costs to the Medicare program will increase if access to the full range of monitoring options is lost or if the frequent in-person counseling by retail pharmacists is disrupted.
- The complexity of using glucose monitors, particularly for an elderly beneficiary, is a major concern. Pharmacists play an important role in helping beneficiaries select the optimal monitors and in the correct use of such monitors, both in terms of initial instruction and subsequent reinforcement of that instruction over time. Much of the professional support originates from the ongoing relationship between beneficiaries and pharmacists.
- CMS excluded blood glucose monitors and supplies from the DME competitive bidding demonstration project, due, in part, to concerns regarding the complexity of matching glucose monitors with the appropriate testing supplies.
- The competitive bidding program could operate contrary to Medicare's current and future initiatives that are designed to promote adherence to blood glucose regimens and reduce overall costs in managing diabetes.

[8] Pharmacy Times, *The Ashville Project: A Special Report* (October, 1998), *available at* http://www.pharmacytimes.com/files/articlefiles/TheAshevilleProject.pdf (last accessed May 12, 2008).

CMS should not create national or regional competitive bidding areas for mail-order diabetes supplies.

Although CMS excluded diabetes supplies sold at retail from the first and second rounds of competitive bidding and diabetes supplies sold anywhere from the second round, CMS continues to maintain that it will soon create a national or regional mail-order program for diabetes supplies.

CMS' decision to expand the mail-order program for diabetes products would not be supported by any evidence that mail-order program would ensure quality products and services or guarantees as to patients' access to life-saving diabetes products. As CMS' primary motivation appears to be financial savings, it is quite likely that a winning mail-order supplier may limit access to high quality products and eliminate patients' choice in their diabetes care in order to cover reduced reimbursement under the mail-order competitive bidding program.

Further, CMS has not engaged in any study or evaluation of the impact of a mail-order diabetes program on patients' health outcomes and overall increase in cost to the Medicare program from patients' failure to abide to their prescribed testing regimen. As mentioned earlier, proper match between diabetes test strips and monitor is critical to optimal diabetes management. If patients are unable to access proper diabetes test products or find it difficult to manage their diabetes with low-quality products, they are much more likely to stray from proper testing regimen or stop testing entirely. These behaviors are likely with a mail-order program, which will undoubtedly harm patients and increase Medicare spending.

Like many other chronic diseases, diabetes has a disproportionate impact on minority and low income patients. These populations are less likely to be able to navigate a competitively bid mail-order market for their diabetes products. As retail pharmacies and providers are selectively forced out of diabetes supplies business through the expansion of the mail-order program, minority and low income populations will find it increasingly difficult to access these products. Expansion of the mail-order program will effectively compel these vulnerable populations to go without proper diabetes management.

As previously stated, the majority of older patients prefer to obtain DME supplies for conditions such as diabetes from their local pharmacist with whom they have an ongoing relationship. The presence of a licensed pharmacist at their community retail pharmacy gives patients the opportunity to discuss the best glucose test monitors for their individual needs and the proper matching of the test strips to the glucose test monitors. This individualized attention is critical to helping increase patient compliance with therapy regimen and improving health outcomes for diabetic patients. The benefit of such interaction should not be taken lightly as it provides a valuable patient care forum for early awareness and treatment of diseases, and translates into substantial savings for the Medicare program. Expansion of the mail-order diabetes program will make it more difficult for Medicare patients to gain access to the community pharmacist they trust creating a likelihood for miscommunications and misunderstandings and eroding the

benefits of the pharmacist-patient relationship that has been proven to improve health outcomes and reduce overall health care spending.

Finally, we also urge Congress to be cautious of CMS' implementation of the first round of competitive bidding, which included bidding for mail-order diabetes supplies. With less than two months remaining before first round mail-order diabetes supplies contracts go into effect in the 10 MSAs, CMS has not embarked upon an effective patient outreach program. As the first round becomes effective on July 1, 2008, patients are likely to be confused about where they can obtain their DMEPOS products and services. In particular, diabetes patients in the 10 MSAs may mistakenly believe that they are required to utilize a mail-order facility for their diabetes supplies. CMS should be required to clearly state on any beneficiary communication material that patients in the 10 MSAs may continue to utilize their local pharmacies for their diabetes test supplies. As mentioned earlier, interaction with licensed pharmacists at retail pharmacies provides benefits that are not achievable when patients receive their diabetes products through mail-order. Congress should require CMS to work with the retail pharmacy community to develop proper communication materials to ensure that patients are not steered away from retail pharmacies, depriving them of professional counseling by pharmacists.

State-licensed retail pharmacies should be exempt from CMS' proposed surety bond rule.

During the midst of competitive bidding program implementation, CMS also proposed to require a $65,000 surety bond from all Medicare DMEPOS suppliers. As if the costs associated with accreditation and bidding did not create enough disincentives for small suppliers, CMS' proposal to require a surety bond is likely to keep many interested suppliers from participating in the DMEPOS program.

In its proposal, CMS estimated that annual administrative costs related to the surety bond would be $2000.[9] For many DMEPOS suppliers, the administrative fees required in obtaining the surety bond could be prohibitive as such fees may not be recouped even through their total annual Medicare billing. Ultimately, small DMEPOS suppliers, particularly those serving rural and underserved areas, may be unable to cope with the recurring and rising administrative costs in providing DMEPOS services and may be forced to turn away Medicare beneficiaries.

According to CMS' own calculation, up to 15,000 DMEPOS suppliers currently enrolled in Medicare (22 percent of whom are in rural areas) could cease providing items to Medicare beneficiaries as a result of the surety bond.[10] CMS envisions that, "most, if not all, of the Medicare business conducted by these DMEPOS suppliers would be assumed by other DMEPOS suppliers remaining in the program (for example, by mail-order or via

[9] Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 72 Fed. Reg. 42007 (August 1, 2007).
[10] *Id* at 42008.

the World Wide Web)."[11] Clearly, CMS indicated that this proposed rule will result in even fewer small pharmacies participating in the Medicare DMEPOS program. As a result, patients could face tremendous difficulties in obtaining their necessary DMEPOS items and services.

CONCLUSION

NACDS appreciates the opportunity to testify today and share our perspectives about current CMS regulations and policies affecting small health care providers and their patients. We look forward to working with Members of this Committee and Congress to address these harmful policies to ensure that Medicare and Medicaid beneficiaries' health is not placed in jeopardy.

[11] *Id.*

TESTIMONY OF MICHAEL C. SCHWEITZ, M.D.

ON BEHALF OF

THE ALLIANCE OF SPECIALTY MEDICINE

ON

"THE IMPACT OF CMS REGULATIONS AND PROGRAMS ON SMALL HEALTH CARE PROVIDERS"

BEFORE THE HOUSE SMALL BUSINESS COMMITTEE

SUBCOMMITTEE ON REGULATIONS, HEALTH CARE AND TRADE

May 14, 2008

Testimony of
Michael C. Schweitz, M.D.
On Behalf of
The Alliance of Specialty Medicine
On
"The Impact of CMS Regulations and Programs on
Small Health Care Providers"
Before the Subcommittee on Regulations, Health Care and Trade
May 14, 2008

Good afternoon Mr. Chairman, Mr. Westmoreland, and members of the Subcommittee. I am Dr. Michael Schweitz, a practicing rheumatologist from West Palm Beach, Florida. I am Vice President of the Coalition of State Rheumatology Organizations (CSRO), which represents 28 of the approximately 37 state and regional rheumatology societies in the country. CSRO's principal purpose is to promote access to the highest quality care for patients with autoimmune inflammatory and musculoskeletal diseases. I am here testifying on behalf of the Alliance of Specialty Medicine, a coalition of 13 national medical specialty societies representing more than 200,000 physicians. This non-partisan group is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care.

I would like to discuss physicians' experience with one aspect of the impact of CMS regulations on small health care providers, namely the CMS demonstration project referred to as the Recovery Audit Contractors program, or RAC. The RAC demonstration was mandated by Congress in the Medicare Modernization Act of 2003. In implementing the demonstration, CMS initially awarded three contracts in 2005: one

in my home state of Florida, and two others in California and New York. These three states were the largest states in terms of Medicare utilization, accounting for 25% of total Medicare payments made each year. In 2007, the demonstration was expanded to include three additional states: Massachusetts, South Carolina, and Arizona. As a result of a provision included in the Tax Relief and Health Care Act of 2006, Congress required CMS to make the RAC program permanent and nationwide by no later than January 1, 2010.

Physicians concur with the original intent of the Congress in establishing the authority of the RAC program. Medicare should be paying only for those claims that are proper and appropriate and should be correcting improper payments to any provider who was underpaid or overpaid. But something went very badly wrong in CMS' implementation of the demonstration, which created unfair and very expensive burdens for physician practices. I hope the Subcommittee understands that physician practices are small businesses, which have little capacity for dealing with arbitrary, ill-informed and often confusing policies of contractors who seem to have little interest in communicating clearly with physicians about what to expect and why. I am here to elaborate on these problems and their implications for physicians' practices and to suggest what needs to be changed before the RAC becomes nationwide and permanent.

Before I begin to describe physicians' experience with the RAC, I would like to point out to the Subcommittee that the RAC is but one example of the regulatory burden that comes with a decision by physicians to participate in Medicare. While we understand

that a large and complex program like Medicare requires refinement on a continual basis, more thought needs to be given by CMS and its contractors to the impact regulations, guidelines and manual instructions have on our small businesses. This is especially the case at a time when the fees paid to us by Medicare are declining in terms of inflation-adjusted dollars—about a 16% decline since 2002. Physicians simply can not afford the capricious application of new law and policy if we are to continue to serve Medicare beneficiaries.

The Recovery Audit Contractor (RAC) Program

The first problem encountered by physicians in Florida occurred shortly after CMS hired its contractor, HealthDataInsight (HDI), to begin operations in 2005. HDI sent letters to multiple physicians demanding repayment for claims from dates of service extending back four years. Many of these claims had already been adjudicated upon record review by the Florida Medicare carrier, First Coast Service Options, and should not have been eligible for RAC recovery.

Upon receiving numerous requests for copies of medical records from the RAC, practices across the state began retrieving charts from storage and copying records, once again. It seemed like "double jeopardy" to many providers; we were being asked by another organization hired by CMS to review these claims again. Upon review of these documents physician staff members discovered that the majority of these requests had

been previously reviewed, appealed and paid at different levels of the Medicare appeal process. These claims clearly should not have been subject to RAC audit. Sadly, many physicians paid upon receipt of the requests rather than divert office staff and administrative attention to the matter. They did not have the funds to pay for staff to review the numerous records, pull charts, retrieve charts from storage, and pay the fees for chart retrieval from the medical records storage companies. Many did complain to HDI and subsequently to CMS, and many appealed. Eventually HDI was directed by CMS to cease requests for previously reviewed claims because it was a violation of Medicare policy.

Another problem occurred in December 2007, when HDI sent demand letters to hundreds of Florida physicians asking for refunds or records pertaining to procedure codes 64470 – 64476, facet joint injections. These injection procedures are done on the small joints of the spine to relieve spinal pain. The premise for the refund request was that these joint injections must be done utilizing fluoroscopic guidance and billed with a concurrent code for the fluoroscopic guidance. The claims in question had not been submitted with the code for fluoroscopic guidance. HDI demanded refunds or records for this procedure done as far back July 2003 and cited "commentary" from the Federal Register as their authority. In fact no policy had been developed or distributed until September 30, 2007, when a Local Coverage Determination was formally adopted and published.

One group of rheumatologists had to copy and mail out over 300 patient records to comply. You can imagine how many staff hours were diverted from patient care and office management to fulfill these requests. Some practices were asked for refund payments. A few had major offsets from current Medicare checks before the 30-day CMS refund deadline had expired. Some practices had to borrow from lines of credit to accommodate the cash flow problems these offsets created. One practice had $166,000 withheld from current Medicare claims, *before* they had received the Refund Demand for payment from HDI. They had little or no time to prepare for this interruption in cash flow to their small business.

Over 75 physicians were forced to hire outside consultants and legal counsel to help deal with this disaster. The sequence of events required of the RAC as part of the identification and recoupment of overpayments was not followed. Eventually, with the assistance of the Florida Society of Rheumatology and the Florida Medical Association, as well as staff of CMS, particularly Dr. William Rogers of the PRIT (Physicians Regulatory Issues Team) and Ms Connie Leonard, both of whom I would like to publicly thank, these egregious demands were stopped. It was apparent that HDI was again not following existing Medicare rules, regulations, and written policy.

To compound the impact to the practices, Medicare notified all of the secondary payers, including but not limited to AARP, United American, Aetna, Cigna, Washington National, BCBS of AL, Michigan and Florida, of the overpayments. These are the

insurers which provide supplemental coverage to beneficiaries and pay 20% of the original Medicare allowed payment for the injection procedures. Now they too were requesting that these amounts be repaid. This created an additional burden of work for practices because their payments are based on what Medicare is required to pay first as the primary payer. In essence, once the basic problem was corrected with the RAC, these same small business practices were expected to engage additional staff time to correct the problem with the secondary payers. This would be the fourth time physician staff members were working on collecting monies and reconciling accounts for claims that were adjudicated properly by CMS in 2005. To this day, May 14, 2008, practices are still dealing with requests for refunds and overpayments on these same RAC claims.

Prior to the debacle pertaining to facet joint injections, a similar scenario, involving the oncology community, played out in Florida. Again, hundreds of practices were accosted for records or refunds, involving hundreds of thousands of dollars. Only after aggressive intervention by the Florida oncology community, the Florida Medical Association, and a national oncology society, the American Society of Clinical Oncology (ASCO), was the process stopped when it became clear that rules governing interpretation of HCPCS code G0345, for IV hydration, was misstated by the RAC in its attempt to recoup monies previously paid to the physicians.

In California urologists were asked to refund payments related to LCA (least costly alternative) policy for LHRH (luteinizing hormone-refractory hormone) drugs used to

treat prostate cancer. The urologists argued, and were successful, at reversing the demands. This reversal was successful because of the RAC's misapplication of written policy in exceeding time limits for reviewing claims.

In other instances it is also unclear what clinical guidelines RACs are utilizing in making their determinations. For example, those governing inpatient vs. outpatient implantation of cardiac devices, such as ICDs (Internal Cardioverter Defibrillator) and CRT--Ds (Cardiac Resynchronization Therapy Devices) do not specify a clear policy directive regarding site of service. Yet, RACs have been ruling that inpatient implantation procedures should have been performed as outpatient procedures and are recouping ostensible overpayment.

In New York obstetrician gynecologists face similar concerns with inpatient vs. outpatient surgery for hysterectomy. RACs have been ruling that such procedures should be performed in an outpatient setting, even though as many as 90% of hysterectomies are currently inpatient procedures. The RAC rulings ignore physicians' concerns regarding the safety of performing this procedure in an outpatient setting, and seem to be trying to establish a dangerous change in the standard of care.

These are but a few examples of the problems that physician practices have encountered. Clearly, the RAC program has not evolved into an efficient, fair and transparent program. Instead, we have come to view the program as an uncontrolled bounty hunter. When

confronted by a RAC demand letter many of our practices are forced to succumb, or turn to outside resources at considerable expense in an attempt to right the unacceptably common errors of the RAC.

It is unclear to many of our physicians of the ultimate necessity of the RAC. Clearly the CERT (Comprehensive Error Rate Testing) Program has been very effective at reducing the error rate to 4%. Would it not also be reasonable to expect our Medicare carriers to do a better job on the front end – appropriate edits, unambiguous rules and better distribution of policy changes? Might the rules be written more understandably? Many physicians must hire consultants to interpret the rules and their applications. Front-end savings should go directly to the Medicare program, not the private RAC businesses. Improved front-end functions would render the RAC redundant.

Recommendations

We support H.R.4105, the Medicare Recovery Audit Contractor Act of 2007, which proposes a moratorium on RAC activities and expansion of the current demonstration until its serious flaws are adequately evaluated and addressed.

Other recommendations include changing the Bounty Hunter payment mechanism that seems to embolden RAC behavior. Their aggressive approach lengthens the time to

resolve challenges and is instrumental in creating the excessive burdens on medical practices, especially small ones.

Also, the current Statement of Work shortens the time frame for review from four to three years, but, it no longer precludes the RAC from reviewing work from the current year. This opens the door for overlapping or concurrent reviews of claims by other contractors, such as fiscal intermediaries, carriers, MACs and quality improvement organizations (QIOs). This could potentially create a double burden in practices that have to respond to concurrent claim reviews.

In addition, the look-back period should be shortened from the current period to a twelve month period, months 12 – 24. This still gives the RAC a substantial full twelve months of claims review.

Most importantly, CMS should remove medical necessity determinations from the RAC Statement of Work. We do not think that these reviews are appropriate for the RAC program and believe they exceed the authority imparted to the RAC by Congress, which requires contracts with RACs "for the purpose of identifying underpayments and overpayments and recouping overpayments under Medicare." Medical necessity determinations are fundamentally distinct from other RAC reviews. These are significantly subjective cases and require considerable attention and expertise. They are not simple "mistakes" or "errors" more suitable for RAC identification. Medical

necessity reviews can not be completed using the automated software-based searches that identify billing errors. These reviews are individualized clinical assessments of compliance with Medicare policy. Each review should be conducted by a clinician with relevant experience and expertise to make these determinations. RACs do not appear to have used appropriately qualified staff for medical necessity reviews. Furthermore, medical necessity reviews are being done by other CMS contractors and, therefore, are redundant for the RAC.

Additionally, notification of overpayments that are sent to secondary payers should be delayed until completion of all appeals. Conversely, if recouped overpayments are reversed after notification to secondary payers, CMS should demand that secondary payers take corrective action regarding coinsurance monies to minimize the onerous burden on practices in trying to reconcile these accounts. Also, for RAC claims that are reversed, the RAC should be responsible for physician practice costs incurred with the work required in the compliance and appeals process.

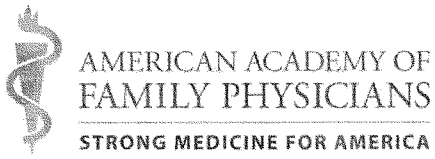
SUMMARY

The RAC Demonstration Project may have been successful from the standpoint of monies restored to Medicare. However, clear evidence, based on recent events in California and Florida, shows that the program suffers from ineffective oversight. Numerous and serious errors in interpretation and application of Medicare policy and

regulations reflect the capricious and pervasive activities of the RACs. If CMS expects a reasonable error rate in its transactions, why shouldn't physicians expect the same?

The program is clearly not reasonably ready for expansion. Recent changes in the Statement of Work may be helpful in correcting some of these errors but there is still no current evidence that this is the case. Medical practices, as small businesses, are already under sobering stresses. Like all other small businesses, our cost of doing business continues to rise. Yet we face the potential of a decrease in Medicare payments of over 10% as of July 1, 2008. On a daily basis any given practice may receive multiple requests for medical records prior to or after payment is made. This is not limited to the Medicare program; other third party payers have followed Medicare's lead and conduct concurrent and retrospective audits of clams submitted for payment. We recognize the need for oversight; most small business' income is not generated from tax dollars as is the case with physicians paid by Medicare. We would, however, ask the Congress to recognize that the RAC program requires considerable fine tuning to fulfill its Congressional mandate without unfairly and unjustly burdening the physicians who provide the care and treatment of our nation's seniors.

I would like to thank you, Chairman Gonzalez, ranking member Westmoreland, and members of the Subcommittee, for the opportunity to speak to you this afternoon.



Statement of the American Academy of Family Physicians

Submitted to the
U. S. House of Representatives

Committee on Small Business
Subcommittee on Regulations, Healthcare and Trade

Concerning

Postpayment Review Conducted by
AdvanceMed
Under the CMS Recovery Audit Contractor Program

Presented By

Karen Smith, MD, FAAFP
Raeford, North Carolina

May 14, 2008

AAFP Headquarters
11400 Tomahawk Creek Pkwy.
Leawood, Kansas 66211-2680
800.274.2237
913.906.6000
fp@aafp.org

AAFP Washington Office
2021 Massachusetts Avenue, NW
Washington, DC 20036-1011
202.232.9033
Fax: 202.232.9044
capitol@aafp.org

Good afternoon, Chairman Gonzalez and ranking member Westmoreland and members of the committee. I am Dr. Karen Smith a family physician and owner of a solo private practice in Raeford, NC.

On Monday morning October 24, 2005 two representatives from AdvanceMed presented to my office with badges identifying themselves as authorized subcontractors for Cigna/Medicare and requested 72 charts for review of clinical documentation of services rendered from July 1, 2004 through June 30, 2005. My staff extracted the requested information from the electronic records system and I personally provided the walking tour of the building including inspection of state and federal licenses for medical business operations. The care of my patients was disrupted in our open access rural family practice as patients, pharmaceutical vendors, and other visitors of the practice observed the unannounced review.

Five months later on March 16, 2006, I received notification that 72 claims with 154 services submitted were reviewed and 91 (of the 154) disallowed for payment. This translated to Medicare overpayment of $48,245.00 based upon CMS extrapolation calculation with a sampling frame size[1] of 2,935 patients. The actual amount paid to the practice for the services questioned was $1,551.11. The practice management system noted 1,287 Cigna/Medicare patients in our practice on March 27, 2006 (list is part of supporting information). This discrepancy was not acknowledged nor corrected in the final calculations.

The reasons for denial included incomplete or no documentation, services incorrectly coded, services not covered by Medicare, lack of documentation for drugs administered, services not medically necessary in the judgment of the reviewer (who was not a physician).

When my staff and I reviewed the summary, we noticed that several items of documentation the reviewer cited as being non-existent, were indeed present in our electronic record system. I called AdvanceMed in an effort to notify them of the discrepancy and request instructions for sending this information. The response was this information could be submitted only in an appeal. This answer was communicated in such an intimidating and aggressive manner, prompting me to call a well-known independent auditor. I participated in several of her coding workshops and quickly recognized additional professional assistance was going to be needed. At my request, the auditor immediately contacted an attorney who also called AdvanceMed only to receive the same answer.

The appeal process was initiated and then delayed due to AdvanceMed sending letters to the wrong medical office and which neither I nor my counsel ever received. Documentation was finally accepted by CMS and forwarded to Q2 Administrators as hired by CMS to review the file and make an independent decision.

The outcome from the CMS review was partially favorable but still translated to a new overpayment with extrapolation calculation of

$18,158.00 and it was still based upon the sampling frame size[1] of 2,935 (a difference of 1,648 patients).

The monetary difference from the findings noted by AdvanceMed, the CMS subcontractor, and Q2 auditor was $30,087.00 (even with the incorrect patient population number as noted in my data base). Our attorney reviewed additional options including an Administrative Law hearing for services performed but required additional appeal presentation. The practice, my family, and myself were at a point of stress never imagined. We were exhausted and emotionally distressed after countless hours and days of preparation and review during the third to fourth year of our new business existence.

This led to the decision to halt further appeals and review. We were financially drained and feeling the pressure to make payroll, pay mortgage, as well as the other expenses. A loan was acquired from my personal home equity and the check sent to CMS to satisfy the calculated obligation. Ninety days later I received notification from the U.S. attorneys office for a possible levy of assets due to nonpayment of the CMS recoupment. After two attempts of providing documentation it was clarified that the payment had not been applied to our debt.

I recognize that every medical office is responsible for providing access to efficient and high quality healthcare. I established a technologically advanced practice in one of the poorest counties in North

Carolina. We implemented a plan in accordance to guidelines for the Future of Family Medicine as outlined by the American Academy of Family Physicians. This is a state-of-the art, primary care practice in rural North Carolina that adheres to the highest standard of care and participates in quality-based projects with the goal of decreasing medical errors, eliminating redundancy in services by using tracking systems and the use of intercommunication tools with the hospitals located about 25 miles away. We also strive to provide same day acute care, and we emphasize disease prevention. We are one of five doctors, who serve 39,000 patients, and we are part of the socioeconomic structure of the community adding to the financial stabilization of our small town. Our practice is the only solo physician-owned practice and we receive no support from the hospital systems which generate revenue from our market area but are located in and subsidize neighboring counties.

The "guilty until proven innocent" audit we endured used sampling and extrapolation calculations which are not properly verified for validity. In addition to the disruption to patient care and possible reputation damage by the surprise and abrupt visit of badge-bearing authorities, the process quickly exhausted our financial reserves.

It defies common business sense to run a high-quality practice that utilizes electronic health records in a financial environment where Medicare does not recognize the true total costs for caring for individual patients with many medical problems, who is, in other words, the typical Medicare

patient. In addition, the refusal of the CMS Recovery Audit Contractor to recognize the presence of appropriate and pertinent documentation in our electronic health record is at best discouraging. In this case, that judgment proved costly to my practice.

The escalating cost of healthcare cannot be subsidized from monies taken out of the businesses of small physician practices. We have the compassion and the desire to remain in operation but will be unable to endure in a world of uncontrolled costs and diminished payment.

Thank you for holding this hearing and seeking this input.

[1] "Sampling Frame: The sampling frame of sampling units was created by first obtaining a universe of claim lines for claims meeting the above criteria[2] and then identifying the list of unique Claim Control Numbers (CCNs) (i.e., unique claims) within the universe of claim lines. The frame was sorted by CCN and then auto-numbered.

[2]"Above criteria" refers to: Sample Design: Simple Random Sampling
"Sampling Unit Claim submitted by the provider with at least one service line Paid > 0. Furthermore, the date of service must fall within the Time Period of interest."

May 13, 2008

United States Representative
The Honorable Charles A. Gonzalez
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gonzalez:

Enclosed you will find a collection of Medicare topics that impact the small business as it relates to a physician practice. When asked to provide comments regarding the impact of Medicare regulations on the small business it seemed appropriate to invite our colleagues at South Texas Oncology and Hematology, PA to provide their perspective, concerns, comments and suggestions.

Sincerely,

Lynn F. Kuhn, CPA, COO
South Texas Oncology and Hematology, PA

And

Terry Allen, BBA
Director of Reimbursement
South Texas Oncology and Hematology, PA

South Texas Oncology and Hematology, PA
7979 Wurzbach, Suite U436; San Antonio, Texas 78229

Medicare Advantage Plans and the Small Business Impact

Medicare Advantage Plans and the perception of how they work:

Information is misleading and difficult to understand even for employees in the Health care industry. For Example, Medicare consumer web-pages state that an individual who elects to join a Medicare Advantage Plan is still in the Medicare Program and that "you don't need to buy Medigap policy[1]".

The reality appears to be that the Medicare member is in fact voluntarily dis-enrolling from the Medicare B Program, which in turn *voids* the Medigap insurance. Thus, there is no reason to buy the coverage or continue paying for the coverage.

Adding to the confusion, the enrollee must continue to pay the Medicare Part B premium thus the illusion is that the enrollee is still in the Medicare Part B program. If this is not an illusion, then why is Medigap policy now void?

Many argue that the Medicare Advantage Plan pays 100% of the Medicare Allowable which cover's the co-insurance. However, many plans pay 100% of the 80% and do not cover the co-insurance. Enrollees do not understand that when selecting a Medicare Advantage Plan they must chose a plan that is between F & J to fill the majority of Medicare Part B "gaps". It should be noted that with the introduction of Medicare Part D "J" type plans are harder to find and none are available to anyone over 65 on the Medicare Options Compare[2] site.

An example of the Medigap confusion is the Dual Eligible Medicare/Medicaid enrollees, South Texas Oncology and Hematology, PA has encountered numerous problems with beneficiaries who have enrolled into a nationally recognized Medicare Advantage Plan and are Medicaid beneficiaries as well. The Medicare Advantage Plan Pays 100% of the 80%; however, the 20% co-insurance is not paid. Upon billing Texas Medicaid, the co-insurance is declined, as Texas Medicaid does not recognize the Medicare Advantage Plan as a Part B plan. Texas Medicaid specifically stated, "According to our records, there is no indication that the above client had or currently has Medicare Part B. According to the 2007, Texas Medicaid Provider Procedures Manual (TMPPM) 4.5.1 indicates Medicaid pays the Part A and Part B Medicare deductibles and co-insurance liabilities. Medicare replacement policies refer to the Medicare Part C and we do not cover Part C at this time."[3] The practice was unable to pursue collection of the $5,000 co-insurance balance.

Administrative Burden on Practice:

Although the Medicare program may not be perfect, it is historically a predictable payor and thus requires minimum administrative attention. Medicare Strengths include:

- Average DSO for 90% of the claims billed is 20 days
- Claims are accepted electronically
- Claims are paid correctly the 1st time
- Appeals rule are clear and concise
- Questions are answered timely or appropriate follow-up is received upon escalation of the issue to Tier II.

Medicare Advantage plans are neither perfect nor or predictable as they have no historical performance indicators. The administrative management of these plans is high and claims often take months to resolve. Medicare Advantage plans weaknesses include:

- Contracts are not required between physician practice and insurance company; thus, there is no re-course for non-payment of claims.

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[1] http://www.medicare.gov/MPPF/Static/TabHelp.asp?language=English&version=default&activeTab=3&planType=MA

[2] http://www.medicare.gov/MPPF/Include/DataSection/MedigapDetails/MGAPPolicyChooser.asp

[3] TMPH A State Medicaid Contractor Letter dated October 8, 2007

- No business history with the vast majority of contracts; thus high risk for slow payment or non-payment.
- Plans do not understand billing codes thus; we're spending a significant amount of time sending them Medicare guidelines on how to process claims.
- Obscure plans are difficult to contact and resolve claims issues.
- Number of plans participating changes monthly and is burdensome to setup so many insurance companies to bill 1-2 claims especially since not all accept electronic claims
- Obscure plans are difficult to contact and resolve claims issues

Physician – Patient Issues:
South Texas Oncology and Hematology, PA has elected not to actively contract with any Medicare Advantage Plans due to the payment risk, co-insurance/supplemental insurance risk and administrative burden.

Existing patients are informed that we do not accept their new insurance and we are left explaining what their true benefits are and what that would mean to them and to us. Unfortunately, the majority of patients tell us the same thing… "I was told this is just like Medicare… It's even called the Medicare Advantage Plan". As our physicians have a long standing relationship and bond with these patients we typically agree to continue seeing these patients. However, we now have to ensure we find 'alternate' funding for the co-insurance. South Texas Oncology and Hematology, PA has hired the following positions:

- Two (2) Financial Counselors – Assists in qualifying and enrolling patients in co-insurance foundations, which is often drug specific and does not cover the entire co-insurance balance but any amount of money is helpful.
    - Practice Expense Associated with Salaries and benefits is $77,459.00 annually

- One (1) Full Time Collector – Collector actively watches patients with foundation benefits, audits accounts, reviews which drugs are eligible for foundation assistance, moves appropriate charges, bills foundation, performs follow-tasks, upon payment assures the correct drug co-insurance was paid, and then re-audits account to ensure patient is billed correctly for their remaining outstanding monies. This is time consuming DSO (days sales outstanding) is high 90 days where as Medicare is 20.
    - Practice Expense Associated with Salaries and benefits is $37,345.00 annually

The practice has numerous other expenses associated with Medicare Advantage plans but as you can see, we are expensing at a minimum $114,804 with no associated "new" revenue.

These additional expenses are not optional but are necessary for the small business owner
survival. The full Medicare Allowable (80% from Medicare and 20% from co-insurance) must be collected to ensure the "cost" of the drug is met. The majority of our patients cannot afford 20% of their chemotherapy treatments. Nor can South Texas Oncology and Hematology, PA afford to write checks for each patients treatment.

The physicians at STOH recognize that the number of patients currently enrolled in Medicare Advantage plans is low; however, given that 23% Medicare beneficiaries in Texas are enrolled in a Medigap program[4] and 50% of our patient population is eligible for Medicare the associated risk is real and increasing on a daily basis.

Patient Issues:

- High pressure sales tactics
- "Deceptive and fraudulent sales practices"
    1. Texas Department of Insurance Issued - Consumer Alert – "Protect yourself against Medicare Advantage fraud"[5]
- Patients are being informed that their Physicians MUST take the insurance if they are Medicare Providers.

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[4] 2005 Medigap in Texas Stats from www.medigapchoice.com – CMS enrollee data & NAIC Medigap data: 543,412 out of 2,390,053 Medicare Enrollee 23% of the Market

[5] Texas Department of Insurance – Consumer Protection Alert; Protect yourself against Medicare Advantage fraud, http://www.tdi.state.tx.us/rules/2007/parules.html

- Patients are calling our office with the insurance representative in their home because the sales representative is insisting they switch today.
- Although South Texas Oncology and Hematology, PA has elected not to contract with any Medicare Advantage Plans the sales representatives are quick to note, that the plan will pay out-of-network providers just as they would in-network providers.
- Texas Department of Insurance issued an Emergency Order Prohibiting Temporary Agents from marketing Medicare Advantage Health, Prescription Drug Plans on November 9, 2007 in direct response to "reports received by TDI, temporary insurance agents had solicited some Medicare beneficiaries to enroll in unsuitable Medicare Plans"[6]
- Medicare Advantage plans are renewed annually. If a company wishes to discontinue participation in the Medicare Advantage market, patients will be dis-enrolled and will need to re-enroll into another plan or back to the Original Medicare Plan. If the patient changes to the "Original Medicare Plan you might have a special temporary right to buy a Medigap policy, even if you have health problems. This is not automatic; the patient must request an application from the supplemental insurance company and has no more than 63 days to execute the enrollment.

In conclusion, there are over 705 Medicare Advantage companies contracted with Medicare as of December 2007 with over 26,246,908 enrollees. [7] Contracting with each one is not practical or an option given their lack of understanding regarding Medicare payment guidelines, and the exposure of patients not understanding that their new plan may not cover the 20% which has historically been covered by Medigap plans. It is twenty percent (20%) small business owners simply do not have and cannot afford to absorb the expense.

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[6] Texas Department of Insurance – Emergency Orders – Prohibits Temporary Agents from Marketing; November 13, 2007

[7] Prepaid Medicare Advantage Plan contracts from the Monthly summary report_Dec 2007 11272007pdf

Medicare Information Structure

Newsletters:
Providers are obligated to understand and abide by all CMS regulatory requirements. However, even with the Medicare Paperwork Reduction Act, finding applicable regulations, new regulations and/or updates to existing regulations is difficult.

"Provider newsletters/bulletins are published at least quarterly and contain local and national policies and procedures, including significant changes to the program."[8] The Medicare Part B Newsletter published on February 28, 2009 is 80 pages long and may have pertinent data woven throughout the document. For example, update to the LCD Abarelix (Plenaxis ®) for Prostate Cancer –I78'LCD is between an update in Psychiatric Codes and Vascular Access for Hemodialysis.[9] A better format would group specialty related updates together. Thus, Cancer updates would be grouped under Oncology and Psychiatric under its specialty. Defined changes by Specialty would minimize the amount of time it took to find information and assist with more timely compliance.

Moreover, it would be helpful if newsletters were published by specialty. In other words, a Newsletter for Hematology, Medical and Radiation Oncology, Cardiovascular, Family Practice ECT… This request may sound daunting; however, Medicare information that is common to all specialties would be included in each newsletter thus the only additional work would be to re-organize the specialty specific data. The "common" newsletter would be the base platform with specialty specific information added to the specialty specific newsletter. Additionally, newsletters published electronically, would allow the common information to be displayed and specialty specific data would be available via links.

Local Coverage Determinations (LCD):
The LCD is a living document it is ever changing and updated. The frequency of the updates is not regular and is often proportional to the amount of political attention being given to a particular drug or vendor. Providers must review and implement changes to the LCD; these changes are published in the newsletters however not necessarily on a monthly basis.

An interesting issue recently arose; what do you do when audits span a period and the claims being reviewed span several bulletin updates. Audits are against the LCD language that was in effect for a particular date of service; however, as the LCD are living documents the published LCD's contain all the changes up to the current date. It would be helpful if a provider could request the LCD by Name and date of service. This would allow the provider to review the LCD, as it existed on that particular date. For now, though the provider must print and keep copies of each LCD to ensure they have access to the LCD as it was written for a particular DOS. This is burdensome, difficult to manage, and often times not possible. The alternative would be to print a current LCD and then redline out the updates as noted on the "revision" date page; this is not an easy task and the revision updates are a summary not a detailed list of what was actually changed.

[8] Trailblazer Health Enterprises Web Page, Publications, Newsletters page 1 paragraph 1
[9] Trailblazer Health Enterprises, Medicare Part B Newsletter No 08-077, February 29, 2008

Local Policies and the Treatment of Cancer:

"Act §1832(a) (1); see also 42 C.F.R. §410.3(a) (1). Coverage of medical and other health services is qualified by the overarching principles of sections 1862 (a) and 1833(e) of the Act. Section 1862(a) limits Medicare Payments to items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, "notwithstanding any other provision of Title XVIII of the Act. See also 42 C.F.R. §411.15(k) (1). Section 1833 (e) of the Act requires a claim for payment under Medicare part B to be supported by sufficient information and documentation. See also 42 C.F.R. §424.5(a) (6)...

The Medicare Benefit Policy Manual (Pub. 100-2) Chapter 15 §50.45 contains the CMS policy for Unlabeled Use for Anti-Cancer Drugs. It states in pertinent part, the following:

Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the uses not listed as "not indicated" in any of the three compendia:

1. American Hospital Formulary Service Drug Information
2. American Medical Association Drug Evaluations
3. United States Pharmacopoeia Drug Information (USPDI)
4. A Use supported by Clinical Research that Appears in the Peer Reviewed Medical Literature in the absence of any of the three compendia...."[10]

In essence, if the Anti-Cancer drug meets the letter of the statute and/or regulation, then the drug should be accepted as covered across all states. This would reduce the administrative burden to small businesses and as well, as provide more consistent access to medically necessary care regardless of which state patients are receiving care.

A specific example of this is for the drug irinotecan (CPT-11) and the use of the drug for the treatment of Brain Cancer. The drug is considered reasonable and necessary and reimbursable in several states for the treatment of Brain Cancer, but not in Texas. Our claims are routinely denied at the first and second level of appeals; however, are the denials are overturned by the Administrative Law Judge.

It is unfortunate that the majority of providers (small businesses) will not provide the drug "off-label" because they are not willing to accept the risk of non-payment nor can they afford to pay for the drug without an expectation of payment for several months.

[10] ALJ Appeal No. 1-127970859; page 2 & 3 of 7, section A. Statutes and Regulations

Technology and the Treatment of Cancer:

Another arena where the disassociated review and implementation of regulatory guidance is with emerging technologies. CyberKnife and/or Stereotactic Radio Surgery are currently undergoing the same issues as the use of anticancer drugs mentioned previously. The overwhelming difference is CyberKnife is FDA cleared for the entire body; however LCD policies are retroactively determined after the small business has purchased the technology based on the FDA clearance for the entire body.

> "FDA – CDRH – PDF 510(k) SUMMARY date prepared May 3, 2007…
> Device Name: CyberKnife® Robotic Radiosurgery System Indications For Use:
>
> The CyberKnife® Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions *anywhere in the body* when radiation treatment is indicated."[11]

Radiation has been around for over 60 years, in essence the drug is same, but the method of delivery has become more precise over the years and with the introduction of new technologies. A more precise delivery mechanism spares healthy tissue, and reduces overall risk. It would make sense if Radiation is accepted treatment for cancer and the technology has been FDA approved for the entire body, then why are we now limiting reimbursement by state different approved sites?

Furthermore, there are currently no CPT codes that accurately reimburse for the resources utilized in treating patients with the CyberKnife in the freestanding setting. CMS has made the inaccurate assumption that the costs in a freestanding setting are lower than in a hospital outpatient setting which makes it very difficult for an independent or small center to function and treat patients. Again the reimbursement policy is site specific and diagnosis driven.

For example, please see the below letter written to Trailblazer Health Enterprises.

> April 28, 2008
>
> Trailblazer Health Enterprises
> Executive Center III
> 8330 LBJ Freeway
> Dallas, Texas 75243-1213
>
> Attention: Charles E. Haley, MD, MS, FACP - Medicare Medical Director
>
> ***RE: Robotic Stereotactic Radiosurgery – Payment for G-codes in the physician office***
>
> Dr. Haley,
>
> We would like to request that the coding and reimbursement for robotic stereotactic radiosurgery (SRS) performed in a physician's office be consistent with the OPPS guidelines. We ask that Trailblazer consider approving reimbursement of robotic SRS carrier-priced G-codes (G0339 and G0340) in the physician's office setting.
>
> Effective January 1, 2007, CMS granted coverage for radiosurgery procedures performed in free-standing centers under the physician fee schedule [CMS-1321-FC and CMS-1317-F].
>
> CMS recommends the use of the robotic radiosurgery G-codes for the hospital outpatient setting and has disallowed the use of the new CPT codes for robotic radiosurgery. The new G-codes G0339 and G0340 were created because CMS realized there were significantly different costs associated with delivering robotic radiosurgery vs. non robotic.

[11] FDA – CDRH – PDF 510(k) SUMMARY date prepared May 3, 2007 http://www.fda.gov/cdrh/pdf7/K071531.pdf

CMS has determined that HCPCS codes G0339 and G0340 are more specific in their descriptors than CPT codes 77371, 77372 and 77373.

The radiosurgery CPT codes included in the physician fee schedule do not accurately describe the service being provided.

- 77371-77373 CPT descriptors do not identify the procedure as **robotic** radiosurgery.
- 77371 and 77372 are specific to cranial lesions.

The reimbursement for these CPT codes in no way reflects the actually cost of the treatment.

- The reimbursement for 77373 is only $1583.37. This is significantly below the OPPS reimbursement for G0339 and G0340.
- For a three fraction treatment, the reimbursement using CPT 77373 is only $4750.11.
- Our cost for a three fraction treatment is three times that amount.

Several states have already approved reimbursement of G0339 and G0340 in the physician office setting. Those states and their respective Medicare carriers are:

- Upstate New York – Health Now, Part B Carrier
- California (San Francisco County, Ventura County, Los Angeles County, & Orange County) – NHIC, Part B Carrier
- Maine – NHIC, Part B Carrier
- Massachusetts – NHIC, Part B Carrier
- New Hampshire – NHIC, Part B Carrier
- Vermont – NHIC, Part B Carrier

We represent two physician practices in Texas that have a robotic radiosurgery system (CyberKnife). Our goal is to offer our patients the most appropriate therapy based on their diagnosis. Treatment with robotic SRS is more closely compared to surgical tumor removal and not traditional radiation therapy. For those patients who would receive better results from surgery vs. standard radiation therapy but who are not candidates for open surgery due to health risks or other factors, should have the option of receiving robotic SRS treatment.

We also noticed with the consolidation of the LCDs for the J4 MAC that prostate cancer is not mentioned in the LCD for Stereotactic Radiosurgery. This is of great concern to our practices because we are currently treating these patients with robotic SRS. It is less costly for the patient, requires fewer treatments and tends to have fewer side effects. We hope this is an oversight but if not, we would like to discuss this further because we believe it is in the best interest of the patient.

There are many benefits to treating a prostate cancer patient with radiosurgery vs. IMRT.

- Financial savings to Medicare - the cost for radiosurgery using the Medicare OPPS payment rate is about one half the cost of IMRT, which results in a 5-digit savings to the Medicare program per patient.
- Cost savings to patients – a very real and significant financial savings for elderly patients who, in addition to the out of pocket coinsurance costs, are having to travel great distances over many days (with the cost of gas being at an all time high) to be treated with IMRT.
- Potential for fewer side effects – the patient receives only five CyberKnife treatments vs. 40-45 IMRT treatments.

We would like the opportunity to meet with you to further discuss our recommendations regarding robotic SRS treatment in the physician's office and physician reimbursement of G0339 and G0340.

Sincerely,

Tammy Chambers, Director of Contracting
CHOP Board Member
The Center for Cancer and Blood Disorders, P.A.
800 W. Magnolia Ave., Fort Worth, Texas 76104
Phone 817-333-0126, Cell 817-269-0294
tchamber@txcc.com

Lynn F. Kuhn, C.P.A., Chief Operating Officer
CHOP Board Member
South Texas Oncology and Hematology, P.A.
7979 Wurzbach, Suite U 420, San Antonio, Texas 78229
Phone 210-616-5763, Cell 210-601-4610
Lynn.kuhn@stoh.com

"CyberKnife® Medicare Payment History

"Medicare has a responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, but must also be a prudent purchaser."
MedPAC
Report to the Congress
March 2003

When assigning codes to a new technology to allow Medicare payment in the Hospital Outpatient Prospective Payment System (HOPPS), CMS has two kinds of decision to make: how to describe the technology/service (Healthcare Common Procedure Coding System [HCPCS] codes), and what resources are used to obtain the technology and provide the service (Ambulatory Payment Classification [APC] groups). For a dramatically new technology, such as the CyberKnife ® (an image-guided robotic stereotactic radiosurgery [SRS] system), adequate data needed to make these decisions are often not available at the time of the decisions. This was the case with CyberKnife and, by its own admission, CMS made a number of significant initial errors in both HCPCS and APC determinations. As a result, the treatment process was not accurately captured and the procedures were significantly under-paid.

Over time, CMS improved both their description of the clinical characteristics of CyberKnife treatment and their understanding of the resource costs associated with treatment. Separate codes were created for robotic/ non-robotic systems and for one-session treatments/sessions two through five. However, inaccuracies remain in both the HCPCS code descriptors and the APC assignments, leading to possible under-payment for the CyberKnife technology and over-payment for older, less resource-intensive radiosurgery technologies.

Medicare payment for CyberKnife treatment was further complicated by the fact that treatment was soon being provided in freestanding settings, with the potential to reduce duplicative Hospital Outpatient Centers, but no appropriate codes available for billing. After a number of years, CMS made the HOPPS HCPCS codes available for billing in this setting, but continues to leave coverage and rate determinations to the local Medicare contractor. This results in coverage and payment discrepancies that could limit or deny access of Medicare beneficiaries to CyberKnife treatment in some regions of the country.

CMS originally assigned HOPPS HCPCS codes to CyberKnife because no Current Procedural Terminology (CPT) codes adequately captured the clinical characteristics or resource use of CyberKnife treatment. Although several CPT codes pertaining to radiosurgery services have been added in recent years, CMS has thus far judged these new codes to be inadequate for CyberKnife use. CMS has indicated that it is planning to reevaluate its decision not to move CyberKnife into the AMA-controlled CPT system this year.

The goal of every CyberKnife Center and the CyberKnife Coalition is to help ensure payments for CyberKnife treatment that are accurate and adequate: to protect Medicare beneficiaries' access to treatment while helping Medicare be a prudent purchaser."[12]

[12] Provided by the CyberKnife Coalition

Erythropoietin Stimulating Agents (ESAs) and the impact on Small Businesses and Patients:

CMS has drawn conclusions as to treatment guidelines using treatment parameters based on studies that clinicians have never and do not currently use. There are many private payers who are not following the CMS National Policy Guidelines on ESA's due to this inconsistency.

With the enforcement of the new guidelines there has been a direct correlation of reduced prescriptions written for chemotherapy drugs; although this may be adverse to the small business line, the true concern lies with the patients who may be receiving reduced or delayed chemotherapy treatments because of the decreased use of ESAs. The below letter from the physicians of South Texas Oncology and Hematology is submitted for your review and consideration:

June 1, 2007

Dear Sir/Madam:

Thank you for giving us the opportunity to comment on the proposed determination by CMS that "there is sufficient evidence to conclude that erythropoietin stimulating agent (ESA) treatment is not reasonable and necessary for beneficiaries with certain clinical conditions because of increased risk of adverse events, or because of a deleterious effect of the ESA on their underlying disease."

Changing ESA prescription practices throughout the nation would return care to an early 1990's timeframe, ignoring the reality that the most effective therapeutic regimens have changed dramatically since that time. These changes have, in large part, been made possible by the level of supportive care we have been able to deliver to our patients. It will be much more difficult, for instance, to treat breast cancer patients with standard polychemotherapy regimens.

It would be very difficult to treat breast cancer patients with TAC or dose dense therapy without ESA support. With TAC, 20 percent of patients will require transfusion without ESA support, and similar numbers of patients undergoing dose dense therapies often develop grade 3 hematologic toxicity requiring transfusion. Likewise, it will be difficult, if not impossible, to administer dose dense R-CHOP to elderly patients with large cell lymphoma. These treatments are generally regarded to be more effective than earlier regimens. Similarly, our ability to deliver ABVD for patients with Hodgkin's disease in a timely fashion is largely due to our use of growth factors and ESA support.

There are several studies proving that anemia increases radio resistance to cancer of the cervix. We used to transfuse these patients routinely in the past, prior to radiation. In general, anoxia in tumors is considered one of the factors that make patients fail radiation therapy. In these days where combination chemotherapy-radiotherapy has been proven to increase local response and control in many clinical settings, anemia is undesirable. The cheapest patient is the one we can cure. The most expensive is the one who fails and requires additional treatments. Clearly, the ability to use ESAs saves patient lives.

Use of hemoglobin < 9g/dl as a point to start treatment with ESAs will require transfusions that are otherwise avoidable because hemoglobin continues to fall for weeks after ESA use begins. Evidence suggests transfusion avoidance is better accomplished by early intervention at a higher hemoglobin level, and treatment at levels < 11g is superior to treatment at levels <10 g.

Further, a rule to stop treatment after four weeks if a 1 gm rise in hemoglobin is not achieved is not consistent with the clinical trial data. A number of studies show that 6-8 weeks of treatment may be required to achieve a 1 gm rise. Further, dose escalation can be critical with these agents. A significant number of patients who fail to respond to initial treatment with ESAs will respond to a dose 50% higher.

To impose a rule to limit treatment to 12 weeks per year will not meet the needs of many of our patients who have metastatic disease and who receive chemotherapy for many months.

We have no doubt that a severe restriction in ESA, as recently proposed, would result in a dramatic increase in the need for transfusion therapy as part of routine treatment protocols. If we increase the transfusion rate of patients, we increase expense to the system through blood banks, the hospital, and the cost of irradiated products to prevent the risk of graft-versus-host disease. We cost our patients precious time in undergoing the ordeal currently required to get a transfusion in the hospital.

South Texas Oncology and Hematology, PA
7979 Wurzbach, Suite U436; San Antonio, Texas 78229

Not so easily measured, but apparent to all of us who care for patients, is the benefit achieved for these patients with higher hemoglobins. It is true that causes of fatigue in the patient with cancer are multifactorial, but anemia is undoubtedly one of the factors and it is likely active in a significant number of patients. Opportunity lost to function in society and to relate to one's family at a high level is hard to measure, but exists, and will exert a tremendous cost to our patients if they do not have access to ESAs.

While the risk of hypertension, fluid retention, and thromboembolism due to a rapid rise in hemoglobin, high hemoglobin levels, and high ESA doses can all be addressed clinically, risks associated with transfusion are not nearly as predictable or as easily managed. Certainly, we will expose our patients, who undergo transfusion, to increased risk of error rates in the hospital and transfusion reactions and infection. Theoretical, but unproven, risk of stimulating tumor growth referenced in the CMS proposal are of concern and merit continued study. But evidence that certain cancer cell types express erythropoietin receptors comes from in vitro evidence. There is no evidence from clinical trials, if functional receptors actually exist, that treatment with ESAs stimulates tumor growth or reduces efficacy of treatment. However, just as troubling is the body of literature that suggests that those patients receiving transfusion during treatment for cancer are at increased risk for poor outcomes as a result of immunosuppression.

All of us involved in caring for patients with cancer would like to find more effective means of treatment, and accordingly, we support clinical trials. Most of these trials require a hemoglobin of 9 mg/dL or greater, and if this is the point below which ESA support may be started, access to clinical trials for our patients will be diminished. We fear that progress for finding better treatment will be delayed.

Further, to exclude patients receiving VEGF and EGFR inhibitors is not based on any clinical evidence and would likely have a dampening effect on the conduct of clinical trials with new agents.

There is no clinical data to support non coverage of patients with MDS and multiple myeloma and in some patients these agents are of life changing value.

Treatment with erythropoietin stimulating agents is expensive, but so is the potential expense, both direct and in opportunity lost, of limiting the availability of these agents. We hope that we do not return to the era of the 1990's, but rather use this important issue to serve as a platform for collaboration between oncologists, patients, and the pharmaceutical industry that will lead to a better understanding of the best way to use these important agents and to provide more focused care for our patients.

Thank you for your attention and consideration of this very important matter.

Sincerely,

Lon S. Smith, M.D.
Ardow R. Ameduri, M.D.
Ronald L. Drengler, M.D.
Keith E. Eyre, M.D.
Lisa M. Fichtel, M.D.
Allison M. Garner, M.D.
Joseph R. Holahan, M.D.
Steven P. Kalter, M.D.
Amy S. Lang, M.D.
Joaquin G. Mira, M.D.
Nena Mirkovic, M.D.
Kyriakos Papadopoulos, M.D.
Amita Patnaik, M.D.
Gladys I. Rodriguez, M.D.
Luis C. Rodriguez, M.D.
Anthony Tolcher, M.D.
Scott C. Ulmer, M.D.
A. J. White, M.D.

South Texas Oncology & Hematology, PA

South Texas Oncology and Hematology, PA
7979 Wurzbach, Suite U436; San Antonio, Texas 78229

May 14, 2008

United States Representative
The Honorable Charles A. Gonzalez
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gonzalez:

I'm writing you to express my concerns about Medicare Coordination of Benefits. Medicare Coordination of Benefits is a process by which Medicare contractors gather enrollee benefit information in order to properly establish the order of claim payment to providers. Medicare Coordination of Benefit overpayments continue to cost Medicare and private insurance companies billions of dollars in unnecessary payments to providers annually.

I am a native resident of San Antonio, Texas and have been professionally employed in San Antonio's healthcare sector for fourteen years. My fourteen years of professional experience has been in the provider billing and reimbursement sector of the industry and the scope of my experience has included resolving Medicare Coordination of Benefits issues related to the population of patients served by the Practice.

The reason I'm very concerned about the issues surrounding Medicare Coordination of Benefits stems from discussions about the financial health and longevity of the Medicare program as we look at the baby boomer generation approaching Medicare eligibility and retirement. According to a February 10, 2008 publication by Walt Overfield of CNO and Associates, a private recovery auditing business that specializes in identifying overpayments for such federal programs as Medicare and Medicaid, $9.8 billion dollars in overpayments were reported in 2007 while over the last twelve years overpayments by Medicare were an astounding $188 billion dollars. While fraud and abuse account for a significant portion of the total Medicare overpayments, Medicare Coordination of Benefits overpayments cost the Medicare program significantly; these overpayments could be avoided if Medicare and private insurance contractors developed new regulations that called for the proactive monitoring of Medicare eligible/Medicare enrollees who are still working. In conjunction, the recovery of COB overpayments should be mandated within a much shorter period than what currently exists today. For health care providers, MSP is an integral component of the Medicare Coordination of Benefits process; Medicare Secondary Payer (MSP) is a tool, developed by Medicare, which health care providers can implement within their Practices to ensure coordination of benefits has been properly established. Yet, for most providers, the patient registration process has become a time consuming effort; HIPAA regulations have forced health care providers to implement additional forms into the normal course of business; requiring all Medicare enrollees to periodically complete MSP questionnaires could impact the flow of business in health care facilities across the country and those Practices, much like the one I work for, who already strive to proactively combat COB overpayments by conducting MSP evaluations are feeling the frustrations of patients who clearly do not understand the need for MSP. While Medicare enrollees continue to struggle with the concept of Medicare Secondary Payer, health care providers find it difficult placing qualified individuals in key patient registration positions who understand the complexities of Medicare Secondary Payer and Medicare's Coordination of Benefit guidelines. For patients and providers who identify Medicare COB issues, attempting to update records with Medicare seems to be a tedious task and the turnaround time on these updates could be greatly improved. Since its' establishment in 1965 under the historic Social Security Act, the Medicare program has provided health insurance for America's elderly and disabled. Since its' inception, health care costs have risen dramatically and with the wave of baby boomers reaching retirement, concerns over Medicare's viability is a huge concern; in the immediate, my concerns are for my family members and parents who are baby boomers, for my peers and those in the patient population fast approaching Medicare age, and for those already on Medicare. I cannot go without stating that my long term concerns focus on myself who, in about thirty or so years, will be of Medicare age and with talks about the Medicare Trust being depleted within in the next decade or so, what will happen to the health of Americans if health care costs are only going to continue to rise and Medicare or Medicaid may not be around to bridge the gap? These are very real economical and social concerns that if not addressed immediately will have an adverse effect on American life today, tomorrow, and in the future.

South Texas Oncology and Hematology, PA
7979 Wurzbach, Suite U436· San Antonio, Texas 78229

Medicare continues to need balanced health care reform and there is a vested interest in addressing Medicare's Coordination of Benefit processes as it relates to the solvency of the Medicare program. I am hopeful that I can count on your help to give this issue an opportunity to be heard and to receive the attention it needs. I would appreciate knowing your views on this matter and want to thank you for your time and consideration of this matter.

Sincerely,

Eric S. Orr, BSHCS, MHA
Billing Supervisor
South Texas Oncology and Hematology, P.A.
San Antonio, Texas
Office: 210.593.5927
Fax: 210.593.5899
Email: eric.orr@stoh.com

United States Representative
The Honorable **Charles A. Gonzalez (TX-20)**
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Gonzalez:

Thank you for the opportunity to speak on behalf of thousands of Medicare Beneficiaries. My name is Allina J. Rumfelt MA, PFA and I am the Admissions Manager for South Texas Oncology and Hematology in San Antonio Texas.[i] It is my role at STOH to research, educate and obtain resources for patients fighting the dreaded disease we call Cancer. It is also my responsibility to fill in any gaps patients and their physicians may experience as they go through this frightening journey.

I assist thousands of patients, family members, and staff members understand the complexities of medical coverage's and help them navigate through the myriad of rules and regulations applied to insurance and Medicare policies.

No doubt Medicare Part D has played an important role in this effort. At the onset of Medicare Part D in 2006 there was an expected adjustment period. However, as the private insurance industry continues to modify the administration of these polices, we are seeing even more complex requirements, more confused patients and increasing costs to a population vastly made up of citizens on fixed incomes.

More Complex Rules: More Confused Patients: Increased Costs: If I may elaborate:

- **Donut Hole Coverage**: While there are many plans that offer some drug coverage during the donut hole for generic prescriptions, there is not one free-standing Prescription Drug Plan (PDP) in Texas that pays for brand name drugs during the donut hole.[ii]
- **Pharmaceutical Assistance Programs**: Prior to Medicare Part D, beneficiaries were able to obtain assistance through PAP's. However, many assistance programs have specific exclusions if there is any prescription drug coverage at all.[iii]
- **Foundations:** Many pharmaceutical companies that continue to offer assistance through the donut hole redirect patients to a non for profit foundation that can take several weeks to get through the application process.[iv]
- **Formulary Finder:** Medicare Part D plans are not required to pay for all drugs and can change the drugs on their formulary during the course of the year as long as they comply with the 60 day notice to affected parties rule.
- **Exception and Appeals rules:** There are currently 55 Medicare Drug Plans available in Texas. Each drug plan has developed its own exceptions process. An unfavorable exception determination gets an enrollee into the appeals process, which further delays their treatment. If a patient's drug is dropped from the formulary in the middle of treatment patients either scramble to find a new plan that will cover their drug or pay out of pocket to continue care. In addition, non-formulary payments are not applied to the donut hole.
- **High Dollar Injectible and Infused Medications:** Many drug plans require enrollees to obtain certain biologicals and injectibles through a specialty care pharmacy. Drugs once overseen and administered under a physician's supervision are now shipped to the patient's home where they are expected to administer them on their own. [v]
- **Late Penalties: Cost Sharing: Income based Premiums:** Gray letters, orange letters, income based premiums, and lifetime penalties have created so much confusion. [vi]

Thank you again Congressman Gonzalez for the opportunity to speak on behalf of the thousands of cancer survivors who need legislative help in Medicare Part D reform.

Respectfully,

Allina J. Rumfelt CMA, PFA
Admissions Manager
South Texas Oncology and Hematology
7979 Wurzbach Ste. Z307
San Antonio, Texas 78229
Phone: 210-593-5957
Fax: 210-593-5906
Allina.rumfelt@stoh.com
www.stoh.com

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[i] South Texas Oncology and Hematology. Also known as STOH
[ii] PharmacyChecker.com: Consumer research and information related to Medicare drug Plans
[iii] MGI Pharma Inc.: Novartis Pharmaceuticals: Roche Pharmaceuticals
[iv] Genetechaccesssolutions.com
[v] Wellcare Specialty Pharmacy: Pharmacare Specialty Pharmacy
[vi] Center for Medicare Advocacy, Inc. "A Potpourri of Part D".

May 12, 2008

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515

RE: The Impact of CMS Regulations and Programs on Small Health Care Providers

Dear Sir/Ma'am,

The following is my testimony regarding the issues surrounding CMS Regulations and Programs and how they have affected Small Health Care businesses. I have been in the healthcare industry for over 18-years and have experienced several challenges as a direct result of the changes set in motion with CMS.

Of all the changes that have taken place over the last decade, reimbursements continue to have a strong ripple effect on the financial stability of small health care businesses. For many small health care businesses, Medicare sets the pace for other commercial health insurance programs outlining how much they will reimburse. Several commercial health insurance companies have setup a reimbursement fees schedule that is tied in with the Medicare's fees schedule, fluctuating there reimbursement fees with Medicare's adjustments. When Medicare increases or decreases their reimbursement allowable, these other health insurance companies automatically adjust their fee schedules accordingly.

When CMS announces they are forecasting a decrease in their fee schedule payments, the clinic administrator must also investigate how this will affect their company's financial performance across the spectrum. It is in every administrators play book to reduce the dependency on Medicare monies and focus more on commercial patients to help make up the difference and enhance their total revenue volume.

Aside from the Oklahoma Allergy and Asthma Clinic in Oklahoma City Oklahoma and the Allergy Clinic of Tulsa, there are no other Allergy and Asthma specialty clinics in Oklahoma that accepts Medicare patients. As a direct result of this limited number of Allergy and Asthma specialists, we have huge Medicare patient population. This scenario is not the exception to the rule, but rather the baseline to a much greater concern. There are a number of other health care specialists who are facing these same challenges.

In order to ensure continued financial success, small medical practices must take creative measures to ensure all their patients are receiving the best care possible. With the increase cost in medical supplies, wages, and technology, small business are beginning to experience a greater challenge finding new ways to balance the quality of live concerns and financial stability of their company.

In the year 2011, Medicare has mandated the implementation of Electronic Health Records for all health care businesses who accept Medicare payments. For the small health care business, this requirement comes with an estimated $300,000 to $800,000 price tag, depending on the size of the practice. With the potential decrease in the reimbursement fee schedule, combined with the cost to implement Electronic Health Records and rising operating expenses, many health care business are currently evaluating the economic impact between the purchasing an Electronic Health Record software or the discontinuance of treating Medicare patients all together.

On a smaller scale, however, one of which may seem trivial in nature, but has an effect on the patient's overall quality of life. Medicare has established a requirement that a physician must be present when a Medicare patient receive their immunotherapy treatment (shot). Medicare is the only health care entity that requires a physician present at the time of treatment. This restriction places undue stain on the medical staff and physician for something as little as a shot to improve the patients overall health and quality of life.

As business expenditures continue to rise coupled with more stringent regulations, CMS will experience a sharp reduction in the number of health care providers that will continue to accept Medicare patients. Any future reduction in Medicare reimbursement will affect the overall quality of life for these beneficiaries, which will in-turn continue to decrease exponentially over a short period of time. Keeping patients out of the emergency room and hospitals, while at the same time, saving money through preventive medicine practices and health lifestyle changes through education would be more beneficial than simply reducing reimbursements.

Joseph A. Schraad, MHA
Chief Executive Officer
Oklahoma Allergy and Asthma Clinic

Testimony of Rina Wolf
Vice President of Reimbursement and Regulatory Affairs
RedPath Integrated Pathology, Inc.
Before the
House Committee on Small Business
Subcommittee on Regulations, Healthcare and Trade
Wednesday, May 14, 2008

Chairman Gonzalez, Congressman Westmoreland, Congressman Altmire and distinguished Members of the Subcommittee, good afternoon and thank you for inviting me here today to share with you my experience and challenges with Medicare regulations that are not keeping pace with, and hampering the evolution of medical technology and personalized medicine in the United States.

My name is Rina Wolf and I am the Vice President of Reimbursement and Regulatory Affairs for RedPath Integrated Pathology, Inc., a genomics-based cancer diagnostics company located in Pittsburgh, PA. RedPath was founded in 2004 as the realization of the dream of renowned pathologist, Dr. Sidney Finkelstein, who's lifework has been the development of a means to answer questions around cancer diagnoses that are unanswerable through previously available technologies.

Today, RedPath operates as a fully accredited laboratory, providing complex testing services that help oncologists and pathologists to resolve indeterminate cancer diagnoses and shape cancer treatment plans. Our test, *PathFinderTG®,* is based upon a powerful proprietary technology platform that was under development for 15 years prior to commercialization. It is clinically validated with strong peer review and support,

and is being used by clinicians in major cancer centers, including half of the major National Comprehensive Cancer Network (NCCN) Cancer Centers in the US.

PathFinderTG allows earlier and more informed diagnosis of cancers, such as pancreatic cancer - a cancer that has historically been very difficult to diagnose and very aggressive. When suspected, but not definitively diagnosed, physicians typically have two options: "watch and wait" to see whether in fact cancer develops over time, or remove major portions of the patient's pancreas to definitively limit the spread of cancer. Neither is without serious consequence. Because of the aggressive nature of this cancer, waiting and thereby delaying treatment can have fatal results. However, removing major portions of the patient's pancreas out of an abundance of caution also has grave implications, including significant surgical morbidity, as well as long-term consequences, such as leaving the patient with insulin-dependent diabetes. Moreover, 70 percent of patients undergoing radical pancreatic surgeries for certain types of tumor are found not to have pancreatic cancer.

By providing a definitive diagnosis, *PathFinderTG* provides information that can help to preserve the patient's quality of life, while assisting physicians in selecting an appropriate, timely and cost-effective treatment plan. A recent study demonstrated that making a definitive diagnosis through *PathFinderTG* reduced the number of pancreatectomies on benign conditions by 34 percent.

RedPath is part of a small, but growing industry that is translating knowledge gained from the Human Genome Project into clinical practice by providing treatments that are tailored to individual patients based on their DNA and specific molecular character of their disease. By understanding the molecular nature of disease, new technologies increasingly allow clinicians and patients to pick individually appropriate treatment options, rather than basing treatment choices on broad assessments of what works best for a population. Personalized medicine has the potential to:

- Detect disease at an earlier stage, when it is easier to treat effectively;
- Enable the selection of optimal therapy and reduce trial-and-error prescribing;
- Reduce adverse drug reactions; and
- Increase patient compliance with therapy.

RedPath also is one of several new technologically-based companies providing job growth for Southwestern Pennsylvania as its economy shifts from manufacturing and service to a life science and robotics industry. A decade ago, only 1 or 2 life science companies were being created every year in southwestern Pennsylvania - which is amazing when one considers the research universities and world-class teaching hospitals located in the Commonwealth. Today, with RedPath and fellow biotechnology companies leading the way, 15-20 life science companies are being created each year in Southwest Pennsylvania.

In just 4 years, we have grown to 51 employees, and have expanded from 2,000 square feet to 20,000. And, as is the case with most life sciences companies, our workforce is

highly-educated and well-compensated. We're not just providing jobs, but better quality jobs to our region. We're also bringing venture capital money and investment dollars to the region from national funds that understand the promise of the diagnostics industry.

As you can imagine, ours is a highly regulated industry, and rightly so. Poor quality is not an option. Lives hang in the balance. It is important, in fact necessary, that federal and state authorities and non-governmental accreditation organizations provide rigorous oversight of our research, methodologies, processes and outcomes.

However, it is likewise necessary that all regulatory regimes keep pace with the rapidly evolving world of science and technology, and operate to promote innovation. Out-dated regulations and calcified regulatory agencies can stifle innovation and prevent new life-saving diagnostics and therapies from ever coming to market. They can also serve as a drag on our economy.

RedPath and similarly situated specialty laboratories are currently struggling to cope with a Medicare regulation that is threatening our very viability and patient access to *PathFinderTG*.

Medicare has two regulations that together operate to stymie access to these life-saving diagnostics. First, Medicare's "date of service" regulation (42 C.F.R. § 414.510) generally provides that any test furnished within 14 days after the patient's discharge from a hospital is deemed to have been performed on the day the specimen was

collected, for example, when the blood was drawn or tissue biopsied. In other words, the date of service will be when the patient was in or at the hospital. Intuitively, this rule makes no sense given that the *PathFinderTG* and other specialized laboratory tests are typically performed and reported to the treating physician after the patient has left the hospital, and the results are used for management of the patient following discharge from the hospital, and bear no relationship to the services furnished to the patient during the hospital stay.

Under separate Medicare rules (42 C.F.R. §§ 411.14(m) and 410.42), hospitals are obliged to assume professional and financial responsibility for tests furnished during a patient's hospital stay. The combination of these rules creates a host of financial and administrative problems and disincentives for hospitals to allow access to our technology. For example, Medicare's bundling rules require hospitals to exercise professional responsibility over all services they provide, even those for which they contract. Hospitals are unwilling to assume professional responsibility for tests like ours that are not offered by the hospital, and which are, in fact, offered by laboratories that are completely unfamiliar to the hospital, and may not even be ordered by a physician affiliated with that hospital. In one common scenario, a hospital may physically possess a patient specimen as a result of a procedure that was performed at that hospital. The patient decides to have a consult at a completely different institution. The second institution makes the determination that a *PathFinderTG* is medically necessary. As a courtesy, the first hospital will forward the specimen to RedPath for testing. Because of Medicare's rules, the first hospital is now professionally responsible for the test, even

though it had nothing to do with ordering the test, does not furnish the test, and does not see the results.

Additionally, hospitals also have financial reasons to block these tests. Because Medicare requires that the hospital bill for services furnished during the hospital stay (even when the services technically are not furnished during the hospital stay, but are related back to the hospital stay by the date of service rule), the hospital must assume the financial risk that the service is covered and that Medicare will pay for it, or, in those instances where a specimen was collected as part of an in-patient stay, absorb the cost of these tests as part of their Medicare DRG payment.

In light of these and other administrative and financial disincentives, hospitals are encouraging physicians to delay ordering the tests until after the 14 days; others are cancelling orders altogether. Imagine, if you will, that you or someone you love is faced with a suspicion of pancreatic cancer. After the biopsy, it usually takes two to three days for a traditional pathology analysis to determine whether cancer is present. If that analysis were inconclusive, and a need for *PathFinderTG* testing was indicated and subsequently ordered by the patient's treating physician, the hospital may seek to delay sending the specimen to RedPath for two weeks until the 14-day time period lapses. From the time RedPath receives the specimen, it typically takes another five days to get a result. Consequently, three to four weeks pass before the patient receives a diagnosis of whether cancer is present. Besides the tremendous anxiety while waiting for this answer, if there was a diagnosis of a malignancy, the additional time before

treatment or surgery could affect the outcome. Physicians and patients are faced with an untenable choice: order the test when it is clinically appropriate, or artificially delay ordering the test (and initiating therapy) until such time as the specialty laboratory can accept full responsibility for its service and liability for Medicare's reimbursement. This leaves the patient and physician in limbo at a time when each passing day can have clinical consequences, and when they are desperate to make critical treatment decisions to determine if there is cancer and, if so, arrest the spread of cancer.

In January 2008 alone, 66-percent of specimens for Medicare beneficiaries that would have been the hospitals' responsibility to bill were cancelled when the hospitals learned they were responsible for furnishing the test under arrangements.

CMS almost certainly did not intend for Medicare's date of service rule to restrict access to specialized *in vitro* diagnostic tests as it is. Nonetheless, the rule remains in place. RedPath and other similarly situated laboratories, as well as the American Clinical Laboratory Association, have met with CMS, including the agency's senior leadership, on numerous occasions about this issue. We appreciate the agency's willingness to meet with us and review these serious issues; we remain hopeful that CMS will propose a new remedy for this problem in the forthcoming update to Medicare's physician fee schedule this summer. It is completely within CMS's authority to make the necessary change.

It is important that payors, especially public payors, establish reimbursement policies that enable them to be good stewards of public funds. However, it is more important that these policies take a broad view, and not be pound foolish to be penny wise. The federal government should be a prudent purchaser of healthcare items and services, but also enable patient access to new technologies, especially those that can ultimately save patients and taxpayers money – for example, by avoiding unnecessary and expensive surgeries. Federal health care agencies also should seek to promote technological innovation and support companies that are vital economic engines.

I applaud this Subcommittee for studying and focusing attention on this important area, and implore CMS to remove this impediment to the promise of personalized medicine. Again, thank you for inviting me here today and for listening to my statement. I would be delighted to take questions.

Home Care: Keeping Texans Proud and Independent

Statement of Mary Helen Tieken, R.N., B.S.N.
Owner/Administrator, Nurses In Touch, Inc.
President-Elect, Texas Association for Home Care

ON

The Impact of CMS Regulations and Programs on Small Health Care Providers

Before the House Committee on Small Business
Subcommittee on Regulations, Health Care and Trade

May 14, 2008

3737 Executive Center Drive, Ste. 268, Austin, Texas 78731 ★ (512) 338-9293 ★ fax (512) 338-9496 ★ www.tahc.org

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Hearing on
"The Impact of CMS Regulations and Programs on Small Health Care Providers"

May 14, 2008

Chairman Gonzalez, Mr. Westmoreland, distinguished Members of the Committee, thank you for inviting me here today to discuss the impact of CMS regulations and programs on small health care providers, particularly small home and hospice care providers.

My name is Mary Helen Tieken. I am a registered nurse and the owner and administrator of Nurses In Touch, Inc., a Medicare-certified home health and hospice provider located in Floresville, Texas. I have operated this company since 1990, serve 280 patients over 16 counties, and have 185 employees. I am also here today as the President-Elect of the Texas Association for Home Care, a non-profit trade association that represents more than 1,200 licensed home and community support services agencies that provide home health, hospice and personal assistance services in Texas.

I come before you today to share the impact of regulations and policies issued by the Centers for Medicare and Medicaid Services (CMS) have on small providers. Home health agencies and hospices face numerous challenges in delivering quality services to Medicare beneficiaries. We frequently must adhere to policies that were instituted many years ago that are no longer relevant when delivering services in today's world. In other cases, we must deal with policies that do not reflect the challenges we face in operating a business that serves Medicare beneficiaries.

I will address five such CMS regulations and programs that directly impact small providers in the home health and hospice industry.

I. One Service Provided Directly By Employees

Section 2180D of the State Operations Manual requires that all home health agencies must provide skilled nursing services and at least one of the following other therapeutic services: physical therapy, speech language pathology, or occupational therapy; medical social services, or home health aide services in a place of residence used as a patient's home. The agency must provide at least one of these six services directly and in its entirety by employees of the agency. CMS considers a service to be provided "directly" when the person providing the service for the agency is an agency employee for whom the agency must issue a Form W-2.

This requirement makes it extremely difficult for agencies to respond to sudden changes in patient needs and caseload. The current nationwide shortages of nurses and therapists have made it increasingly difficult for Medicare home health agencies to satisfy the requirement to provide one of their services entirely by their own employees at all times. Agencies must have some flexibility to use contracted staff when necessary to meet unique patient needs and accommodate fluctuations in caseloads. This is particularly true for small home health agencies who serve primarily rural areas like mine, as I do not have the resources to add more employees when my caseload may temporarily increase.

CMS claims that this policy is needed to ensure that agencies are not simply "shell" companies staffed by employees of a staffing company, but the "all or nothing" application of this requirement results in small agencies lacking needed flexibility to adapt to changes in their caseload.

II. Telehealth As A Reimbursable Cost

The use of technology, such as telehealth, that results in more efficient and effective delivery of health care services should be encouraged. However, CMS does not recognize telehealth technology and visit costs as reimbursable under the Medicare home health benefit. Studies indicate that some activities performed by a home health nurse can successfully be done remotely through telehomecare while maintaining or improving quality of care and patient satisfaction. In fact, the Quality Improvement Organizations (QIOs) designated by CMS to assist health care providers to improve their quality of care have urged home care agencies to adopt telehealth interventions for patients with certain diagnoses because they can result in larger yet cost effective improvements in quality of care compared to other types of interventions.

However, small agencies such as mine are unable to invest in such technologies because those costs are not recognized as reimbursable, and there are few resources available to small businesses to make such investments. If CMS moves beyond a pay for performance pilot project for home health services and expands this to all Medicare home health agencies without changing this policy, small agencies like mine will be perpetually disadvantaged by their inability to invest in telehealth technologies to the same degree as larger agencies.

III. Signature Of Home Health Plans Of Care By Physician Assistants And Nurse Practitioners

Nurse practitioners (NPs), clinical nurse specialists (CNS), certified nurse midwives (CNMs) and physicians' assistants (PAs) are playing an increasing role in the delivery of our health care. Many state laws and regulations authorize these non-physician health professionals to complete and sign medical certification documents, and the Balanced Budget Act of 1997 (P.L. 105-35) allowed Medicare to reimburse PAs and NPs for providing physician services to Medicare beneficiaries. In addition, CMS now allows PAs and NPs to sign orders for Medicare hospice services, but not the certification of terminal illness.

However, PAs and NPs and other non-physician health professionals are still prohibited from certifying and signing orders for home health services provided to Medicare beneficiaries. According to CMS, the Medicare statute requires "physician" certification on home health plans of care.

PAs and NPs are increasingly providing medical services to Medicare beneficiaries, especially in rural and underserved areas, and are sometimes more familiar with the particular patient's needs than the attending physician, so allowing PAs and NPs to sign the orders may be more appropriate. In addition, PAs and NPs are sometimes more readily available than physicians to expedite the processing of paperwork, ensuring that home health agencies will be reimbursed in a timely manner and that care to the beneficiary will not be interrupted. Home health agencies cannot submit a final bill for payment without all orders being signed.

For a small agency such as mine located in a rural area, we spend a significant amount of staff and administrative time tracking physicians down to sign orders for treatments and services they ordered for their patients. In some cases, we must literally "camp out" in the physician's office to wait for them to sign their orders. If NPs, PAs, and other non-physician health

professionals could sign the orders, it would reduce our administrative costs and allow us to bill more timely for the services we have provided.

IV. Gas Prices

Rising gas prices have an immediate impact on home health and hospice care, as we are unique among all services provided to Medicare beneficiaries. We travel to the patient because the patient is unable to travel to obtain the care they need. Since patients do not come to us as they do when they seek services at a physician's office, hospital, outpatient clinic, or nursing facility, we incur an additional cost in delivering services that no other provider can claim because we travel to see each and every patient.

Gas prices in Texas have increased more than 25 percent in the past three months and more than 150 percent in the past five years, with no signs of letting up. In 2007, my staff drove 700,000 miles to see home health and hospice patients. The area of Texas that I serve is primarily rural—there is no public transportation that my staff can take to see patients in order to save money. I do my best to ensure that my staff knows which routes will minimize the amount of driving they do. It is not unusual for my nurses to drive more than 100 miles per day. As a small Medicare provider, I don't have the resources to lease a fleet of cars to my staff, as I know some larger agencies have done to cope with this rapidly increasing cost. Rising gas prices have also deterred nurses and therapists from even working for home health agencies and hospices because of the amount of driving involved.

The reimbursement methodologies for home health and hospice services have no way to account for this particular factor that disproportionately impacts their costs compared to other Medicare providers. Home health reimbursement rates are adjusted using a hospital wage index and general inflation indices, which are not accurate or appropriate indicators of home health agency costs. Paying the Internal Revenue Service's mileage rate of $.50 per mile is not an option for most small providers under the current reimbursement methodology. It is imperative that CMS change its rules to reflect the impact of this disproportionate cost on home health and hospice providers through the reimbursement methodology rather than using inappropriate adjustors such as the hospital wage index and general inflation indices.

V. Contingency Plans For Claims Payment Delays

This year marked the first time that CMS had made a substantive change in the home health prospective payment system (PPS) methodology since its inception in 2000. These "refinements" significantly increased the complexity of the methodology in order to more appropriately match payments to patient resource needs. While these refinements were generally supported by the home care industry, there was grave concern that claims payments could be significantly disrupted during the transition. This concern was based on experience from previous years, when "routine" changes in payment amounts that required software and computer programming changes resulted in claims payment delays and/or inappropriate denials of claims that lasted several weeks.

In 2000, CMS created a "contingency plan" during the transition to PPS whereby home health agencies could request advance payments based on their claims payment history if delays in payment occurred. The home care industry requested a similar type of contingency plan be put in place for 2008 during the rulemaking process last year. However, CMS refused to provide for such a contingency plan, stating that they were taking steps *"...internally, to test systems changes before implementation. We do not feel that the vulnerabilities that existed when we moved from a cost-based system to a prospective payment system exist today in moving to a refined HH PPS. Consequently, we do not feel it is necessary to create an elaborate contingency plan as was needed for the implementation of the HHS PPS."* [72 FR 167 p. 49769]

I am here to tell you that now, five and one-half months after the implementation of this refined PPS methodology, CMS is still installing "software fixes", agencies frequently receive only 40 to 50 percent of the episode payment that they are owed, and claims are mysteriously "suspended" for weeks at a time before being released for payment. At the beginning of 2008, it was three weeks into January before any home health agencies saw any claims being paid. Disruptions of this length and magnitude did not occur during the 2000 transition. Many small agencies that I know have had to take out lines of credit with high interest rates (due in large part to the soft economy) just to meet payroll because CMS is still unable to deliver software to their claims payment contractors that will actually pay claims correctly and timely.

CMS claims that this is not a valid concern because agencies are still getting paid (unfortunately not the correct amount) and they are paying claims within the mandated time limit

once they are released. However, this is difficult to absorb for a small business when cash flow is half what it used to be and employees and contractors expect to be paid on time.

These types of "technical problems" disproportionately hurt small agencies. CMS's lack of a contingency plan should not result in providers being unable to maintain their ongoing operations. CMS should be required to have contingency plans in place that are accessible for all Medicare providers when there is a change in the reimbursement system that results in substantive disruptions in claims payments.

The foundation of the Medicare home health and hospice benefits are small companies such as mine, who struggle daily against a mountain of regulations, bureaucracy and paperwork with the simple goal of providing quality services to Medicare beneficiaries. Yet, at times, CMS's policies and regulations sometimes seem to lose sight of that goal and make it difficult for small businesses, like mine, to operate effectively. Thank you again Mr. Chairman and Members of the Committee for the opportunity to testify before you today.

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