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MEDICARE ENFORCEMENT ACTIONS: THE FEDERAL GOVERNMENT'S ANTI-AGING EFFORTS

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

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MEDICARE ENFORCEMENT ACTIONS: THE FEDERAL GOVERNMENT'S ANTI-FRAUD EFFORTS

THURSDAY, JULY 26, 2001

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 10:03 a.m., in room SD–124, Dirksen Senate Office Building, Hon. John B. Breaux (chairman of the committee) presiding.

Present: Senators Breaux, Carper, Craig, Collins, and Ensign.

OPENING STATEMENT OF SENATOR JOHN B. BREAUX, CHAIRMAN

The CHAIRMAN. The committee will please come to order.

Good morning, everyone, and thank you all for being with us.

I would like to begin the hearing by thanking Senator Larry Craig for his initiative in this area, started before the changeover in the Senate. We are still trying to work in a cooperative fashion in order to complete some of the things that he took the lead on when he was chairman of this committee, and we will, of course, continue to try to make sure that these issues are addressed because they indeed are very important. I also want to thank the witnesses who will be with us this morning and look forward to hearing their testimony.

I think all of us in the Congress, and I know that I have spent a great deal of time trying to do whatever is necessary to improve the Medicare system. It is an incredibly important system that provides medical coverage to over 40 million Americans, and indeed in the future, it is going to be increasingly important as the baby boom generation becomes eligible for this very important program.

The challenges are great. I honestly think that we have to make major changes in the system. One reason why we have problems that we are addressing today is because of the fact that the Medicare program which was designed in 1965 micro-manages health care in this country. That is completely and totally unacceptable in the 21st century as far as I am concerned.

It is ludicrous for members of this committee and others to have to sit on a regular basis and try to micro-manage how much we pay for each product that each provider provides to the seniors who are the beneficiaries. We cannot continue to do that.

When we talk about adding a prescription drug program to Medicare, it is truly inconceivable that somehow, Members of Congress will sit and determine how much we are going to pay for each pill.

Obviously, spending $270 billion a year to medical providers to serve the needs of the beneficiaries is very complicated. There are bound to be mistakes. Any time you have that much money on the table, there are also bound to be people who will try to scam the system—and some have done it very successfully.

It is interesting that we have had people testify before this committee who have actually had to be let out of the penitentiary in order to come and testify, because they have fraudulently misused some of the programs that the Government and the taxpayers provide to serve the needs of people who have health concerns.

That is not to say that that is reflective on the providers at-large. There are literally millions of providers who play by the rules, abide by the rules, and provide top-quality medical services to the people of this country. American hospitals, home health care providers, durable medical goods suppliers all, by and large, play by the rules.

The question is how do we enforce the rules, and the subject of the hearing today that Senator Craig has laid out addresses some of these very important questions.

There have to be rules, and the rules have to be enforced, because if we do not do that, we will obviously have chaos. So the question is how do we enforce the rules in a way that is fair to everyone and ultimately fair to the beneficiaries and to the taxpayers. That is the challenge.

I would now like to recognize Senator Craig for any comments that he might have.

STATEMENT OF SENATOR LARRY E. CRAIG

Senator CRAIG. Mr. Chairman, again let me thank you and your staff for facilitating this hearing and working with myself and my staff and the work that had been done prior to you becoming the chairman and being willing to move forward on the issue of Medicare enforcement.

Let me make it clear this morning that we must continue to devote significant resources to combatting fraud in Medicare programs. Those who violate the public trust I think have to be punished to the fullest extent of the law.

Chairman Breaux has already outlined, I think, the complex character of this issue and the fact that it is a substantially large ticket item.

Having said that, however, I believe it is equally important that we also take a step back and seriously evaluate the full effects, both good and bad, of our Medicare enforcement efforts. I know of no other person in the Senate who has devoted as much time to making Medicare work as has John Breaux. Now I am committed, as are many others, to working with him to have a positive, functioning program for those who are eligible and participants in it.

I began to listen to my seniors in Idaho as they expressed to me their deep concern and the difficult time they were having finding doctors who would accept new Medicare patients.

Physicians in turn generally identified three major reasons for limiting Medicare participation—first, the complexity of Medicare regulations; second, the alleged concerns about payment rates; and third, the alleged unfairly aggressive enforcement activities of Federal agencies.

Providers tell me they are deeply fearful of exposing themselves to zealous audits or dramatic penalties for innocent errors—errors which frequently result, ironically enough, from the very complexity of the Medicare rules being enforced. We want them enforced, but in the process, as Senator Breaux has said, we have made them so complex in the business of micro-managing that they may now be the problem.

Specifically, I have been hearing from physicians and other health care providers in my State who are simply overwhelmed by the documentation required for the Medicare program. Many are also now so terrified—and that is the word they use—of being caught up in an audit or enforcement action, that they are spending significant resources, both in terms of money and time, on compliance which has become a very major part of their time.

Compliance officers, consultants, attorneys, internal audits, endless documentation—these represent resources diverted from patient care. I think we need to fight genuine fraud—there is no question about it, and the chairman and I have no disagreement there—but we also need to care for the provider making the good faith effort to comply with the law, and we should provide an environment where the provider does not have to live in fear or chooses to not care for the patients that he or she might otherwise have within their health care system.

Through these inquiries, I hope the committee can begin to assess whether fear of overzealous enforcement is justified. If it is, we will correct the problem. If it turns out that the providers' concerns are overblown, I want to hear that. I think all of us are here this morning to listen to the witness panel that this committee has assembled.

We need to take a hard look at the incentives that exist in the system and ask whether they place too much emphasis on money and collection and not enough on combatting true fraud.

We also need to look at overlaps of the authority exercised by various Federal enforcement entities, principally, CMS, the HHS Inspector General, and the Department of Justice. Where is this overlap helpful, and where is it duplicative or even coercive? Where does there need to be more coordination among the agencies?

I am very pleased that the GAO is among our witnesses here today. They will discuss the work that they are doing currently. Following this hearing, I hope to work closely with John and the committee and to engage with GAO in expanding and deepening the inquiries on these important issues.

Mr. Chairman, enough said. I am pleased that our colleague, Susan Collins, has joined us this morning. This is an issue that is critical. We now have a Secretary, Secretary Thompson, who announced last week that he is forming a group of experts to look into ways in which we can reduce the burden on providers without increasing costs or undermining the quality of care. I am confident that if we work together collectively as a team, this administration,

this committee and our staffs, and certainly CMS and others, can solve this problem.

Thank you.

The CHAIRMAN. Thank you, Senator Craig.

Senator Collins, do you have any opening comments?

STATEMENT OF SENATOR SUSAN COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman.

Senator Craig, first let me apologize for swiping the microphone from you prematurely. I thought that was your last sentence. [Laughter.]

Mr. Chairman, Senator Craig, let me start by applauding both of your efforts to strengthen the Medicare program by ensuring that the Medicare trust fund is protected from those who engage in fraud and abuse.

Under my chairmanship, the Permanent Subcommittee on Investigations undertook an extensive investigation and held several days of hearings over a 2-year period on the issue of Medicare fraud. What we found was truly alarming. In one instance, we found that career criminals posing as health care providers were responsible for as many as 169 sham medical entities, billing for services and equipment that were either never provided at all or were not medically necessary.

We found cases of criminals who posed as health care providers, stole beneficiaries' numbers, and then billed Medicare for literally hundreds of thousands of dollars.

What was most striking to me, however, in those hearings was the testimony of one felon who said that he used to be a drug dealer, but he turned to Medicare fraud because it was much more lucrative, much easier, and much safer. That was really startling testimony.

According to the most recent report issued by the Office of Inspector General, in fiscal year 2000, waste, fraud, abuse, and other improper payments drained almost $12 billion from the Medicare trust fund in fiscal year 2000. I know we would love to have that money as we are working on Medicare reform and prescription drug coverage.

I want to indicate that that figure is certainly an improvement—a few years ago, it was up to $23 billion in improper payments—but it is still a staggering amount of money and far too high.

Those who commit Medicare fraud hurt legitimate health care providers, cost taxpayers vast sums of money, weaken the Medicare trust fund, deliver substandard services, and endanger our elderly by not providing needed medical treatment.

However, I think it is very important to note—and Senator Craig has made this point—that the vast majority of health care providers are dedicated, honest professionals whose top and indeed only priority is the welfare and health of their patients. They too are just as appalled as we are by outright criminals and unscrupulous providers who steal millions and indeed billions of dollars from the Medicare program.

Sometimes errors—outright errors, not fraud—do occur, and we must not harm those health care providers who inadvertently com-

mit billing mistakes. This is a complaint that I hear from the physicians in my State regularly.

It is vital that those at the Centers for Medicare and Medicaid Services be able to distinguish between honest and innocent billing errors and outright fraud. It is also important that Government agencies responsible for fighting Medicare fraud coordinate their efforts to avoid unnecessary duplication and that those providers who have been accused of billing improprieties have an opportunity to appeal those decisions in a timely manner.

Moreover, it is imperative that the Centers furnish health care providers with the necessary tools to make certain the claims they submit are correct. I hear numerous complaints about the complexity of regulations and guidelines, and physicians and other providers have told me that sometimes they simply cannot even get an answer from the agency, no longer known as "HCFA"—I understand you get fined in the Department if you call it by its previous name. The point is that the Medicare program and its regulations have become increasingly complex, and it is simply not fair to hold a provider who is trying to comply with the law and the regulations accountable if the agency has not properly disseminated the relevant information, and given the kind of guidance that providers are seeking.

I am very pleased that the new administrator, Mr. Scully, who is with us today, as well as Secretary Thompson, have expressed their intent to improve efficiency and expand educational outreach and work more closely with providers.

I also believe that we need some legislative reforms in this area, and I am pleased to be a cosponsor of the Medicare Education and Regulatory Fairness Act.

Protecting the Medicare trust fund from unscrupulous individuals is a serious responsibility. We must strike the right balance. We must not be overzealous in our efforts and harm innocent providers in the process while ensuring that those who would rip off the Medicare fund are dealt with severely.

Thank you, Mr. Chairman, Senator Craig, for holding these hearings, and I appreciate the opportunity to give this statement.

[The prepared statement of Senator Collins follows:]

PREPARED STATEMENT OF SENATOR SUSAN COLLINS

Mr. Chairman, I applaud your efforts to ensure that the Medicare trust fund is protected from those that seek to unjustly enrich themselves by means of fraud and abuse. Under my chairmanship, the Permanent Subcommittee on Investigations conducted an extensive investigation into the abuses of Medicare. In one instance, we found career criminals posing as health care providers that were responsible for as many as 169 sham medical entities billing for services and equipment that were either not provided or not medically necessary.

According to the most recent report issued by the Office of Inspector General for the Department of Health and Human Services, in fiscal year 2000, waste, fraud, abuse, and other improper payments drained almost $12 billion from the Medicare trust fund in fiscal year 2000. While that figure is certainly an improvement from the $23 billion in improper payments that the Inspector General reported a few years ago, it is still a staggering amount of money, and far too high.

Those who commit Medicare fraud drive legitimate providers out of business, cost taxpayers vast sums of money, deliver substandard services, and endanger our elderly by not providing needed treatment.

However, as I have pointed out on numerous occasions, the vast majority of health care providers are dedicated, honest professionals whose top priority is the welfare

of their patients. They, too, are surely appalled by the unscrupulous providers and others who take advantage to steal millions of dollars from the Medicare program.

Sometimes errors do occur and we must not harm those who inadvertently commit billing mistakes. It is vital that those at the Centers for Medicare and Medicaid Services (CMS) be able to distinguish between innocent billing errors and fraud. It is also important that the government agencies responsible for fighting Medicare fraud coordinate their efforts to avoid unnecessary duplication, and that those providers who have been accused of billing improprieties have an opportunity to appeal those decisions in a timely manner.

Moreover, it is imperative that CMS furnish health care providers with the necessary tools to make certain that claims are submitted correctly. The regulations and guidelines of the Medicare program have become increasingly complex, and it is unfair to hold providers accountable if the agency has not properly disseminated the relevant information. Thomas Scully, CMS Administrator, has expressed his intent to improve efficiency and expand educational outreach at the agency, and I look forward to his testimony.

Protecting the Medicare trust fund from unscrupulous individuals is a serious responsibility but we must not be overzealous in our efforts and harm innoncent providers in the process.

Mr. Chairman, thank you for holding this morning's hearing.

The CHAIRMAN. Thank you very much, Senator Collins, for your involvement and participation and your observations.

We are pleased to welcome as our first witness the Administrator of CMS, the Center for Medicare and Medicaid Services, Mr. Tom Scully. We deal with Mr. Scully on a regular basis both in the Finance Committee and obviously on this committee as well.

Previous to his service as Administrator, Mr. Scully was head of the Federation of American Hospital Associations, representing privately owned hospitals in the country. I think that that knowledge and experience will be helpful in the position that he holds now.

We are delighted to have you appear and look forward to your testimony, Mr. Scully.

STATEMENT OF THOMAS SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. SCULLY. Thank you, Mr. Chairman, and Senators Craig and Collins, for having me here today.

I have worked with all of you for years, especially Senator Breaux, I think, since I was in the first Bush Administration trying to reform the health care system and make Medicare better. I am glad that, after a long sabbatical, I have been able to come back to the Government, and I look forward to working with you.

I have, in fact, become one of the bigger creditors in the Department, because I think I owe the Secretary a couple hundred dollars for slipping back into "HCFA" myself. I have to pay him a buck every time I refer to it as "HCFA"—but I am getting better.

Anyway, one of the first steps we took—and I will return to the fraud, and in my view, balance, as Senator Collins mentioned, is the key on that issue—but I want to run through some of the things that we have changed at CMS, the agency formerly known as HCFA, and why we have made some of the changes and some of the things that we are actually doing.

Secretary Thompson, as you all know, was probably one of the great HCFA-haters of all time, because as Governor of Wisconsin, he was pretty frustrated and had a very bad experience, he felt, with HCFA on Medicaid issues primarily. But he is a very open-minded and creative guy, as you know, and one of the best things

he did, before I was even confirmed, was to come up and spend a week at the then HCFA, now CMS, with me in Baltimore. And he found out what I already know, which was that the people up there are actually very dedicated and very good. They really know the programs, they work hard, and they really do try to do the right thing. But after years and years of pounding, for a variety of reasons, some deserved and some undeserved, they became kind of insular, and they are not particularly good at explaining what they are doing and what their policy rationales are.

We are going to push hard to change that, but one thing the Secretary felt strong about, from going up there the first week, was that HCFA's people are good, they do a good job, much better than he had expected, but HCFA has a lot of baggage, and he felt, as did I, that very few people outside the Beltway knew what HCFA was. The States know Medicare; seniors love Medicare; nobody liked HCFA. It is a small first step, but we felt that if you are trying to change the image of the agency, both internally in the way people think about the agency, and externally in the way the country thinks about the agency, that changing the name was a good idea.

We did seven focus groups around the country. We had an employee contest within the agency, and came up with "Centers for Medicare and Medicaid Services," because that is what we do—we provide services in Medicare and Medicaid—and we think that that is more representative than HCFA. But deserved or undeserved, HCFA had a bad name, and we think "CMS"—it may not help us a lot, but at least it is a little breath of fresh air to get a clean start and try to show that we are determined to change the agency.

It is a big agency. The budget of the agency, if you combine Medicare and Medicaid, is $470 billion this year, which is pretty big. The Medicare program alone is $240 billion. So it is a big ship to turn, it is not easy to do, it is a complex program, but we are determined to do it.

I just want to run through a few things before we get into the fraud issues that we are focused on doing. In addition to concerns about overzealous fraud efforts, we found a lot of concern about the perception that CMS is insensitive and the program is insensitive, to the issues that your hospitals, your seniors, your doctors, and everybody around the country raise. We have tried to make big efforts to address that.

There are three efforts that the Secretary announced last week, and the Ways and Means Chairman, which I have worked with them on. The first is basically to improve outreach outside the Beltway, the second is to improve outreach inside the Beltway, and the third is to stir up a little more creative thinking within CMS.

It started out with the Secretary going to do field hearings, and it ended up with me going to do field hearings. We are going to start later this month doing outreach field hearings around the country—we have already scheduled three in late August in Montana, Arkansas, and Chicago—and we will continue to do that as long as I can remain married and have a family. We want to spend a fair amount of time out there, trying to talk to people outside the Beltway, to tell them what we are trying to do at CMS, make a much bigger effort to hear what their problems are and how they

want to fix the agency, and to talk to people who actually run facilities, and doctors who actually have to practice under these guidelines, to figure out things that we can fix day-to-day.

The second, which we also announced last week, are seven what we call our "open door policy groups." There is one each for physicians, hospitals and rural health, long-term care, health plans, nurse and allied health professionals, home health and hospice, and ESRD and dialysis. In each of those groups—we had initial meetings last week—we are going to try to meet with everybody involved. For instance, I picked the long-term group to chair myself—I will be involved with all of them—but I met last week, in the first meeting, with Ray Scheppach, who is executive director of the NGA, who will co-chair that group with me; with Chip Groveman, who runs the biggest nursing association; with the SEIU, which is the biggest nursing home union; the AARP, whom I have a great relationship with and work with every day.

That was the beginning of figuring out how we can broaden the scope and get virtually everybody with a significant interest in long-term care to sit in a room and talk about what we can work out. As you all probably know, it is not often that the nursing homes and their unions agree on things, so my expectation here is not to fix long-term care reform—although I hope that will be an issue and we will talk about it—but day-to-day, there are lots of problems with nursing homes, hospitals, and dialysis clinics that we can fix, and there are lots of burdens that we put up, as an agency, that we can tear down and make better.

So my goal is to get everybody around the table with all the different groups in Washington, come up with issues that we can fix, and methodically churn through them and fix them. If we can get to bigger reform issues, terrific, but day-to-day managing the agency more efficiently, reducing the burdens, and finding the right balance on a regulatory basis, is clearly the goal here, and I think it will work.

As a former Hospital Association CEO, I sat around with the AHA and the Catholic Health Association, the public hospitals, and all the other groups every week and talked about our issues, and somebody would eventually wander over to CMS/HCFA and talk to them about it. So my view was why not have HCFA and CMS in the room with these groups to begin with to understand their problems up front and try to resolve them as they come up. I expect that it will work—I do not see why it cannot—but it is going to be an effort to engage every group from the providers, patients, seniors, across the board earlier in our decisionmaking process and find out what we can fix for them.

Third, the Secretary announced that he wanted to put together a group of internal folks in CMS to get the CMS staff to start coming up with new ideas to reduce regulatory burdens, or at least make them better where they should be, and fewer where they should be. I think some people perceive that as "We are from the Government, and we are here to help you." That is not going to happen. We do have terrific staff, but to make sure that I drove them to more creative ideas, I recruited a doctor who ran the Alexandria Hospital emergency room for years and now is an actual practicing physician in Northern Virginia, running an emergency

room every day, to come and work with us 1 day a month, and he is going to chair that group to try to push our employees. He has to actually go back and explain to his doctors and nurses and hospital colleagues every day what he has come up with. His name is Bill Rogers, and he is a long-time practicing physician in this area, and he actually has to go back and run his emergency room every day. So I hope that the combination of him coming in and meeting with some of our more creative employees, and bringing back his ideas every day, will get their juices going to come up with some new ideas to reform the agency and make it work better.

We have also announced streamlining the regulatory process. In another career, after I was thrown out of Government the last time, I was a health care lawyer, and I know that I was paid rather outrageous sums to read The Federal Register every day to figure out what was going on. So one of my other ideas, which we have also implemented, is that we are going to put out a compendium of all the HCFA regs once each quarter. So for instance, in the fourth quarter this year, we are going to publish a list of everything that is going to come out in that quarter—if it is not on that list, it will not come out—and then, one day a month, we will publish all of our rules in The Federal Register, so that if you are a provider, or a physician, or a hospital, or a nursing home—anybody who is interested in what CMS is doing across the board—one day a month, you will have advance notice of what the regulatory agenda is, and you will only have to look in The Federal Register one day a month to figure out what is coming. It is a small reform, but I think the perception of the outside world, fairly or unfairly, is that CMS/HCFA has had regulatory strafing runs, and you have to hire a full-time law firm just to follow what we are doing. So the effort here is to reduce that effort.

As far as responding to other needs, I think I have spoken to all of you individually at various times. When I came into OMB, I was the health care person at OMB in the White House in the last Bush Administration for 4 years, and I remember when I got there in 1989, I said "The Medicare contractor system is outrageous. We have 72 contractors. How can anybody possibly manage this program? We are going to get it down to 10." And I failed miserably and came back 10 years later, and we have 51 contractors.

I think one of the fundamental problems with the Medicare program is that we have 51 contractors. It is a construct of 1965. It is crazy. It is one of the things that drove Secretary Thompson crazy. When he went up to CMS, then HCFA, and learned how it worked, he could not believe the way we contracted to pay claims in Medicare. CMS does not pay claims. It is generally the Blue Cross plans, Mutual of Omaha, EDS that pay claims for us. It is a construct of a very antiquated system, and we are determined, hopefully with your help, to pass contractor reform this year, and our goal is to work cooperatively with our existing contractors to find the best ones, to get it down to 18 to 20 contractors nationally—they will probably be the Blue Cross plans—to work with them on better systems, to work with them on better, more responsive rules for dealing with providers and patients, and to get to a point where we have good, well-incentivized contractors.

Medicare contractors, for example, have cost-plus contracts; they have no incentive—they do not make any money, theoretically—I do not really believe that, and I do not think anybody else does, either. It is like the old hospital-based cost system. Theoretically, you do not have any profit incentive in there, but the reality is that they shift costs around. But there is very little incentive for our contractors to really do a good job for us in the long run. We would like to change that and restructure the Medicare contracting system where we can come up with 18 to 20 good, well-motivated, incentivized contractors that we like, that we work well with, and give them the appropriate financial incentives to perform for us. And I think that you will find that in the long run, that may have as much to do with streamlining and improving the Medicare payment system as just about anything else.

There is a variety of other things that we are involved in. We have an educational effort this fall that I will touch on which we have already announced and the appropriators have supported. We are taking $35 million from our budget for a Medicare education campaign for seniors. When I came into the agency, our polling showed that seniors fundamentally do not understand the Medicare program. It is not just Medicare+Choice, which Senator Breaux and I have spent a lot of time on over the years; it is also how to pick a nursing home, and how to pick a dialysis clinic. All across the board, the information that seniors have about what to get out of the program is very limited.

So from October 15 to December 15, we are going to have a $35 million advertising campaign to educate seniors about their choices and get them to ask the right questions. The reason that number was picked was because that is what a Presidential campaign spends in 2 months, so the level of advertising effort that you are going to see I think is going to be unprecedented, and that is the goal.

Tied into that, you can imagine that if we tell seniors to ask more questions, we need to be prepared to answer them, so our 1–800-MEDICARE number is going to be tripled in size. It is going to go from being 8 hours a day, 5 days a week to 24 hours a day, 7 days a week; and it is going to go from having very basic information to having very localized information, so if you call from Idaho Falls, or from New Orleans, you will reach someone who can answer your specific questions about where to go to pick a health plan, how to pick a nursing home, which dialysis center you should go to, and a lot more consumer information. That is our goal, and we certainly hope that seniors will be very receptive to finding a lot more information and a lot more help about how to use their Medicare program.

This is a program that spends $240 billion a year, as I said, and we firmly believe that spending $35 million on an ad campaign, which works out to 90 cents per senior—and I can tell you that, for better or for 'worse, that is well within what we are spending on every senior per day it will be a big help in getting seniors more engaged in the program.

Shifting to Medicare fraud issues—which I know is part of what you wanted to talk about, and I will wrap up quickly—I was co-chair with then Deputy Attorney General Bill Barr—and later, I

guess he was Acting Attorney General—of the Fraud and Abuse Tax Force in the first Bush Administration when I was at OMB. And I would say that we were starting to ramp up on our fraud and abuse efforts at that time and maybe, arguably, could have done more, but I think some of the things that happened in the last 7 or 8 years were probably positive. When I left the Government in 1993, Medicare inflation was running about 15 percent, and Medicaid was running about 18 percent, and there was clearly a lot of stuff going on in the program that should not have gone on.

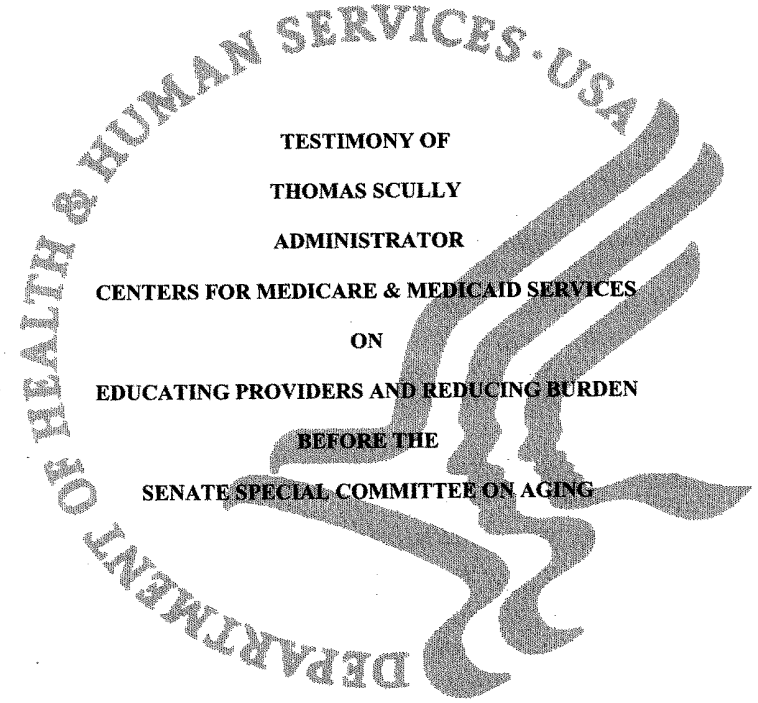
On the other hand, I would argue, over the last 8 years, you could argue that the pendulum may have swung a little too far, and we need to get it back in balance, and I think this issue is really all about balance. I have very little desire to preside over double-digit Medicare or Medicaid inflation again, but Medicare inflation went from 15 percent in 1993 to negative 1 percent in 1999. There were a lot of things involved in that, including the 1997 BBA, but part of it was fraud enforcement, and there is no question that that had a behavioral impact on everybody in the system. It has also scared people to death. I personally believe that most providers are very good people, but there are a lot of people out there who are doing the wrong thing; and trying to find the balance is, I think, the appropriate question here.

While I was out of the Government, I was chairman of the compliance committees of two large corporations, and I can tell you that in one, we spent $25 million putting together a compliance plan, and in the other one, $30 million. I had a good reaction with the Federal Government from that. I came in and met with Mac Thornton and other people in the IG's office, and they gave us a lot of guidance about how to put together compliance plans, and I think it was helpful. But the fact is that if you are a good provider, you do not get a lot of feedback about what you are doing, so the people who are doing the right thing, following the right incentives, and doing the appropriate behaviors, really do not get much for it from the Federal Government, and my own personal view is that one of my goals while I am here is to find a way to incentivize good people who are doing the right thing to continue to do it, and to get appropriate reaction from the Federal Government, and to focus our resources even more on the many people who are still not behaving appropriately and are still gaming the Medicare program.

So I think the issue here, as Senator Collins said, is balance; it is finding a way to keep incentivizing CMS, the Inspector General, and Justice to go after people who are abusing the program—and there are clearly quite a few of them—but also to make sure that people who are trying to do the right thing and are spending a significant amount of resources doing that get fair guidance from the Federal Government and are treated fairly. And that is a tough balance to come up with.

Mr. Chairman, thank you for having me.

[The prepared statement of Mr. Scully follows:]



TESTIMONY OF

THOMAS SCULLY

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

EDUCATING PROVIDERS AND REDUCING BURDEN

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

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Chairman Breaux, Senator Craig, distinguished Committee members, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS's) work to streamline Medicare's regulatory processes and our provider and beneficiary education efforts. Many physicians, health plans, providers, and Members of Congress, have raised concerns about Medicare's regulatory and paperwork burden and the cost of doing business with the Medicare program. We can appreciate these concerns, and are taking every effort to identify and address areas where improvements can be made. Physicians and other health care providers play a critical role in ensuring that Medicare beneficiaries receive quality health care. We know that in order to make sure beneficiaries continue to receive the highest quality care, we must streamline Medicare's requirements, bring openness and responsiveness into the process, and make certain that regulatory and paperwork changes are sensible and predictable. In the coming months, we will take aggressive action to meet these critical goals.

In June, Secretary Thompson and I announced that, as a first step in reforming the Medicare program, we were changing the Agency's name to the Centers for Medicare & Medicaid Services. The name-change is only the beginning of our broader effort to change the face of the Medicare program and bring a culture of responsiveness to the Agency. These are not empty words: creating a "culture of responsiveness" means ensuring high-quality medical care for beneficiaries, improving communication with providers, beneficiaries and Congress, and redoubling our education efforts. As we work to reduce Medicare's regulatory and paperwork

burden, and further improve our provider education efforts, we look forward to our continued partnership with Congress and the physician and provider community.

BACKGROUND

This year, Medicare will pay approximately $240 billion for the health care of nearly 40 million beneficiaries, involving nearly one billion Medicare claims from more than one million physicians, hospitals, and other health care providers. CMS strives to ensure that Medicare pays only for the services allowed by law, while making it as easy as possible for qualified health care providers to treat Medicare beneficiaries. We have to carefully balance the impact of Medicare's laws and regulations on physicians and other providers with our accountability for billions of dollars of Medicare payments.

Medicare's requirements, as outlined in the law, generate many of the concerns that our constituents bring to your attention and mine. Of course, there is a genuine need for some rules. But rules should exist to help, not hinder, our efforts to assist people, help control costs, and ensure quality, though the rules must remain consistent with our obligation and commitment to prevent fraud and error. When regulations, mandates, and paperwork obscure or even thwart the services providers are trying to give, those rules need to be changed. Our constituents, the Americans who depend on Medicare, and the physicians and other health care providers who care for them, deserve better. And so I am working with the Secretary to reform the way Medicare works, making it simpler and easier for everyone involved. We are dedicating ourselves to listening closely to Americans' concerns, learning how we can do a better job of meeting providers' needs, and serving them in the best way we can. We also have to ensure that we focus our efforts appropriately, and that means being less intrusive to the providers who participate in Medicare and more responsive to the beneficiaries who depend on Medicare.

IMPROVING AGENCY RESPONSIVENESS

As I mentioned, we are taking aggressive steps to bring a culture of responsiveness to CMS. This culture, this spirit, is rooted in a commitment to compassion and responsibility to beneficiaries and the physicians and providers who serve them. We intend to reinvigorate the entire Agency with a spirit of responsiveness to our constituents – to you, members of Congress;

to our colleagues in government here in Washington, and throughout the nation; and to the men, women, and children our programs protect. To promote responsiveness, the Agency is:

- ***Creating Senior-Staff Level Primary Contacts*** for beneficiary groups, plans, physicians, providers, and suppliers, to strengthen communication and information sharing between stakeholders and the Agency. We recently designated senior-level CMS staff members as the principal points-of-contact for each specific provider group, such as hospitals, physicians, nursing homes, and health plans. These designees will work with the industry groups to facilitate information sharing and enhance communication between the Agency and its business partners. The designees will help ensure that each of these important voices is heard within CMS. I will discuss this effort in greater detail later.

- ***Enhancing Outreach and Education*** to providers, plans, and practitioners, by building on the current educational system with a renewed spirit of openness, mutual information sharing, and partnership. The Agency is developing and improving training on new program requirements and payment system changes, increasing the number of satellite broadcasts available to health care industry groups, and making greater use of web-based information and learning systems for physicians and providers across the country.

- ***Establishing Key Contacts for the States*** at the regional and central office level. Similar to the senior-staff level contacts for industry and beneficiary groups, these staff members are available to work directly with the Governors and top State officials to help eliminate Agency obstacles in obtaining answers, feedback, and guidance. Each State now has one Medicaid staff member assigned to them in the regions, and another in Baltimore, both of whom are accountable for each State's specific issues.

- ***Responding More Rapidly and Appropriately to Congress and External Partners*** by promptly responding to their inquiries. We are developing an intra-Agency correspondence routing system, and timeliness standards, to respond more efficiently and promptly to congressional inquiries. We also are also exploring ways to make data, information, and trend analyses, more readily available to our partners and the public in a timely manner. In

addition, CMS will make explicit, and widely publicize, the requirements for obtaining data and analyses from us, including protecting the confidentiality of the data.

REGULATORY REFORM

A culture of responsiveness alone will not alleviate the regulatory and related paperwork burdens that for too long have been associated with the Medicare program. Thus, the Secretary is forming a new regulatory reform group to look for regulations that prevent hospitals, physicians and other health care providers from helping Medicare beneficiaries in the most effective way possible. This group will determine what rules need to be better explained, what rules need to be streamlined, and what rules need to be cut altogether, without increasing costs or compromising quality. To assist this group, we have developed a multifaceted approach, focusing on listening and learning, which will get us on the right track. This methodical, sector-by-sector approach will enable us to administer our health care programs as effectively and efficiently as possible.

Under the first aspect of the plan, CMS will conduct public listening sessions across the country to hear directly from physicians and health care providers away from Washington, DC, and away from Baltimore, and out in the areas where real people live and work under the rules we develop; where these people may not have such easy access to policymakers to share their good ideas and legitimate concerns. Most of you in Congress have these kinds of listening sessions with your local constituents on a regular basis. I want to hear from local seniors, large and small providers, State workers, and the people who deal with Medicare and Medicaid in the real world. I want to get their input so we can run these programs in ways that make sense for real Americans in everyday life. We hear from some of these people now, but we want to get input from many, many more.

I want to hear from the broad range of providers, from those in rural offices and inner city clinics to the suburban health centers and urban hospitals. I want to hear from the large hospital systems and the small, two doctor practices and the solo providers. I want input from folks like group practice managers, physician assistants, and nurses. These professionals who are in the field every day can give us good ideas that improve our management of these vitally important programs. This type of input is good for our beneficiaries because regulatory reform will allow

physicians and providers to spend more time caring for beneficiaries, and it will encourage physicians and providers to remain in the Medicare program.

The second aspect of the plan is to meet with the various health-sector workgroups – these are the industry folks here in Washington. Some of the people who we hear from the most are the individual and institutional providers who are dealing with our rules every day. They are the ones caring for our beneficiaries, and they are the ones filling out many of the forms, trying to understand the rules, and working to do the things they spent years training to do – making people healthy. And so the second aspect of our approach will focus specifically on the collective expertise of the industry groups who represent these physicians and providers, working with CMS senior staff. We are convening seven health-sector workgroups with a senior CMS person as each group's principal contact. The purpose of these groups is to suggest ways that we can improve their interactions with CMS and the Medicare program to reduce regulatory complexity and burden. For example, the American Hospital Association (AHA) recently released a report, "Patients or Paperwork: The Regulatory Burden Facing Hospitals." The AHA found that due to regulatory burden, every hour spent providing actual patient care generates at least 30 minutes – and sometimes an hour – of paperwork. We need more input like this to improve our operation of Medicare, so that health care professionals can spend more time delivering the care for which they were trained, and so that beneficiaries can spend more time with their doctors and other providers – not in waiting rooms.

Like the physicians, providers, and beneficiaries who live and work with Medicare every day, CMS staff have dealt with the system for years, and they have suggestions about how we can operate the Medicare program more simply and effectively. They certainly have heard from all of you and from many, many providers about what could be fixed. To examine these important concerns, the third aspect of our plan is forming a group of in-house experts from the wide array of Medicare's program areas. I am asking them to think innovatively about new ways of doing business, reducing administrative burdens, and simplifying our rules and regulations, without increasing costs or compromising quality. Today, providers are forced to spend more time keeping up with the latest rules and interpretations rather than keeping up with providing patient care. Frankly, the complexity of the program makes it difficult for those of us who administer it

to keep up. It is difficult to educate beneficiaries, providers, and our business partners, when there is so much complex information to explain. This group of experts will develop ways that we can reduce burden on providers, eliminate complexity wherever possible, and make Medicare more "user-friendly" for everyone involved.

In no way will we diminish our interest in fighting waste, fraud and error in the Medicare program. Most physicians, and other providers, are honest and want only to be fairly reimbursed for the high-quality care they provide; but for the small percentage of people who take advantage of the system, we will continue our aggressive efforts to protect the funds that taxpayers have entrusted to our use.

These outreach efforts will allow us to hear from all segments of people who deal with Medicare and Medicaid, from the beneficiaries and the public at large, to the physicians and providers, to the CMS employees. We are going to listen to them, and we are going to learn how we can do a better job. But listening is not enough. Getting together and generating great solutions is not enough. So we are going to take action. To improve the way we do business, and make Medicare and Medicaid easier for everyone involved with them, without increasing costs or compromising quality, the Secretary and I have already announced some important changes and we plan to announce more in the coming weeks.

STREAMLINING THE REGULATORY PROCESS

In addition to easing the regulatory burden on health plans, physicians, and other providers, we are working with providers and Congress to streamline the regulatory process. Although the Agency has made some progress on this front, we still have important work to do. I am committed to making common-sense changes and ensuring that the regulations governing our program not only make sense, but also are plain and understandable. The Secretary has made this a priority for the Department, and I am committed to this effort. Streamlining will go a long way towards alleviating providers' fears and reducing the amount of paperwork that has all too often in the past been an unnecessary burden on the providers who care for Medicare

beneficiaries. In the coming months, with the leadership and support of Secretary Thompson, we will take important steps towards reaching these goals.

As a first step, we will develop a quarterly compendium of all changes to Medicare that affect physicians, and other providers, to make it easier for them to understand and comply with Medicare regulations and instructions. The compendium will be a useful document for predicting changes to Medicare's instructions to physicians and providers, and will contain a list of all regulations we expect to publish in the coming quarter, as well as the actual publication dates and page references to all regulations published in the previous quarter. All changes – both regulatory and non-regulatory – will be treated the same, regardless of whether the change results in increased or decreased payment, coverage, or reporting burden. The compendium will be published only at the beginning of a quarter, unless the Secretary or Administrator directs otherwise. By publishing changes in the quarterly compendium, physicians and other providers will no longer be forced to sift through pages and pages of the *Federal Register* – or pay someone to do it for them – for proposed rules, regulations, and other changes that may affect them. The compendium will include all program memoranda, manual changes, and any other instructions that could affect providers in any way. It will provide predictability, and will ensure that physicians, and other providers, are fully aware of Medicare changes and that they have time to react before new requirements are placed on them.

In addition to the quarterly compendium, we will develop a system of electronic rulemaking to make the rulemaking process more efficient and to reduce the flow of paper between providers and CMS. Today, in an effort to make updated regulations more readily accessible, we routinely post them on our website, www.hcfa.gov. These postings coincide with the display of these documents in the *Federal Register* and have been well received by providers and other interested parties. Over the next six months, we will further explore the use of emerging technologies and the electronic exchange of information, such as posting proposed rules and taking comments on-line. We will work closely with the provider, plan and practitioner communities, as well as with Congress and other parts of the executive branch, to better understand their needs as we move towards an electronic rulemaking environment.

IMPROVING PHYSICIAN AND PROVIDER EDUCATION

As part of our efforts to reinvigorate the Agency and bring a new sense of responsiveness to CMS, we are enhancing our provider education activities and opening lines of communication to our physician and provider partners. The Medicare program primarily relies on private sector contractors, who process and pay Medicare claims, to educate physicians and providers and to communicate policy changes and other helpful information to them. Working with the Medicare contractors, we have taken a number of steps to ensure the educational information that is shared with physicians and providers is consistent and unambiguous. CMS is responsible for providing policy guidelines to these private contractors, and ensuring that the contractors then perform their activities in a timely and accurate manner.

We recognize that the decentralized nature of this system has, in the past, led to inconsistency in the contractors' communications with physicians and providers, and we have recently taken a number of steps to improve the educational process. For example, we have centralized our educational efforts in our Division of Provider Education and Training, whose primary purpose is to educate and train the contractors and the provider community regarding Medicare policies. We are also providing contractors with in-person instruction and a standardized training manual for them to use in educating physicians and other providers. These programs provide consistency and ensure that our contractors speak with one voice on national issues. For example, in coordination with the Blue Cross/Blue Shield Association, we developed train-the-trainer sessions for implementing both the Hospital Outpatient and Home Health Prospective Payment System regulations, which included a satellite broadcast that was rebroadcast several times prior to the effective date of the regulation. Following these sessions, we held weekly conference calls with regional offices and fiscal intermediaries to enable us to monitor progress in implementing these changes. We are continuing to refine our training on an on-going basis by monitoring the training sessions conducted by our contractors, and we will continue to work collaboratively to find new ways of communicating with and getting feedback from physicians and providers.

Just as we are working with our contractors to improve their provider education efforts, we also are working directly with physicians and other health care providers to improve our own

communications and ensure that CMS is responsive to their needs. We are providing free information, educational courses, and other services, through a variety of advanced technologies. We are:

- ***Expanding our Medicare provider education website.*** We provide a variety of resources online at the Medicare Learning Network homepage, www.hcfa.gov/MedLearn. MedLearn provides timely, accurate, and relevant information about Medicare coverage and payment policies, and serves as an efficient, convenient provider education tool. The MedLearn website averages over 100,000 hits per month, with the Reference Guides, Frequently Asked Questions and Computer-Based Training pages having the greatest activity. I would encourage you to take a look at the website and share this resource with your physician and provider constituents. We want to hear feedback from them on its usefulness so we can strengthen its value.
- ***Providing free computer and web-based training courses.*** Doctors, providers, practice staff, and other interested individuals can access a growing number of web-based training courses designed to improve their understanding of Medicare. Some courses focus on important administrative and coding issues, such as how to check-in new Medicare patients or correctly complete Medicare claims forms, while others explain Medicare's coverage for home health care, women's health services, and other benefits.
- ***Creating a more useful Agency website.*** We are creating a new website architecture and tailoring it to be intuitive and useful to the physician user. We want the information to be helpful to physicians' and their staffs' office and billing needs. The same design is being used in creating a manual of "Medicare Basics" for physicians. We just completed field-testing the first mock-ups for the project at the recent American Medical Association House of Delegates meeting. Once this new website is successfully implemented, we will move to organize similar web navigation tools for other Medicare providers.

In tandem with our efforts to improve physician and provider education, we are also focusing on improving the quality of our provider customer service. Last year, our Medicare contractors received 24 million telephone calls from physicians and providers, and it is imperative that the

contractors provide correct and consistent answers. Now that we have toll-free answer-centers at all Medicare contractors, the need is even more pressing. We have performance standards, quality call monitoring procedures, and contractor guidelines in place to ensure that contractors know what is expected and so that we can be satisfied that the contractors are reaching our expectations. This year, for the first time, Medicare contractors' physician and provider telephone customer service operations are being reviewed against these standards and procedures separately from our review of their beneficiary customer service. During these week-long contractor performance evaluation reviews, we identify areas that need improvement and best practices that can be shared among our other Medicare physician and provider call centers. As a result of the reviews, performance improvement plans will be instituted when needed, and CMS staff in our Regional Offices will continue to monitor the specific contractor throughout the year.

We also want to know about the issues and misunderstandings that most affect provider satisfaction with our call centers so that we can provide our customer service representatives with the information and guidance to make a difference. To improve our responsiveness to the millions of phone calls our call centers handle each year, we are:

- ***Developing Call Center Profiles***. Earlier this year, we visited eight of our largest Medicare contractors to collect information on their operations, their use of technology, their performance data, their most frequently asked provider questions, and their training needs. We are now collecting similar information from all of the remaining Medicare call centers via an online profile. The profiles will be completed by early August, and we will analyze them to identify additional training needs and other improvements we can make at our contractors.

- ***Creating a Customer Service Training Plan***. Based upon the call center profiles we have gathered, we have drafted a Customer Service Training Plan to address the training needs of our Medicare customer service representatives. This training plan will bring uniformity to the contractor training, and improve the accuracy and consistency of the information that representatives give to physicians and providers across the country. Our first training effort will focus on the widely misunderstood Correct Coding Initiative. Customer service

representatives will be trained on the language and concepts of coding issues so that they can properly direct physicians and providers to the best sources of information. We plan to offer this and other training via a satellite network. We expected to provide training to all of our contractors this fall.

- ***Holding Telephone Customer Service Conferences.*** In March, we held our first National Telephone Customer Service Conference for Medicare contractor call center managers and our Central and Regional Office staff. The conference emphasized our goal of making Medicare customer service as uniform in look, feel, and quality as possible.

- ***Conducting Monthly Call Center Meetings.*** We currently hold monthly conference calls with contractor call center managers and CMS Central and Regional Office staff to identify problems, give contractors additional information, and increase the accuracy and consistency of call center service nationwide.

At the same time, we are working to develop effective standards for appropriately meeting the customer service needs of physician and provider communities we serve. We are:

- ***Analyzing Baseline Performance Data.*** Medicare call center managers were required to report data from October 1999, through May 2001 (and monthly thereafter), on a variety of performance measures. We are analyzing this data to determine contractors' relative performance and the impact of the installation of toll free lines on contractor workload and performance.

- ***Modernizing Customer Service Representative Workstations.*** To the extent resources permit, we are looking at modernizing the workstations and other tools used by our customer service representatives to ensure that they have instant access to the most current information in responding to provider inquiries.

- ***Monitoring Call Quality.*** We also formed a contractor workgroup with CMS staff to review and improve the scorecard and criteria chart that was used to measure beneficiary telephone

customer service, so that it also could effectively measure the customer service of our provider customer service representatives. This new scorecard, now used by both groups, places greater emphasis on accuracy of information given in determining the final score.

IMPROVING AND EXPANDING BENEFICIARY EDUCATION

As Medicare requirements frustrate plans, physicians and providers, beneficiaries also have difficulty understanding the program's benefits and options. We know, from our research and focus groups, that far too many Medicare beneficiaries have a limited understanding of the Medicare program in general, as well as their Medigap, Medicare Select, and Medicare+Choice options. We firmly believe that we must improve and enhance its existing outreach and education efforts so beneficiaries understand their health care options. In addition, we will tailor our educational information so that it more accurately reflects the health care delivery systems and choices available in beneficiaries' local areas. We know that educating beneficiaries and providing them more information is vital to improving health care and patient outcomes.

With that goal in mind and in an effort to ensure that Medicare beneficiaries are active and informed participants in their health care decisions, we will expand and improve the existing *Medicare & You* educational efforts with a new advertising campaign. We will launch a multimedia campaign using television, print, and other media, to reach out and share information and educational resources to all Americans who rely on Medicare, their families, and their caregivers. We are also:

- ***Increasing the Capacity of Medicare's Toll-Free Lines*** so that the new wave of callers to 1-800-MEDICARE generated by the advertising campaign receive comprehensive information about the health plan options that are available in their specific area. By October 1, 2001, the operating hours of the toll-free lines will be expanded and made available to callers 24 hours a day, seven days a week. The information available by phone also will be significantly enhanced, so specific information about the health plan choices available to beneficiaries in their state, county, city, or town, can be obtained and questions about specific options, as well as costs associated with those options, can be answered. Call center representatives will be able to help callers walk-through their health plan choices step-by-step and obtain

immediate information about the choices that best meet the beneficiary's needs. For example, a caller from New Orleans, Louisiana, could call 1-800-MEDICARE and discuss specific Medigap options in Louisiana. Likewise, a caller from Twin Falls, Idaho, could call and get options and costs for Medigap or Medicare+Choice alternatives in their areas. If requested, the call centers will follow-up by mailing a copy of the information discussed after the call.

- ***Improving Internet Access to Comparative Information*** and providing a new decision making tool on the Agency's award winning website, www.medicare.gov. These enhanced electronic learning tools will allow visitors, including seniors, family members, and caregivers, to compare benefits, costs, options, and provider quality information. This expanded information is similar to comparative information already available, such as *Nursing Home Compare* and *ESRD Compare* websites. With these new tools, beneficiaries will be able to narrow down by zip code the Medicare+Choice plan options that are available in their area based on characteristics that are most important to them, such as out-of-pocket costs, whether beneficiaries can go out of network, and extra benefits. They also will be able to compare the direct out-of-pocket costs between all their health insurance options and get more detailed information on the plans that most appropriately fit their needs. In addition, the Agency will provide similar State-based comparative information on Medigap options and costs.

CONCLUSION

Physicians and other providers play a crucial role in caring for Medicare beneficiaries, and their concerns regarding the program's regulatory burden must be addressed. Enhancement of our communication and education efforts is essential to the success of Medicare, and we believe will ultimately reduce the level of physicians' and other providers' frustration with the Medicare program, as well as increase beneficiaries' options and satisfaction. We recognize we have a number of issues to address and improvements to make. We have already taken some critical first steps, and we are seeking input from the health care community and Congress as we work towards our goals. I appreciate having had the opportunity to discuss these issues with you today, and I am happy to answer your questions.

The CHAIRMAN. Thank you very much, Mr. Scully, for your presentation and for recognizing the challenge that you have in running an agency as large and as complicated as the CMS system is and the Medicare program in general.

Hopefully, maybe this year, Congress can actually modernize the program and bring it into the 21st century and eliminate many of the problems we have in the program that are statutorily created by Congress.

Five years ago, GAO said we had about $23 billion in improper payments. I think the current figure that we use is about $11.9 billion in improper payments. That is still a huge amount. We in the Congress are constantly faced with presentations by concerned citizens who have legitimate feelings and will tell us that there is too much fraud in the program. Others will come in who are providers and tell us there is too much enforcement. That is the conflict.

The question is how do we eliminate improper payments and at the same time do it in a proper manner. That is really what we are trying to do.

My question to start with is do you feel and does the administration feel that the tools that are currently in place are sufficient to get the job done. I mean, $11.9 billion is far too much, but it is a lot less than it used to be, so there are some signs of improvement. Do you need more tools, do you need different tools, or is what we have in place now sufficient—and if you could comment on whether what we have in place now needs to be modified.

Mr. SCULLY. Well, Chairman Breaux, one thing I know from spending 4 years at OMB is that I do not want to get shot for making administration policy. My own opinion is—Janet Rehnquist is the new IG nominee, hopefully to be soon confirmed; she is someone I have known since college, and I look forward to working with her. I have worked with a lot of the Justice Department folks, including Senator Ashcroft back when he was Governor Ashcroft in Missouri. I think really, the issue about how you appropriately enforce the fraud laws is a three-legged stool between CMS, and HHS; Inspector General, and Justice. So I think I would like to sit down with the three of us and figure out the appropriate strategy.

My personal opinion on this is that I think we have the tools to do it. I think there has been a tendency—there is no question that a lot of the fraud and abuse in the program has been cleaned up in the last few years. I think you can debate about whether $22 billion or $11 billion is legitimate, and what comprises that number, but there is no question there have been great gains made in the program.

I would also say, however, that I think the focus in our fraud efforts has generally been on high-profile big systems, and some of the real problems tend to be getting down to the nitty-gritty of smaller providers. It is the nature of enforcement efforts to go after the University of Pennsylvania or to go after a big provider.

In my opinion, a lot of the behavior of the big providers has been changed for the better. As I said, I was chairman of the Oxford Health Plan Compliance Committee for the last 6 years—it did not exist when I came on the board 8 years ago—and I was recruited to be the chairman of the compliance committee for DaVita Health Care about a year ago, which did not have one before that. In both

cases, I spent a lot of money and recruited a lot of people, to put together very comprehensive compliance plans.

The good news from the last 8 to 10 years is that these companies did not have compliance plans before. Now they have compliance plans, and they are scared to death, for better or for worse, of the Government, but they are doing the right thing, and that is good, and I think that that needs to be incentivized, and we need to keep doing that.

I personally think that we need to come up with some structure in the Government, rather than just keeping people scared. The reality is that we have relatively modest enforcement tools. We only look at a small percentage of the bills coming through the Medicare program. The number of people we actually go after in the Government—if you look at physicians, for instance, I think there were 25 physicians last year who actually had significant action taken against them. But the perception is that we are scaring people to death and that we are not giving them guidance. To me, the goal is to find the people who are doing the right thing, especially some of these large hospital systems, physician practices, and health care systems, who are trying to do the right thing, and setting up significant compliance programs, find a way to give them guidance, incentivize them to continue to do the right thing and move on to the next tier of providers who, in my experience, are the ones who probably have not gotten to the more compliant stage yet. So I think we are doing a lot.

The CHAIRMAN. There are different approaches depending on the cause of the improper payments. Some will argue that the bulk of the improper payments is the result of mistakes that are honest mistakes by providers. Others will say that it's fraud—they are trying to scam the Government and to cheat the Government, and they are keeping two sets of books or whatever. Is there any way to quantify, of the almost $12 billion of improper payments, what percentage is the result of fraudulent activities on behalf of providers versus what may be labeled as mistake, confusion, inability to understand the rules and regulations?

Mr. SCULLY. I do not think I could pick a number out of that. I would say that the $12 billion—and this is my opinion, and I will probably have a fun discussion with the IG later—I have always thought that those numbers were not all that solid, and that is from my long experience in health care. I think it would be difficult to show that.

There is clearly a lot of fraud going on in the system, but out of $240 billion, there's $11 or $12 billion—I would say that probably a third of that is fraud, and the rest is probably billing mistakes. And Senator, as you know, if you go back and look at the mid-nineties, some of it was fraud that was incentivized by really bad policy. If you look at home health, when I left the Government in 1992, home health payments were $3 billion a year; I think they went up to $18 billion a year by 1997 and then back down to $9 billion. That probably was not rational policy, and we incentivized a lot of people who probably should never have been in the home health business to get into the home health business. And if you look at a lot of the volume of fraud over the years, a lot of those

people were in home health. Some of that was incentivized by bad Federal policy.

There is certainly a lot of fraud there, but I believe that some of the best policies to prevent fraud are capitating programs, going to things like prospective payment for skilled nursing facilities, going to prospective payment for rehabilitation hospitals. We went to prospective payment for outpatient last year. Setting up rules that are more rational and incentivizing people to have more rational payment policies has probably the biggest impact, and I personally think that equally as important as aggressive fraud enforcement is to have the Government set up rational payment rules that make it easier to incentivize people to do the right thing. I think that methodically, we are going through and doing that and capitating these programs.

The CHAIRMAN. We went through this on the Finance Committee in an effort to reform the Internal Revenue Service and how it interacts with taxpayers in this country and have tried to create a whole new relationship between the Internal Revenue Service and the taxpayers so that American citizens are not fearful and frightened and scared to death of their own Government when it comes to dealing with it on matters of financial concern.

I daresay we are probably going to hear from some providers that that is the same kind of fear they have of the Medicare program, that they live under the constant threat that they are going to be prosecuted for honest mistakes.

Can you spell out how this administration and the Medicare program—what kind of relationship do you think is appropriate with the providers?

Mr. SCULLY. Well, as you know, Senator, I lived in the provider world for the last 8 years, both as a lawyer and running a hospital association. I think the key things with providers—98 percent of them are trying to do the right thing, and the key thing is to set rules that are understandable and clear. If you look in the mid-nineties, you can determine what was fraud and what was not fraud, but there are a lot of things—I will give two examples.

One is you created DRGs in 1983, and then, people have other facilities on a cost basis like nursing homes and affiliated home health agencies. You can incentivize people, but unless you make the rules extremely clear, they will push the edge of the envelope, which a lot of people did, trying to shift their costs to their home health agencies and nursing homes. A lot of the cases of abuse in the program in the early nineties came from that. I think we solved a lot of that with new payment policies.

We have a big problem right now which the Justice Department and the IG are very focused on, and I am very focused on, which is that we pay—Congress has debated this for years—we clearly on the outpatient side, pay acquisition costs for devices and average wholesale prices for drugs that are absurdly high. There is a great debate on whether that is a kickback by definition or not. That is a policy issue. Congress has looked at it for years and has not done anything about it. On the merits, I think there is absolutely no question that we are overpaying in those areas. Is that a question of cheating the program? Arguably, it is. Is it a question of bad pol-

icy that probably should be fixed by Congress? Arguably, I think it is.

So I guess my No. 1 view is that most providers are trying to do the right thing. Some of them are going to push the edge of the envelope thinking they are doing the right thing, and some are going to flat out be cheating the program. We need to focus on making clear rules for people so they know exactly what they are getting, and I think that is the key with providers; and then, focus on enforcement efforts on the small minority of people who are really illegitimate and trying to cheat the program.

The CHAIRMAN. Thank you.

GAO will testify later that although CMS has taken positive steps to move in the right direction with regard to restricting and ultimately eliminating improper payments, weaknesses in your communications with providers and your oversight of contractors still exist. Can you comment on both of those areas?

Mr. SCULLY. Yes. It is a complicated program, and I do not want to criticize the previous administration. As you know, the previous administrator is a good personal friend of mine. I think there is an awful lot of stuff going on with the different budget bills in the last 3 or 4 years. I think there was an awful lot of restructuring that went on in HCFA that made their lives more complicated. There were a lot of challenges 2 or 3 years ago, and to be honest, coming in, my challenges, administrative, with reacting to Y2K, reacting to the BBRA, may be a little less than they were 2 or 3 years ago. For whatever reason, I think the perception was that the communication with providers was not that good. Clearly, that is one of my No. 1 goals, communication with seniors and providers to tell people what we are doing.

The CHAIRMAN. I take it the bulk of the communication with providers is not through CMS and the providers but through your third-party payers?

Mr. SCULLY. I would say the bulk of it is through third-party payers, and I think we are making a big effort to improve that through the FIs and the carriers as well. The bulk of the enforcement is also done with them. The average person in Louisiana who is running a home health agency is not going to hear from me; they are going to hear from their local carrier, local FI.

The CHAIRMAN. Can you do that without complicating the system further? Are local providers going to have to deal with CMS on these disputes as well as with their third-party providers, or can you consolidate it in a manner that the providers deal with one contact point on disputes and questions about what are proper payments? If they are going to have to deal with CMS and with their third-party provider, is that not more work if that is in fact what happens?

Mr. SCULLY. Well, I think we have to be clear about what is going to be paid for and what our rules are; that is the first step. But if you want to have a frightening experience, you should look at the appeals process for either seniors or providers from CMS up to HHS. It is incredibly complicated. Arguably, it was made more complicated last year by the BIPA changes, and we would like to work with you to streamline it.

The CHAIRMAN. OK. If I am a hospital in Louisiana, and I have questions about whether something is reimbursable and at what rate it is reimbursable, in the future, is the best way for that problem to be resolved by having that local hospital deal directly with CMS, or deal directly with the third-party provider?

Mr. SCULLY. They clearly get information from us about national program policies, and hopefully, our regional offices talk to them. But generally, I think every major hospital usually has a very direct relationship with their fiscal intermediary. So almost any hospital in Louisiana probably has a day-to-day relationship with the fiscal intermediary, which is their contractor, and they probably get a lot of information from them.

I think the trouble comes, in a lot of cases, when they appeal cases—whether you are a senior, whether you are a doctor, or whether you are the hospital, when you appeal, the process is long, and gruesome, and tortuous, and I think that is where a lot of the unhappiness in providers comes from.

The CHAIRMAN. On the appeals process, as to what is covered or not?

Mr. SCULLY. Yes, I think that is probably right in most cases.

The CHAIRMAN. Are you planning to change that in any way, and if so, how?

Mr. SCULLY. I would love to change that with your help this year, as would the Secretary. We have some proposals that we are talking to people on the Hill about in regard to streamlining the process. Most of our appeals eventually come up through ALJs, beneficiary appeals, that actually work for the Social Security Administration, and the Inspector General—who I hope will bring it up today—has been supportive of us saying that we should phaseout those ALJs—probably 10 to 15 percent of the Social Security ALJs is Medicare claims. It is not their primary focus. There is an enormous backlog. People are very frustrated by it. I would like to find a happy way with the Social Security Administration to phase our ALJs out of Social Security and put them in Medicare, with people who actually focus on Medicare appeals on a daily basis. That is more on the beneficiary side.

When you come up as a provider, depending on—there are a number of ways that you can come up through the system as a provider. If it is an individual claim, you come up through the carriers, through an appeals process that is very complicated. If it is on your cost report, there is a totally separate appeals process that comes up through something called the PRB, provider reimbursement board. But it would be a frightening organizational chart if I were to show it to you.

The CHAIRMAN. There are some efforts in Congress to deal with this. Are you in a position to comment on the Medicare Regulatory Education Fairness Act that Senators Murkowski and Kerry have introduced?

Mr. SCULLY. Yes. I think it is a legitimate effort to make some changes. I would say that we think a fairly significant portion of that bill includes reasonable changes that we can make, and a lot of them we are making. We have talked to both the Finance Committee and the Ways and Means Committee about it, because they have parallel efforts, to take some of those ideas and fold them and

be more responsive to providers and physicians in our constituencies.

There is also a number of things in the bill—I will not go through them one-by-one—that would significantly weaken our enforcement efforts that I think would be a big mistake and that we will not support.

The CHAIRMAN. And what would those be?

Mr. SCULLY. Well, I have a long list of them, but just to give you one example, there is a provision in the MERFA bill that I think is vague, that says essentially that if you turn in a claim, let us say an pneumonia claim, and you are a hospital, and you send the pneumonia claim and ask is this claim OK, in theory, the rest of your pneumonia claims for the rest of the year are unreviewable, which is clearly not a good idea. If you send in one pneumonia claim and ask is this the way we should bill, OK, fine, and then you basically have an affirmative defense to say that nobody can look at those claims for the rest of the year, that is not a rational policy approach. I do not think it was intended to be that way. But there are a number of things in the bill that would significantly water down our enforcement capabilities.

The CHAIRMAN. Can you comment on the viability of the use of the False Claims Act versus the appeals process with regard to going after improper payments, and which is the proper procedure and which is the best procedure?

Mr. SCULLY. That is a very complicated issue, and I will give you my own opinion from being on the outside. As you know, Senator Grassley feels very strongly about the False Claims Act. I think it was originally created to deal more with defense issues. I spent a lot of time in various roles talking with Senator Grassley over the last couple of years, and I do not think the False Claims Act should necessarily be changed or watered down. In my opinion, the way it is utilized by the Government, both inside and outside the Government, has frequently not been appropriate. So to some degree, I think it is a matter of giving more rational guidance to folks around the country, not in my agency, about how to utilize the False Claims Act.

The CHAIRMAN. All right. We may have some additional questions, Mr. Scully, but we appreciate very much your being with us today and will let you get back to CMS.

Mr. SCULLY. Mr. Chairman, I always enjoy working with you, and I hope we can get a reform bill with a prescription drug benefit done by the end of the year and fix CMS at the same time.

The CHAIRMAN. We are working on it. Thank you very much.

Mr. SCULLY. Thanks.

The CHAIRMAN. I would like to welcome our next panel, which will consist of Mr. Stuart Schiffer, Acting Assistant Attorney General at the Department of Justice; Mr. Lewis Morris, Assistant Inspector General for Legal Affairs at Department of Health and Human Services, Office of Inspector General; and Ms. Leslie Aronovitz, Director of Health Financing and Public Health at GAO.

Folks, we welcome you and will be pleased to receive your testimony.

Ms. Aronovitz, please proceed.

STATEMENT OF LESLIE G. ARONOVITZ, DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Ms. ARONOVITZ. Mr. Chairman, I am pleased to be here today as you discuss the administration of the Medicare program and activities undertaken to safeguard the Medicare trust fund.

At the heart of effectively administering Medicare is CMS' responsibility to protect the integrity of the program while at the same time, ensure that providers, beneficiaries, and other stakeholders are well-informed and treated fairly.

Last month's renaming of the Health Care Financing Administration is indicative of the heightened attention being placed on the agency that runs Medicare, and for good reason. Medicare will always pose enormous management challenges, primarily because of its size and extremely complex mission—that of assuring access to and paying for needed medical services for approximately 40 million beneficiaries, delivered by almost one million providers.

In attempting to fulfill this mission responsibly, agency actions may inevitably make it a target of parties who feel disadvantaged or harmed by some of its decisions.

Since 1996, the HHS OIG has repeatedly estimated that Medicare contractors inappropriately paid claims worth billions of dollars annually. The depletion of Medicare's Hospital Trust Fund and the projected growth in Medicare's share of the Federal budget have focused attention on program safeguards to prevent and detect health care fraud and abuse. It has also reinforced the importance of having CMS and its contractors develop and implement effective strategies to prevent and detect improper payments.

As safeguard and enforcement actions have increased, so have provider concerns about their interaction with CMS' carriers and fiscal intermediaries. While most would agree that these activities are part of CMS' fundamental stewardship mission, individual physicians and representatives of medical associations have made a number of serious charges—for instance, that the information that they receive from CMS and its contractors is poorly organized, difficult to understand, often inaccurate and not always communicated promptly; that contractors have inappropriately targeted them for claims review and that they have been subject to excessive paperwork demands of the medical review process; that contractors use unfair methods to calculate Medicare overpayments; and that the process to appeal denied claims is lengthy, and on successful appeals, does not provide for interest for the period during which the administrative appeal was pending.

We do not have any answers yet, but we are conducting several studies which are underway to examine the regulatory environment in which Medicare providers operate. Specifically at the request of the House Committee on the Budget and the Ways and Means Subcommittee on Health, we are reviewing the adequacy of CMS' communications with providers. We are also in the preliminary stages of a second study that examines how claims are reviewed and how overpayments are detected to assess the actions of contractors as they perform their program safeguard activities.

CMS is faced with the challenge of protecting program dollars while interacting with all program participants including providers in a transparent and timely manner. Because the Medicare claims administration contractors conduct the day-to-day operations of the fee-for-service program and are the primary face to providers, CMS' oversight of its contractors is essential to assuring that Medicare is administered efficiently and effectively.

Historically, the agency's oversight of its contractors has been weak, and although it has made substantial improvements in the past 2 years, our ongoing work suggests that there is quite a lot of room for improvement in the area of provider relations. You mentioned some of them; I would like to elaborate a bit.

In our contractor communication study, our review of several information sources such as bulletins, telephone call centers, and internet sites found a disappointing performance record. In regard to contractor bulletins, we found that many of them contained lengthy discussions with overly technical and legalistic language that providers may find difficult to understand. These bulletins also omitted some important information about mandatory billing procedures.

Similarly, we found that the calls we placed to telephone call centers this spring were rarely answered appropriately. For example, call center representatives provided an incomplete or inaccurate answer 85 percent of the time. And it was not a statistically valid sample, but it did involve 60 phone calls to five call centers over a period of about 6 weeks.

We were also very clear to tell the call representatives that we were from the General Accounting Office and that we were interested in them answering the question as though we were a provider.

Finally, in reviewing the websites of 10 carriers, we found that they rarely met all of CMS' requirements, and they often lacked user-friendly features such as site maps and search functions.

We just heard from Mr. Scully about CMS' ambitious agenda to develop a more transparent, responsive, and consistent approach to interacting with its provider community. Some of the activities included in this plan are underway or have been ongoing for quite some time, but most of CMS' plans are just being announced, and the details are yet to be revealed.

We are anxious to hear more about these efforts as we formulate our recommendations for how CMS can do better as it performs important activities to protect the integrity of Medicare while striking a balance of simplicity and responsiveness to the providers and others who participate in the program.

That concludes my short statement. I would be more than glad to answer any questions you have.

The CHAIRMAN. Thank you, Ms. Aronovitz. We will get to questions in a moment.

[The prepared statement of Ms. Aronovitz follows:]

United States General Accounting Office

GAO

Testimony

Before the Special Committee on Aging, U.S. Senate

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MEDICARE MANAGEMENT

CMS Faces Challenges in Safeguarding Payments While Addressing Provider Needs

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

GAO-01-1014T

Mr. Chairman and Members of the Committee:

We are pleased to be here today as you discuss the administration of the Medicare program and activities undertaken to safeguard the Medicare trust fund. In fiscal year 2000, Medicare made payments of over $220 billion to hundreds of thousands of providers who delivered services to nearly 40 million beneficiaries. Because of Medicare's vast size and complex structure, in 1990 we designated it as a high-risk program—that is, at risk of considerable losses to waste, fraud, abuse, and mismanagement—and it remains so today. Since that time, we have consistently reported on the efforts of the Health Care Financing Administration (HCFA), recently renamed the Centers for Medicare and Medicaid Services (CMS),[1] to safeguard Medicare payments and streamline operations.

Each year improper payments cost Medicare billions of dollars. Therefore, the process of enforcing program payment rules is critical to the viability of the program. My remarks today will focus on the importance of performing activities to protect the integrity of Medicare, while striking a balance of simplicity and responsiveness to the providers that bill the program. My comments are based on our previous and ongoing work and published reports by others.

In brief, at the heart of effectively administering Medicare is CMS' responsibility for protecting the integrity of the program while, at the same time, ensuring that providers are treated fairly. CMS relies on its claims administration contractors to administer Medicare and interact with all of its stakeholders—including providers. As CMS' contractors and others have become more aggressive in identifying and pursuing inappropriate payments, providers have expressed concern that Medicare has become too complex and difficult to navigate. Although CMS monitors the effectiveness of contractors' program management and safeguard activities, the agency's oversight of its contractors has historically been weak. In the last 2 years, however, the agency has made substantial progress. Our ongoing work has identified several areas in which CMS still

[1]Our statement will continue to refer to HCFA where our findings apply to the organizational structure and operations associated with that name.

needs improvement—especially in ensuring that contractors are providing accurate, complete, and timely information to providers about Medicare billing rules and coverage policies.

BACKGROUND

The complexity of the environment in which CMS and its contractors operate the Medicare program cannot be overstated. CMS is an agency within the Department of Health and Human Services (HHS) but has responsibilities over expenditures that are larger than those of most other federal departments.[2] Under the fee-for-service system—which accounts for over 80 percent of program beneficiaries—physicians, hospitals, and other providers submit claims for services they provide to Medicare beneficiaries to receive reimbursement. The providers billing Medicare, whose interests vary widely, create with program beneficiaries and taxpayers a vast universe of stakeholders.

About 50 Medicare claims administration contractors[3] carry out the day-to-day operations of the program and are responsible not only for paying claims but for providing information and education to providers and beneficiaries that participate in Medicare. They periodically issue bulletins that outline changes in national and local Medicare policy, inform providers of billing system changes, and address frequently asked questions. To enhance communications with providers, the agency recently required contractors to maintain toll-free telephone lines to respond to provider inquiries. It also directed them to develop Internet sites to address, among other things, frequently asked questions. In addition, CMS is responsible for monitoring the claims administration contractors to ensure that they appropriately perform their claims processing duties and protect Medicare from fraud and abuse.

[2]Medicare ranks second only to Social Security in federal expenditures for a single program.

[3]Contractors that process and pay part A claims (i.e. for inpatient hospital, skilled nursing facility, hospice care, and certain home health services) are known as fiscal intermediaries. Contractors paying and processing part B claims (i.e. for physician, outpatient hospital services, laboratory and other services) are known as carriers.

In 1996, the Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), in part to provide better stewardship of the program.[4] This act gave HCFA the authority to contract with specialized entities, known as program safeguard contractors (PSC), to combat fraud, waste, and abuse. HCFA initially selected 12 firms to conduct a variety of program safeguard tasks, such as medical reviews of claims and audits of providers' cost reports. Previously, only claims administration contractors performed these activities.

INAPPROPRIATE PAYMENTS UNDERSCORE THE IMPORTANCE OF INTEGRITY EFFORTS, RAISING PROVIDER CONCERNS

In response to the escalation of improper Medicare payments, Congress and executive branch agencies have focused attention on efforts to safeguard the Medicare Trust Fund. HIPAA earmarked increased funds for the prevention and detection of health care fraud and abuse and increased sanctions for abusive providers. The HHS Office of Inspector General (OIG) and the Department of Justice (DOJ) subsequently became more aggressive in pursuing abusive providers. In response, the medical community has expressed concern about the complexity of the program and the fairness of certain program safeguard activities, such as detailed reviews of claims, and the process for appealing denied claims. Recent actions address some of these concerns.

Program Integrity Efforts Have Intensified in Response to Improper Payments

Since 1996, the HHS OIG has repeatedly estimated that Medicare contractors inappropriately paid claims worth billions of dollars annually. The depletion of Medicare's hospital trust fund and the projected growth in Medicare's share of the federal budget have focused attention on program safeguards to prevent and detect health care

[4]P.L. 104-191.

fraud and abuse. It has also reinforced the importance of having CMS and its contractors develop and implement effective strategies to prevent and detect improper payments.

HIPAA provided the opportunity for HCFA to enhance its program integrity efforts by creating the Medicare Integrity Program (MIP). MIP gave the agency a stable source of funding for its safeguard activities. Beginning in 1997, funding for antifraud-and-abuse activities has increased significantly—by 2003, funding for these activities will have grown about 80 percent. In fiscal year 2000, HCFA used its $630 million in MIP funding to support a wide range of efforts, including audits of provider and managed care organizations and targeted medical review of claims. By concentrating attention on specific provider types or benefits where program dollars are most at risk, HCFA has taken a cost-effective approach to identify overpayments. Based on the agency's estimates, MIP saved the Medicare program more than $16 for each dollar spent in fiscal year 2000.

CMS is only one of several entities responsible for ensuring the integrity of the Medicare program. HIPAA also provided additional resources to both the HHS OIG and DOJ. The HHS OIG has emphasized the importance of safeguarding Medicare by auditing providers and issuing compliance guidance for various types of providers. It also pursues potential fraud brought to its attention by contractors and other sources, such as beneficiaries and whistleblowers. DOJ has placed a high priority on identifying patterns of improper billing by Medicare providers. DOJ investigates cases that have been referred by the HHS OIG and others to determine if health care providers have engaged in fraudulent activity, and it pursues civil actions or criminal prosecutions, as appropriate.[5] The False Claims Act (31 U.S.C. sec. 3729 to 3733) gives DOJ a powerful enforcement tool as it provides for substantial damages and penalties against providers who knowingly submit false or fraudulent bills to Medicare, Medicaid, or other federal health programs. DOJ has instituted a series of investigations known as national

[5]In fiscal year 2000, DOJ filed 233 civil cases and reported recoveries of over $840 million related to civil health care fraud.

initiatives, which involve examinations of similarly situated providers who may have engaged in common patterns of improper Medicare billing.

Provider Concerns Grow With the Expansion of Safeguard and Enforcement Activities

As safeguard and enforcement actions have increased, so have provider concerns about their interaction with contractors. Individual physicians and representatives of medical associations have made a number of serious charges regarding the following.

- **Inadequate communications from CMS' contractors.** Providers assert that the information they receive is poorly organized, difficult to understand, and not always communicated promptly. As a result, providers are concerned that they may inadvertently violate Medicare billing rules.

- **Inappropriate targeting of claims for review and excessive paperwork demands of the medical review process.**[6] For example, some physicians have complained that the documentation required by some contractors goes beyond what is outlined in agency guidance or what is needed to demonstrate medical necessity.

- **Unfair method used to calculate Medicare overpayments**. Providers expressed concern that repayment amounts calculated through the use of samples that are not statistically representative do not accurately represent actual overpayments.

- **Overzealous enforcement activities by other federal agencies.** For example, providers have charged that DOJ has been overly aggressive in its use of the False

[6]Contractors conduct medical reviews--either prior to or after payment--to identify claims that should not be or should not have been paid because services are not covered or are not medically necessary.

Claims Act and has been too accommodating to the OIG's insistence on including corporate integrity agreements in provider settlements.[7]

- **Lengthy process to appeal denied claim.** Related to this issue is that a provider who successfully appeals a claim that was initially denied does not earn interest for the period during which the administrative appeal was pending.

We have studies underway to examine the regulatory environment in which Medicare providers operate. At the request of the House Committee on the Budget and the House Ways and Means Subcommittee on Health, we are reviewing CMS' communications with providers and have confirmed some provider concerns. For example, our review of several information sources, such as bulletins, telephone call centers, and Internet sites, found a disappointing performance record. Specifically, we reviewed recently issued contractor bulletins—newsletters from carriers to physicians outlining changes in national and local Medicare policy—from 10 carriers. Some of these bulletins contained lengthy discussions with overly technical and legalistic language that providers may find difficult to understand. These bulletins also omitted some important information about mandatory billing procedures. Similarly, we found that the calls we placed to telephone call centers this spring were rarely answered appropriately. For example, for 85 percent of our calls, the answers that call center representatives provided were either incomplete or inaccurate. Finally, we recently reviewed 10 Internet sites, which CMS requires carriers to maintain. We found that these sites rarely met all CMS requirements and often lacked user-friendly features such as site maps and search functions. We are continuing our work and formulating recommendations that should help CMS and its contractors improve their communications with providers.

We are also in the preliminary stages of examining how claims are reviewed and how overpayments are detected to assess the actions of contractors as they perform their

[7]A corporate integrity agreement is an obligation imposed on a provider by the HHS OIG as part of a settlement of a potential fraud matter. It requires the provider to improve compliance and to report periodically to the OIG.

program safeguard activities. Although we have not yet formulated our conclusions, agency actions may address some provider concerns. For example, HCFA clarified the conditions under which contractors should conduct medical reviews of providers. In August 2000, the agency issued guidance to contractors regarding the selection of providers for medical reviews, noting, among other things, that a provider's claims should only be reviewed when data suggest a pattern of billing problems. Although providers may be wary of the prospect of medical reviews, the extent to which they are subjected to such reviews is largely unknown. Last year, HCFA conducted a one-time limited survey of contractors to determine the number of physicians subject to complex medical reviews in fiscal year 2000. It found that only 1,891, or 0.3 percent, of all physicians who billed the Medicare program that year were selected for complex medical reviews—examinations by clinically trained staff of medical records.[8]

In regard to physician complaints about sampling methodologies, HCFA outlined procedures to give providers several options to determine overpayment amounts. Contractors would initially review a small sample (probe sample) of a provider's claims and determine the amount of the overpayment.[9] A provider could then (1) enter into a consent settlement, whereby the provider accepts the results of this probe review and agrees to an extrapolated "potential" overpayment amount based on the small sample, (2) accept the settlement but submit additional documentation on specific claims in the probe sample to potentially adjust downward the amount of the projected overpayment, or (3) require the contractor to review a larger statistically valid random sample of claims to extrapolate the overpayment amount. According to agency officials, although providers can select any of these options, consent settlements are usually chosen when offered because they are less burdensome for providers, as fewer claims have to be documented and reviewed.

[8]*Regulatory Issues for Medicare Providers* (GAO-01-802R, June 11, 2001).

[9]To identify improper billing by a provider, CMS requires contractors to conduct a "probe" review of roughly 20 to 40 claims. If the probe sample indicates improper billing, the contractors determine the provider's overpayment amount by either selecting a statistically valid random sample of claims or basing the amount on a small sample that is not statistically representative.

In response to concerns regarding its use of the False Claims Act, DOJ issued guidance in June 1998 to all of its attorneys that emphasized the fair and responsible use of the act in civil health care matters, including national initiatives. In 1999, we reviewed DOJ's compliance with its False Claims Act guidance and found that implementation of this guidance varied among U.S. Attorneys' Offices.[10] However, the next year we reported that DOJ had made progress in incorporating the guidance into its ongoing investigations and had also developed a meaningful assessment of compliance in its periodic evaluations of U.S. Attorneys' Offices.[11] Regarding corporate integrity agreements, we noted in our March 2001 report that these agreements were not always a standard feature of DOJ settlements.[12] For example, 4 of 11 recent settlements that we reviewed were resolved without the imposition of such agreements.

Finally, some providers' concerns about the timeliness of the appeals process could be addressed by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which imposes deadlines at each step of the appeals process. For example, initial determination of a claim must be concluded within 45 days from the date of the claim, and redetermination must be completed within 30 days of receipt of the request. These revisions are scheduled to take effect on October 1, 2002.

CMS' OVERSIGHT OF CONTRACTORS IS KEY TO BALANCING PROGRAM SAFEGUARDS AND PROVIDER CONCERNS

CMS' oversight of its contractors is essential to ensuring that the Medicare program is administered efficiently and effectively. CMS is faced with the challenge of protecting program dollars and treating providers fairly. However, to accomplish these goals, contractors must implement CMS' policies fully and consistently. Historically, the

[10] *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies* (GAO/HEHS-99-170, August 6, 1999).

[11] *Medicare Fraud and Abuse: DOJ Has Made Progress in Implementing False Claims Act Guidance* (GAO/HEHS-00-73, March 31, 2000).

[12] *Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance* (GAO-01-506, March 30, 2001).

agency's oversight of contractors has been weak, although it has made substantial improvements in the past 2 years. Continued vigilance in this area is critical as CMS tries to cope with known weaknesses and begins to rely on new specialty contractors for some of its payment safeguard activities.

Various Factors Have Contributed to Weak Contractor Oversight

Medicare's claims administration contractors are responsible for all aspects of claims administration, conduct particular safeguard activities, and are the primary source of Medicare communications to providers. However, oversight of Medicare contractors has historically been weak, leaving the agency without assurance that contractors are implementing program safeguards or paying providers appropriately. For years, HCFA's contractor performance and evaluation program (CPE)—its principal tool used to evaluate contractor performance—lacked the consistency that agency reviewers need to make comparable assessments of contractor performance. HCFA reviewers had few measurable performance standards and little direction on monitoring contractors' payment safeguard activities. The reviewers in HCFA's 10 regional offices, who were responsible for conducting these evaluations, had broad discretion to decide what and how much to review as well as what disciplinary actions to take against contractors with performance problems.

This highly discretionary evaluation process allowed key program safeguards to go unchecked and led to the inconsistent treatment of contractors with similar performance problems. Dispersed responsibility for contractor activities across many central office components, limited information about how many resources are used or needed for contractor oversight, and late and outdated guidance provided to regional offices have also weakened contractor oversight.[13]

[13]The weak oversight of contractors helped create an environment in which a number of HCFA contractors committed fraud. The fraud was not detected through the agency's oversight efforts but instead was reported by whistleblowers and resulted in settlements for millions of dollars. HCFA failed to uncover the

Over the years, we have made several recommendations to improve HCFA's oversight of its claims administration contractors. For example, we recommended that the agency strengthen accountability for evaluating contractor performance. In response to our recommendations, HCFA has established an executive-level position at its central office with ultimate responsibility for contractor oversight, instituted national review teams to conduct contractor evaluations, and provided more direction to its regional offices through standardized review protocols and detailed instructions for CPE reviews.

Although the agency has taken a number of steps to improve its oversight efforts, our ongoing work suggests that opportunities for additional improvement exist. Last month, we joined CMS representatives as they conducted a CPE review at a contractor's telephone center. Although providers' ability to appropriately bill Medicare is dependent on their obtaining accurate and complete answers to their questions, the review focused primarily on adherence to call center procedures and the timeliness of responses to provider questions. Moreover, the CMS reviewer selected a small number of cases to evaluate—only 4 of the roughly 140,000 provider calls this center receives each year.

While CMS' management of claims administration contractors suffers from weak oversight, its contracting practices for selecting fiscal intermediaries and carriers may contribute to these difficulties. Unlike most of the federal government, the agency was exempted from conducting full and open competitions by the Social Security Act. Thus, for decades, HCFA has relied on many of the same contractors to perform program management activities, and has been at a considerable disadvantage in attracting new entities to perform these functions.

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contractors' fraudulent practices, in part, because it relied on contractor self-reporting of management controls and seldom independently validated contractor-provided information.

New Contracting Authority Provides Opportunity for Improving Safeguard Performance

Congress included provisions in HIPAA that provided HCFA with more flexibility in contracting for program safeguard activities. It allowed the agency to contract with any entity that was capable of performing certain antifraud activities. In May 1999, HCFA implemented its new contracting authority by selecting 12 program safeguard contractors—PSCs—using a competitive bidding process.[14] These entities represent a mix of health insurance companies, information technology businesses, and several other types of firms.

In May of this year, we reported on the opportunities and challenges that the agency faces as it integrates its PSCs into its overall program safeguard strategy.[15] The PSCs represent a new means of promoting program integrity and enable CMS to test a multitude of options. CMS is currently experimenting with these options to identify how PSCs can be most effectively utilized. For example, some PSCs are performing narrowly focused tasks that are related to a specific service considered to be particularly vulnerable to fraud and abuse. Others are conducting more broadly based work that may have national implications for the way program safeguard activities are conducted in the future or which may result in the identification of best practices.

In our report, we recommended that the agency define the strategic directions for future use of the PSCs, including the establishment of long-term goals and objectives. We also recommended that clear, quantifiable performance measures and standards be established and related to well defined outcomes in order to lay the groundwork for meaningful future performance evaluations. We recognize that it will take some time for the agency to develop appropriate performance criteria, but believe it is important to start

[14]Almost all of the PSCs have had experience as Medicare contractors: as of May 2001, six were Medicare claims administration contractors and an additional five had other types of contracts with CMS. Two of the six PSCs with claims administration contracts have established new entities to perform PSC work.

[15]*Medicare: Opportunities and Challenges in Contracting for Program Safeguards* (GAO-01-616, May 18, 2001).

experimenting with different approaches, such as using performance-based contracts, and refine them as time goes on. This need for better performance measures, standards, and outcomes will become especially critical if CMS awards contracts that are performance-based and contain financial incentives and penalties.

CONCLUDING OBSERVATIONS

Medicare is a popular program that millions of Americans depend on for covering their essential health needs. However, the management of the program has fallen short of expectations because it has not always appropriately balanced or satisfied beneficiaries', providers', and taxpayers' needs. Although the agency has taken some positive steps, weaknesses in its communications with providers and its oversight of contractors still exist. CMS' ability to successfully address these and other shortcomings will ultimately enhance its program safeguard activities and improve Medicare program operations.

This concludes my statement. I would be happy to answer any questions that you may have.

GAO CONTACT AND STAFF ACKNOWLEDGMENTS

For further information regarding this testimony, please contact me at (312) 220-7767. Susan Anthony and Geraldine Redican-Bigott also made key contributions to this statement.

(290103)

The CHAIRMAN. Mr. Schiffer.

STATEMENT OF STUART E. SCHIFFER, ACTING ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. SCHIFFER. Thank you, Mr. Chairman, and good morning.

I appreciate the opportunity to appear again before this committee to discuss the Justice Department's efforts to combat health care fraud.

I will state at the outset that although our testimony was not prepared at all in collaboration with each other, I did not find it surprising that there is substantial overlap between the testimony of my colleague in the Inspector General's Office and our own testimony, since we work in very close partnership in investigating and prosecuting health care fraud cases. Of course, for that reason, I will also feel free to refer any difficult questions to Mr. Morris, on my left.

Health care fraud quite obviously directly affects the Nation's most frail and elderly citizens, and of course, nowhere is this more true than with respect to Medicare fraud, which strips the trust fund of dollars intended for the care of beneficiaries.

In a very real and direct sense—and Senator Collins alluded to this—we think it is clear that such fraud is also an offense against the vast majority of honest and dedicated providers, as it decreases the pool of funds available to pay for the good and proper services rendered by these providers.

My prepared statement discusses our use of the False Claims Act, which is the principal tool we use certainly on the civil side to recover funds defrauded from Government health care programs. We firmly believe that our enforcement efforts are carried out in a fair and evenhanded manner.

Three or 4 years ago, the hospital industry brought to our attention concerns with a limited number of cases where certain U.S. Attorneys' offices had not followed the procedures we consider sufficient to lay a predicate for making allegation of violations of the False Claims Act.

In response to those concerns, which were brought to our attention and to Members of Congress, the Deputy Attorney General issued guidelines that memorialize what we consider to be our longstanding enforcement policies. We also formed working groups with experienced Assistant U.S. Attorneys and Department attorneys to coordinate and oversee these projects.

The General Accounting Office has monitored our compliance with these guidelines and has reported that the guidelines are being followed in a consistent manner at our U.S. Attorneys' offices.

The False Claims Act is a relatively straightforward statute. It applies to the knowing submission of false claims. It does not and is not intended to punish innocent mistakes; it is in no sense a trap for the unwary. Since its amendment 15 years ago, the Act has been used to recover literally billions of dollars that have been defrauded from Government programs, and we believe that the deterrent effect of our efforts has safeguarded many more billions.

At my last appearance, I described many of the collaborative efforts we have undertaken with other Federal, State, and local agencies and with many dedicated private sector groups which provide valuable service in combatting fraud. I will not dwell on these today. Suffice it to say the 1996 Health Insurance Portability and Accountability Act provided needed funding and encouragement for these collaborative efforts to go forward and improve.

The Act itself provides a public sector/private citizen partnership in giving monetary incentives and other safeguards for private whistleblowers to file suits on behalf of the United States. I think one of your later witnesses will speak more extensively to the whistleblower provisions. I want to assure the committee that our efforts to combat health care fraud and to safeguard the rights of our elderly citizens and of honest care providers will continue to be a high priority of this administration.

I too look forward to taking your questions.

The CHAIRMAN. Thank you, Mr. Schiffer.

[The prepared statement of Mr. Schiffer follows:]

Department of Justice

STATEMENT

OF

STUART E. SCHIFFER
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

CONCERNING

COMBATING FRAUD AGAINST HEALTH CARE PROGRAMS

PRESENTED ON

JULY 26, 2001

STATEMENT OF STUART E. SCHIFFER

ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

JULY 26, 2001

Mr. Chairman, I appreciate the opportunity to appear before you to discuss some of the important issues which are the focus of today's hearing. We are grateful for this Committee's leadership on the important topic of fraud and abuse and its impact on our elder citizens and government health care programs. I also would like to thank this Committee's former Chairman, Senator Grassley, for his continuing work on the False Claims Act and for promoting quality health care for older Americans.

At its core, fraud and abuse of the Medicare program is an aging issue. When the Medicare trust fund is illegally depleted, its beneficiaries – today's and tomorrow's Americans over 65 – lose. Similarly, Medicaid fraud and abuse harms our frailest and most impoverished older citizens. Those who defraud programs intended to benefit older Americans steal from all those who contribute to and rely on those programs.

Health care fraud remains a serious problem that has an impact on all health care payers, and affects every person in this country. Health care fraud cheats taxpayers out of billions of dollars every year. But it does not only harm beneficiaries. It also harms the majority of honest

providers by decreasing the potential pool of funds as demand grows, necessitating increased scrutiny, and giving the industry generally a black eye. Tax dollars alone do not show the full impact of health care fraud on the American people. Beneficiaries must pay the price for health care fraud in their copayments and contributions. Fraudulent billing also may disguise or lead to inadequate or improper treatment for patients, posing a threat to the health and safety of countless Americans, particularly the most vulnerable. The funds that we recoup through our efforts to combat fraud and abuse of the healthcare programs then can be used properly – to fund the requisite care for those who need it.

Thus, given the burgeoning demand on our healthcare programs caused by the aging of our population, stopping those who prey on the health care system and the losses they cause remains one of the Department's top law enforcement priorities. The types of schemes uncovered by the Department, in conjunction with the Department of Health and Human Services, the US Postal Service, the Defense Criminal Investigative Services, the Defense Department's TRICARE program, and other entities range from physicians billing the government for services never rendered, to corporate entities engaging in complex and sophisticated fraud in submitting claims to the Medicare system. Other examples of fraudulent schemes include: health care providers who exaggerate the level of care they provide to their patients or bill for services not provided; medical supply companies that falsify records to obtain payment for supplies that are not medically necessary; nursing homes that bill for nonexistent or grossly substandard care leading to harm or death of residents; and providers of home health services that employ unqualified and untrained personnel to render medical care.

As required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Department is involved in a number of activities aimed at coordinating our health care fraud enforcement efforts with other investigative agencies and the health care program agencies, such as the Centers for Medicare and Medicaid Services (CMS). These activities involve both exchange of information and consultation on the development of legislation, rules and policies. They concern prevention of health care fraud, as well as the detection, investigation, and use of legal tools to remedy health care fraud. Department attorneys who specialize in various health care related areas often are asked to speak to outside groups about the Department's activities in those areas. Similarly, the Department participates with other federal and state agencies, such as the Office of Inspector General, Department of Health and Human Services (OIG), CMS, the Department of Defense's TRICARE program, the National Association of Medicaid Fraud Control Units, and the National Association of Attorneys General on numerous committees and Task forces, such as the Executive Level Healthcare Working Group chaired by the Deputy Attorney General, the Healthcare Fraud Working Group, the Nursing Home Steering Committee, and an Interagency Elder Justice Workgroup.

Our health care fraud coordination activities include the following, among others:

- focusing resources and working with the CMS and the OIG, State and other entities on several high priority areas for the Department, including fraud and abuse by nursing homes and by managed care organizations;

- administering the systemic weakness reporting program, pursuant to which Department attorneys and investigators report vulnerabilities in federal health care programs that create opportunities for fraud and abuse;

- proposing and commenting on legislation and regulations aimed at preventing health care fraud and abuse, or relating to the legal tools used to address health care fraud and abuse;

- developing training and other instructional materials for Department attorneys, federal government investigators, and others;

- developing policies on issues such as disclosing quality of care allegations to regulatory and licensing authorities, and protecting the confidentiality of patient records; and

- providing advice and information to federal program agencies to assist them to develop policies designed better to prevent and detect health care fraud and abuse.

As members of this Committee know, the nation's healthcare system operates largely on an "honor system," trusting health care providers and suppliers of goods and services to submit honest claims for payment. Quite simply, and despite our best effort to work collaboratively, the government is simply not able to closely audit each claim submitted to assure that the care or

service has been provided and was "reasonable and necessary for the diagnosis or treatment of illness or injury." Government enforcement efforts, therefore, provide a necessary and unquantifiable (but very real and oft-cited) deterrence to those who would cheat the system, and serve as a reminder that there will be serious consequences for fraudulent conduct. These consequences may include incarceration, debarment from federal health care programs, administrative fines and penalties, and damages or restitution in an amount two or three times that which was obtained through fraud.

These enforcement efforts also are instructive to the nation's policy makers, illustrating weaknesses in current payment systems and illuminating the need to take proactive measures in certain areas the future. Also, these efforts form a basis for extensive training offered to government attorneys, auditors, investigators, and others charged with the task of enforcing the rules and regulations of the nation's health care delivery system. In the past 18 months, the Department's Office of Legal Education conducted 8 training courses related to health care fraud and use of the False Claims Act and trained over 600 Assistant United States Attorneys, Department Attorneys, and Auditors/Investigators. This training takes place primarily at the Department's National Advocacy Center in Columbia, South Carolina, and includes lessons gleaned from past experiences in these cases and the types of allegations that are coming to the forefront.

In addition, health care fraud working groups and/or task forces meet in many of the 94 federal districts and are composed of representatives of the United States Attorneys' offices, the

FBI, HHS/OIG, DCIS, and state and local officials charged with the task of coordinating health care fraud enforcement efforts.

The Department and CMS also are launching new interagency efforts to enhance our use of technology and high-tech tools to combat health care fraud and abuse. Advanced technologies provide yet another mechanism to ensure that no provider is prosecuted for simple billing errors or mistakes lacking any evidence of fraudulent intent and, conversely, that providers whose billings reflect enduring and consistent patterns of fraudulent or abusive behavior receive further scrutiny from law enforcement. In June 2000, CMS and the Department of Justice co-sponsored a national conference on the use of technology to combat fraud and abuse in health care programs. Recently, our agencies formed a National Technology Group to help implement key recommendations from last year's conference.

Examples of Achievements

HCA: In December, we announced the $840 million criminal and civil settlement with HCA - The Healthcare Company (formerly Columbia/HCA), the largest for-profit hospital chain in the United States. That settlement, for $95 million in criminal fines and $745 million in civil recovery, is the largest health care fraud settlement ever reached by the government and reflects the coordination of resources and collaboration we have brought to bear in investigating health care fraud. This was the largest investigation of a health care provider ever undertaken, involving a multi-agency investigation by attorneys, investigators, auditors and agency personnel,

over the course of several years. There are yet additional issues unresolved by the civil settlement.

In FY 2000, before the HCA settlement, the Department's extensive health care fraud efforts, in partnership with other federal and state enforcement agencies, won or negotiated more than $1.2 billion in judgments, settlements in health care fraud proceedings and cases. The Department collected and disbursed more than $674 million in connection with health care fraud cases and matters, with $535 million either deposited directly into the Medicare Trust Fund, or returned to the Trust Fund as amounts equal to other health care fraud collections. These funds now can be used properly – to fund the requisite care for those who need it. Some of the schemes brought to light by our investigations in the last fiscal year include the following:

- The world's largest provider of kidney dialysis products and services, Fresenius, Inc., agreed to pay the United States government $486 million to resolve a sweeping investigation of health care fraud. This investigation revealed that an acquired subsidiary of Fresenius submitted false claims seeking payment for nutritional therapy provided to patients during their dialysis treatments, for services that were provided to patients as part of clinical trials, for hundreds of thousands fraudulent blood testing claims, for kickbacks, and for improper reporting of credit balances. The criminal fine and the civil settlement were, at the time, the largest ever recovered by the United States in a healthcare fraud investigation.

- The nation's largest operator of nursing homes, Beverly, Inc., resolved allegations that it fabricated records to make it appear that nurses were devoting more time to Medicare patients than they actually were. The settlement required the company to pay $170 million in civil settlement -- a figure negotiated based on the chain's limited ability to pay.

- Anthem Blue Cross and Blue Shield of Connecticut, a former Medicare fiscal intermediary (a contractor who processes Medicare claims for the government), agreed to pay $74 million to resolve claims that it falsified interim payments on settled hospital cost reports in order to meet CMS's Contractor Performance Evaluation standards.

- A $53 million settlement with GAMBRO Healthcare resolved allegations of false billings for laboratory services primarily provided to dialysis clinics treating patients with end-stage renal disease (ESRD).

- Community Health Systems (CHS) paid $31 million to resolve allegations improperly assigning diagnostic codes for the purpose of increasing reimbursement amounts. Seven states received a portion of the settlement for losses to their Medicaid programs.

- More than 70 entities that provided, or assisted in the provision of, radiation oncology services to cancer patients, as well as their billing companies, agreed to pay almost $10 million to settle allegations of false claims to federally-funded health care programs.

These providers often billed Medicare for services that were not provided, billed twice for the same service, or sought a higher rate of reimbursement than that to which they were entitled.

- In the first settlement with a Medicare managed-care company, Humana, Inc., paid $14.5 million to settle allegations that the company provided inaccurate payment information from 1990 through 1998. Humana incorrectly listed beneficiaries as eligible for both Medicare and Medicaid, thus securing the higher reimbursement afforded such dually eligible beneficiaries.

- The United States recovered $2.6 million from clients of the Oklahoma-based Emergency Physician Billing Services (EPBS) to settle claims of overpayments based on false claims submitted by EPBS. These settlements follow on the heels of a September 1999 settlement with EPBS and its physician founder for $15 million for fraudulent billing to Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefit Program.

National Projects

Through working groups composed of experienced Assistant United States Attorneys and Attorneys from the Department's Civil Division, the Department maintains four so-called "national projects" to recover the government's losses from similar types of false claims submitted by hundreds of hospitals around the country. These four projects are referred to as the

"DRG 72-Hour Window Project," the "Hospital Laboratory Unbundling Project," the "Pneumonia Upcoding Project," and the "PPS Transfer Project." The projects stem from analyses of national claims data by the Office of Inspector General of the Department of Health & Human Services. These working groups were established as part of the Department's "Guidance on the Use of the False Claims Act in Health Care Cases," which was issued by the Deputy Attorney General on June 3, 1998, in response to concerns expressed by some in the provider community. The guidance memorializes existing policies requiring allegations of False Claims Act liability to be based on an adequate factual and legal predicate, and institutes new procedures for "national projects," including coordination and oversight by the working groups discussed above, and the use of "contact letters" that offer health care providers an opportunity to discuss the government's allegations before a demand for payment is made. The guidance was updated by a February 3, 1999, memorandum from the Deputy attorney General.

In a March, 2001, GAO issued its Report to Congress titled "Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance." In its report, GAO specifically found that the Department has an evaluation process that provides meaningful assessment of compliance with the guidance, that United States Attorneys' offices certify compliance with the guidance, and that interaction with hospitals was consistent with the guidance. GAO also found that the Department has taken substantive steps to strengthen oversight of compliance with the guidance and that the two most recent national initiatives (PPS Transfer and the Pneumonia Upcoding projects) are being handled in a manner consistent with the guidance. GAO concluded that the Department "has demonstrated its continued commitment to promoting the importance of

compliance with the False Claims Act guidance at its U.S. Attorneys' Offices."

Elder Abuse and Neglect

In my testimony before this Committee on June 14, 2001, I highlighted the Department's continuing efforts to protect our nation's most vulnerable citizens - its older people through our Nursing Home Initiative and Elder Justice efforts. At that time I explained that the Department's efforts to combat elder abuse, neglect and exploitation have been multi-faceted, and include: (1) stepped up prosecution, (2) education and training, (3) broad-based interagency and multi-disciplinary coordination, (4) promotion of medical forensics, and (5) funding, research, programs, and statistics, to fight elder victimization.

The majority of the Department's cases alleging institutional abuse and neglect – failures of basic care leading to profound malnutrition, dehydration, pressure ulcers, scalding, and other illness, injury or death – have been pursued under the civil False Claims Act, a financial fraud statute. The theory in these cases is straightforward – the United States paid for requisite care and services that the defendant knowingly did not provide, but for which it sought reimbursement. Two courts have affirmed this theory, and approximately ten failure of care cases have settled in the last five years. Settlement terms in the majority of these cases have required imposition of a temporary monitor and implementation of specific protocols and training to improve care -- for example in wound care or diabetes management -- if that is where the entity demonstrated problems.

The last two and one-half years have presented new challenges, with the financial decline and bankruptcy filings of five of the nation's seven largest nursing home chains – owning approximately 300 to 450 facilities each. For five such substantial entities to file for bankruptcy in such a short a period (in addition to many smaller entities) was extraordinary (and the subject of a hearing by this Committee last September). The Department's False Claims Act investigations against some of these entities involved monetary claims of tens or hundreds of millions of dollars, in addition to troubling failure of care claims.

The precarious financial state of these chains required that the Department of Health and Human Services closely monitor the care offered by the facilities and formulate "contingency plans" in the event any of the chains suddenly closed or liquidated. The Department of Justice worked closely and productively with both CMS and OIG to negotiate appropriate settlements that balanced the interests of the residents of these facilities with the need to make restitution to government health programs.

Telemarketing Schemes Against Older People

The Department has detected a major trend in telemarketing fraud against consumers in this country (including Internet fraud) where the schemes are directed both within and from outside the United States. These schemes often target our nation's older citizens. Older people in declining health, mobility, and varying cognitive capacity, are not only more vulnerable to physical and psychological abuse and neglect, but also to financial exploitation. Indeed, there

appears to be a correlation between the two, with victims of financial exploitation appearing to be at higher risk for other forms of abuse and neglect. The Department's United States Attorneys' offices and its Criminal and Civil Divisions have successfully pursued both civil and criminal cases to redress these schemes.

One method available to the Department for combating this problem is the filing of civil proceedings by our Civil Division's Office of Foreign Litigation in the foreign jurisdiction where the fraudulent telemarketing activities are based. In appropriate civil cases, we can seek to shut down boiler rooms, enjoin con-artists from telemarketing into the United States, and freeze corporate and individual assets for eventual restitution to victims of the fraud. For example:

- In United States v. Fortuna Alliance, LLC, et al, we filed an action in the High Court of Antigua, freezing all trust accounts in an offshore bank controlled by Fortuna Alliance, which was involved in a pyramid scheme that operated over the Internet. $2.8 million was eventually returned from those accounts and distributed to victims of the scheme by the Federal Trade Commission.

- In United States v. Euro-Can-Am, et al., Canadian telemarketers recently paid $1 million to the United States in settlement of a suit filed in Canada. The funds provided partial restitution to victims of a cross-border telemarketing scheme involving the sale of fake gemstones. The Canadian action was parallel to a criminal case brought in the Middle District of Pennsylvania and effectively froze defendants' assets until the settlement. As

part of the global resolution of the matter, defendants plead guilty to criminal charges and were sentenced to 12 months in prison.

Other cross-border fraud civil cases are presently pending in Canadian courts. These suits arise from Canadian telemarketing fraud operations directed at consumers in this country, with proceeds of the fraud going to other countries in the Caribbean and Europe. We anticipate filing additional suits in those countries in which assets are located in order to repatriate them for restitution to injured consumers in the United States.

Similarly, the Department's Criminal prosecutors -- using mail fraud, wire fraud, credit card fraud, conspiracy, money laundering, and other federal criminal charges – have successfully prosecuted many people who defraud older people through telemarketing, Internet, credit card, and advance-fee fraud. Three major undercover operations directed at telemarketing fraud, for example, resulted in prosecution of more than 1,400 persons for telemarketing-fraud charges. Sentences in these cases have ranged as high as 14 and 18 years. In one very recent case, a telemarketer who preyed upon elderly victims -- including an 82-year-old woman who told the defendant that her husband was in the hospital dying of cancer -- was sentenced in the Central District of California to 115 months imprisonment.

Conclusion

In conclusion, I assure the Committee, as I did in June, that the Department of Justice will continue to play a lead role and to work with this Committee in addressing fraud and abuse committed against the nation's health care programs as well as those committed against our nation's older citizen's. I welcome your comments and questions.

The CHAIRMAN. Mr. Morris.

STATEMENT OF LEWIS MORRIS, ASSISTANT INSPECTOR GENERAL FOR LEGAL AFFAIRS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. MORRIS. Good morning, Mr. Chairman.

Health care providers can reasonably expect the Federal Government to provide clear and consistent guidance when administering the Medicare program. At the same time, health care providers reasonably must ensure that the care they provide to Medicare beneficiaries and the claims they submit conform to program requirements.

The Office of Inspector General is committed to continuing its work with providers and the Centers for Medicare and Medicaid Services to advance these mutual goals. The OIG's mission to prevent and detect fraud, waste, and mismanagement is carried out through a nationwide program of audits, inspections, and investigations. With the increased resources provided by the Congress in 1996, we and the Department of Justice have sought to protect the integrity of the Medicare trust fund by diligently pursuing health care fraud.

Our enforcement actions are taken against those who knowingly submit false claims or otherwise intentionally engage in misconduct. It is important to note that under the laws that we help enforce, providers are not subject to nor do we pursue civil or criminal penalties for innocent errors or negligence.

The Government's primary civil enforcement tools—the civil False Claims Act and the civil monetary penalty laws—cover only offenses that are committed with actual knowledge of the falsity of the claim or reckless disregard or deliberate ignorance of the falsity of the claim.

For criminal penalties, the standard is even higher—criminal intent to defraud must be proven beyond a reasonable doubt.

Thus our enforcement actions focus on those companies and individuals who have clearly violated the law. Fortunately, the great majority of providers want to bill the program correctly. These providers are our allies in the fight against health care fraud and abuse, and accordingly, we devote significant efforts to educating providers about their compliance obligations.

As my written testimony describes in detail, the OIG issues legally binding opinions regarding the lawfulness of specific business arrangements, promulgates regulations that protect certain business practices from being prosecuted under the anti-kickback statute, publishes bulletins identifying conduct the Inspector General considers suspect, and issues guidance to implement voluntary compliance programs.

The American Hospital Association was instrumental in the design of the Compliance Guide for Hospitals, and we are very appreciative for its support.

Regrettably, despite these efforts, some providers continue to knowingly abuse and defraud the Federal health care programs. When individuals or entities are found to have engaged in fraud,

the OIG is responsible for determining whether to exclude them from future participation in the Federal health care programs.

This typically arises in connection with the settlement of allegations of fraud between the provider and the Department of Justice. In the appropriate circumstances, the OIG may offer to waive its exclusion remedy in exchange for the provider entering into a Corporate Integrity Agreement, or CIA.

The OIG has never required a CIA without evidence that the provider has engaged in fraudulent conduct. Each CIA addresses the specific facts of the particular case and is tailored to the existing capabilities and structure of the health care provider. It also considers any pre-existing voluntary compliance measures of the provider. It allows that provider to implement a CIA consistent with cost-effective auditing, training, and reporting requirements.

In response to feedback from the health care industry, we continually evaluate each element of the CIA, make modifications as appropriate, to decrease the cost and burden of operating under these agreements.

Additionally, we are seeking guidance from the provider community by holding another of our series of roundtable discussions with the health care industry. Specifically, on July 30, representatives of health care providers that are currently operating under CIAs will meet with the OIG in Washington to discuss issues surrounding the implementation and maintenance of compliance programs and CIAs.

Mr. Chairman, the OIG is committed to protecting the integrity of the Federal health care programs and will continue to work with health care providers to achieve this mission. Our enforcement efforts will continue to focus on those providers who have engaged in fraudulent conduct. We will also continue to collaborate with providers to assist in their efforts to comply with program requirements.

We appreciate the strong support we have received from the Congress and your continued interest in this critically important subject.

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

[The prepared statement of Mr. Morris follows:]

Testimony

Senate Special Committee on Aging

United States Senate

"Medicare Enforcement Actions: The Government's Anti-Fraud Efforts"

Testimony of Lewis Morris
Assistant Inspector General for Legal Affairs

July 26, 2001
10:00 a.m.
124 Dirksen Senate Office Building

Office of Inspector General
Department of Health and Human Services

Testimony of
Lewis Morris
Assistant Inspector General for Legal Affairs
U.S. Department of Health and Human Services

Good morning Mr. Chairman and members of the Committee.

Health care providers quite reasonably expect the Federal government to provide clear and consistent guidance when administering the Medicare program. At the same time, it is appropriate to expect health care providers reasonably to ensure that the care they provide to Medicare beneficiaries and claims they submit to conform to program requirements. The Office of Inspector General (OIG) is committed to continuing its work with honest health care providers and the Centers for Medicare and Medicaid Services (CMS) to advance these mutual goals.

In my testimony I will describe how the OIG responds to health care providers who submit false claims to the Federal health care programs. I also will discuss the OIG's efforts to promote integrity in the Medicare program through a partnership with the provider community. Finally, I will explain how we are continuing to work with the health care industry to improve many of our integrity initiatives.

The Role of the Office of Inspector General

The OIG plays a critical role within the U.S. Department of Health and Human Services (HHS). Our office's mission is to prevent and detect fraud, waste, and mismanagement, and to promote economy, efficiency, and effectiveness in all HHS programs and operations.

The core mission of the OIG is carried out through a nationwide program of audits, inspections, and investigations related to the operation of HHS programs. Our comprehensive *audits* and *evaluations* are designed to detect problems in the early stages and to define their nature and magnitude. When we find problems, we recommend specific corrective actions to the appropriate policy makers within HHS.

In contrast, our *investigations* are designed to identify and, if appropriate evidence exists, refer for prosecution cases of fraud. In FY 2000 alone, the OIG conducted or participated in 2,597 health care cases, of which 234 resulted in criminal convictions and 352 produced successful civil recoveries. A total of 3,350 individuals and entities were excluded from participation in the Federal health care programs based on criminal

convictions, patient abuse, licensure revocation or other misconduct. The Federal government won or negotiated more than $1.2 billion in health care judgments, settlements and administrative impositions in health care fraud cases.

These enforcement actions were taken against those who knowingly submitted false claims or otherwise intentionally engaged in misconduct. It is important to note that under the laws we help enforce, providers are *not* subject to civil or criminal penalties for innocent errors, or even negligence. The Government's primary civil enforcement tools (the civil False Claims Act and Civil Monetary Penalties Law) cover only offenses that are committed with *actual knowledge* of the falsity of the claim, or *reckless disregard* or *deliberate ignorance* of the falsity of the claim. These statutes do not penalize mistakes, errors, or negligence. For criminal penalties, the standard is even higher – criminal intent to defraud must be proved beyond a reasonable doubt.

Thus, our enforcement actions focus on those companies and individuals who have clearly violated the law. These are not cases of honest mistakes or simple billing disputes. Last year, for example, a major national hospital chain agreed to pay $840 million ($95 million in criminal fines and $745 million in a civil settlement) to resolve allegations of Medicare fraud. The company's subsidiaries entered guilty pleas for: (1) submitting false Medicare cost reports; (2) mischaracterizing the severity of hospital patients' illnesses in order to inflate Medicare reimbursement; (3) paying kickbacks to physicians for patient referrals; and (4) paying kickbacks and filing false cost reports related to a series of acquisitions of home health agencies.

Another OIG case involved three California physicians who purchased Medi-Cal patient identity cards, made up phony patient files, and billed for ghost patients never treated at their clinic. Of about 6,000 patient files, only about 100 were for legitimate patients. Or consider the case of another California physician, who billed for hundreds of services to patients who had died prior to the date of service or who were incarcerated. In another case, six New York practitioners involved in a kickback scheme signed stacks of orders for durable medical equipment without ever seeing the patients, accepted kickbacks for doing so, and filed claims for services not provided.

While the OIG focuses its enforcement efforts on those who engage in reprehensible conduct, we believe that a great majority providers want to bill the program correctly. These providers are our allies in the fight against health care fraud and abuse. Accordingly, I will now describe the OIG's efforts to educate providers about their compliance obligations. I also will describe how the OIG offers a "second chance" to those providers that have defrauded the Medicare program by requiring them to implement an integrity program to ensure future compliance.

The OIG Commitment to a Government-Industry Partnership

The OIG believes that the vast majority of health care providers are honest, are committed to providing quality care, and share our goal of strengthening the integrity of the health care system. As I have explained, these honest providers are *not* subject to civil or criminal penalties for innocent errors, or even negligence. To the contrary, we recognize that by working in tandem with these providers, we can help preserve the Medicare trust funds for future generations. This Government-industry collaboration also "levels the playing field" for honest providers who compete based on the quality and price of their services rather than by cheating the system through kickback schemes and billing scams. In furtherance of this goal, we have dedicated significant resources to communicate with the health care industry. With the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress reinvigorated our mission with the establishment of a national Health Care Fraud and Abuse Control Program under the joint direction of the Attorney General and the Secretary of HHS, acting through the OIG.

One of the five core elements of the HIPAA fraud and abuse control program is the provision of guidance to health care providers regarding potential liability for activities that may be considered fraudulent or abusive. I will focus my comments on four OIG initiatives related to the goal of furnishing guidance to health care providers. Specifically, the OIG: (1) issues legally binding opinions regarding the applicability of the criminal and administrative sanction provisions of the Social Security Act to specific business arrangements and practices; (2) promulgates regulations that protect specified business practices from being prosecuted under the anti-kickback statute; (3) publishes special fraud alerts and bulletins identifying practices that the Inspector General considers suspect or of particular concern; and (4) issues guidance on implementing voluntary compliance programs. Additionally, we participate actively in a variety of public forums where these issues are discussed and debated.

Provision of Binding Advisory Opinions and Safe Harbors

Pursuant to HIPAA, the OIG established an advisory opinion process through which parties can obtain binding legal advice as to whether their existing or proposed health care business transactions or arrangements violate the anti-kickback statute, the civil monetary penalties laws, or any program exclusion provisions. In addition, the OIG annually solicits proposals for the issuance of new, and modification of existing, "safe harbors" under the anti-kickback statute. Since this provider education function began in 1997, we have issued over 60 advisory opinions, promulgated nine new safe harbors, and clarified or modified many existing safe harbors. In addition to assisting the

health care industry comply with the law, the advisory opinion and safe harbor mechanisms enhance the OIG's understanding of new and emerging health care business arrangements and guide the development of new safe harbor regulations, fraud alerts, and advisory bulletins.

Identification of Suspect Industry Practices

The OIG also issues Special Fraud Alerts, Special Advisory Bulletins, and other industry guidance as part of its ongoing efforts to promote ethical and lawful conduct by health care providers. We believe it is sound public policy to notify the public of potentially abusive practices we uncover during our audits, inspections, and investigations so that honest providers can examine their operations and take appropriate corrective actions. As an example, the OIG issued a Special Fraud Alert describing abusive practices associated with the provision of medically unnecessary medical supplies and home health services. These include the payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency and disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of fair market value. The alert also reminds physicians of their responsibilities when certifying the medical necessity of these services for a Medicare beneficiary.

A Special Advisory Bulletin issued earlier this month warned providers of unethical health care business consultants and the types of abusive billing schemes they promote. For example, a billing consultant may promise a prospective client that its advice or services will produce a specific dollar or percentage increase in the client 's Medicare reimbursements. The consultant's fee is often based on a percentage of this increased reimbursement. History has shown that this type of arrangement can encourage exploitation of the reimbursement systems to the ultimate detriment of both the health care programs and the health care provider. The OIG also provided testimony on this subject before the Senate Finance Committee on June 27, 2001.

Development of Voluntary Compliance Program Guidances

In addition to case-specific advisory opinions and industry fraud alerts, the OIG has embarked on a major initiative to promote voluntary compliance programs within health care organizations. The purpose of a compliance program is to ensure that the organization has adequate systems to prevent and detect violations of law, as well as misconduct by its employees and agents. The OIG has found that providers with an effective compliance program in place not only provide quality care and services, but also have fewer systemic billing errors.

In recent years as the Government has stepped up its anti-fraud efforts, health care providers devoted greater attention and resources to the development of compliance programs. Part of the reason they did so is because compliance programs make good business sense and reduce expenses in the long run. We were concerned, however, that the cost of retaining an outside compliance consultant to develop and implement these programs might put this valuable tool beyond the budget of many providers. Accordingly, our office has worked intensively and cooperatively with CMS, health care providers, and related industry groups, such as the American Hospital Association (AHA) and the American College of Physicians-American Society of Internal Medicine (ACP-ASIM), to produce a series of voluntary compliance program guidances for major sectors of the health care industry. Each guidance provides concrete suggestions for designing and implementing internal controls and procedures to address identified risk areas for the applicable health care sector.

These guidances are not mandatory; they are not regulations. Health care providers are free to accept, reject or adapt the applicable guidance to their particular circumstances and budget. Moreover, our office has considered voluntary compliance efforts a mitigating circumstance when determining the appropriate sanctions to be imposed on providers who have been found (despite their compliance efforts) to have engaged in fraudulent or abusive practices.

A measure of the success of this collaborative approach is reflected in the widespread adoption of compliance programs throughout the health care industry. For example, in 1999, a compliance survey reported by the AHA found that 96 percent of its membership responding to the survey either had a compliance program in place or were planning to initiate one in the coming year. ACP-ASIM modeled its own compliance program for members on the OIG's physicians compliance guidance and noted that "we are particularly pleased to see that the OIG included our recommendation that physicians be encouraged to adopt the active application of compliance principles in their practices, rather than implement rigid, costly, formal procedures." The Health Care Compliance Association (HCCA), whose 3,000 members represent the industry's compliance officers, recently passed a resolution acknowledging the OIG's important contribution and the compliance guidances as "having been prepared professionally and represent[ing] a highly valuable resource to health care professionals."

To date, we have issued nine compliance guidances pertaining to hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, Medicare+Choice organizations, nursing facilities, and individual and small group physician practices. Currently, we have

solicited public comment and are developing guidance for ambulance transportation companies and the pharmaceutical industry.

Access to Essential Compliance Information

Compliance guidances and other fraud prevention tools are of little value unless they are easily, promptly, and widely available to providers nationwide. Accordingly, all of the information I have just described is readily accessible to health care providers, in a single location, by logging on to the OIG's web site at www.hhs.gov/oig. Each month the OIG also posts a list of the individuals and entities who are currently excluded from participation in Medicare, Medicaid, and other Federal heath care programs. Publicizing this information to health care providers and prospective employers is critical because excluded individuals present a great risk to the integrity of the business entity, the Federal health care programs and program beneficiaries. In addition, the OIG has created an electronic service that provides an early alert to all interested parties about any new item or document to be posted on the OIG website. There are currently over 9,800 subscribers to this e-mail listserve, which ultimately reaches over 88,000 individuals throughout the health care community.

Promotion of a Government-Industry Dialogue

As a result of our extensive experience in identifying Medicare program vulnerabilities, the OIG must play a leadership role in promoting measures to strengthen the integrity of the program. Equally important, health care providers have insights and perspectives that can only come from operating a business under the complex set of regulations that apply to the Federal health care programs. To devise realistic solutions, the OIG has recognized that we must engage in a continuous dialogue with health care providers. OIG staff have consistently made themselves available to health care provider groups, participating in hundreds of discussion panels and teleconferences on issues as diverse as the OIG work plan and promoting quality care in nursing homes.

For example, the OIG and the HCCA co-sponsored a series of meetings with health care providers to explore new ways to promote compliance. The first of these roundtables in 1999 was an opportunity for the health care compliance industry to inform the OIG of issues encountered in implementing and maintaining compliance programs. This first meeting was also an opportunity for the OIG to present policy objectives underlying its corporate integrity initiatives and compliance program guidance. At the second meeting in 2000, practicing physicians from across the country met with OIG and CMS representatives to discuss the challenges to compliance in physician practices.

Based in part on information obtained from this roundtable, the OIG issued its voluntary compliance program guidance for physician practices in September 2000.

The OIG Voluntary Disclosure Program

If a health care provider implements a comprehensive compliance program, there is a reasonable chance at some point it will discover a violation of Federal health care program requirements. After all, one of the precepts of an effective compliance program is the early detection of billing errors and other problems through a system of internal audits and by empowering employees to do the right thing. Furthermore, to receive credit under the criminal sentencing guidelines for having an effective compliance program, the U.S. Sentencing Commission guidelines require a corporation to have a mechanism to report self-discovered errors. For these reasons, many in the heath care industry sought a mechanism through which to report such fraud and abuse.

In response, the OIG created the Self-Disclosure Protocol (Protocol), a copy of which is also posted on the OIG website. The Protocol provides a detailed, step-by-step explanation of how a provider can assess the extent and financial impact of any discovered wrongdoing and report the results of that assessment to the OIG. Providers that made good faith disclosures to the OIG pursuant to the Protocol have received expedited review of their disclosures and, where appropriate, favorable treatment in the resolution of the matter disclosed.

Since 1995, the OIG has received over 120 self-disclosures from health care providers, and the Medicare Trust Fund has recovered over $42 million. Many of these matters were resolved with a simple recovery of the Medicare overpayments. Others were resolved with no findings of provider liability. In more serious cases, the matter has been referred to the Department of Justice (DOJ) for resolution under the civil False Claims Act. In these latter cases, the OIG has made a commitment to take voluntary compliance efforts into consideration when determining the appropriate administrative sanctions to be imposed on providers found to have engaged in fraud.

Corporate Integrity Agreements - "Second Chances" for Providers who have Committed Fraud

As the foregoing demonstrates, the OIG has devoted substantial resources to working with providers to improve the integrity of the Medicare program. We believe that the majority of health care providers are willing and able to use tools such as the compliance guidances and fraud alerts to minimize the risk of billing fraud and other abuses. Unfortunately, despite these efforts, some providers continue knowingly to abuse

and defraud the Federal health care programs. This fraud includes, among other things, billing for items that are not provided, upcoding of claims, and providing medically unnecessary care.

When individuals or entities are found to have engaged in fraud, the OIG is responsible for determining whether to exclude them from participation in Federal health care programs. In the Social Security Act, Congress directed that health care providers found to be untrustworthy should not be allowed to do business with the Federal Government for some period of time. In the case of felony convictions related to health care fraud or patient abuse, Congress mandated that the defendant be excluded for a minimum of five years. However, in less serious circumstances, Congress gives the OIG some discretion in deciding whether to impose an exclusion, as well as its length.

In exercising this discretion in civil false claims cases, the OIG has adopted non-binding criteria for deciding whether to exclude providers or, despite evidence that they are untrustworthy, allow them to continue to participate in the Federal health care programs. This issue of programmatic exclusion in false claims cases usually arises in connection with the settlement of allegations of fraud between the provider and DOJ. In the appropriate circumstances, the OIG may offer to waive its exclusion remedy in exchange for the provider entering into a corporate integrity agreement or "CIA." This agreement, which is typically in effect for between three and five years, requires the provider to institute or maintain a series of internal controls that better ensure its future compliance with Federal health care program requirements and ultimately protect the Medicare program and its beneficiaries.

Most of the requirements of the CIA are derived from the seven elements of an effective voluntary compliance program, as outlined by the U.S. Sentencing Commission. By adopting these existing standards, the OIG conforms its own enforcement goals with that of other Federal law enforcement authorities. These compliance program elements include appointment of a compliance officer, development of written standards and policies, implementation of a comprehensive employee training program, auditing of claims submissions to Federal health care programs, establishment of a confidential disclosure program, disciplinary measures, and restricting employment of ineligible persons. It is our hope that when the obligations of its CIA end, the provider has in place a comprehensive compliance system that has become an integral part of an ethical organization.

In our experience, most health care companies that have implemented voluntary compliance programs have incorporated these variables into their internal control systems. However, two significant requirements of the CIA are not part of a voluntary

compliance program: the provider's obligation to submit to the OIG for the term of the CIA an annual report that summarizes its compliance efforts and a billing review, conducted either by an independent review organization (IRO) or, in many cases, by the provider's internal auditing mechanism, with a verification review performed by the IRO. This billing review is intended to assist the provider in avoiding improper billings, as well as identifying and correcting improper billings once they occur. This requirement has proved to be an essential aspect of ensuring appropriate claims are submitted to the Federal health care programs.

While the above components are common to all CIAs, each agreement addresses the specific facts of the conduct at issue in the particular case and is tailored to the existing capabilities and structural organization of the provider. This tailoring allows providers the opportunity to negotiate the terms of the CIA and to help design cost-effective auditing and reporting requirements. As more and more providers have instituted compliance measures, increasingly the OIG is able to customize the integrity agreement in a way that makes good business sense for that particular provider and utilizes the provider's resources and pre-existing compliance measures in the most cost-effective manner.

In response to feedback we have received from providers, we continually evaluate the usefulness of each element of the CIA and have modified many of the requirements to decrease the cost and burden of operating under the CIA. However, we continue to develop ways to improve the process.

For example, to ensure that the IRO function in the CIA serves its intended purpose and does not become an unnecessary burden on the provider, the OIG has undertaken a number of measures. For example, the OIG may allow the annual billing audit to be shifted from the IRO to an internal audit department in the later years of the agreement in cases where the provider can clearly demonstrate that it has developed a robust system of internal controls. This reduced reliance on the IRO not only lowers the cost of the CIA, but also strengthens the provider's internal audit capabilities.

The OIG also has worked extensively in the last two years with the American Institute of Certified Public Accountants (AICPA) to address the role and responsibilities of an IRO in the CIA process. With the OIG's assistance, the AICPA issued a Statement of Procedure (SOP 99-1) that provides detailed guidance and advice on IRO engagements and reviews. The OIG continues to work with a task force of the AICPA on modifying the IRO claims review procedures to make them more cost-effective.

Additionally, we are seeking guidance and suggestions from the provider community by holding another in our series of roundtable discussions. Specifically, on July 30, representatives of health care providers that are currently operating under CIAs will meet with OIG staff and the HCCA to discuss the issues surrounding the implementation and maintenance of compliance programs and CIAs. This roundtable, entitled "A Government-Industry Roundtable on Corporate Integrity Agreements," is part of the OIG's ongoing effort to solicit feedback from providers operating under CIAs, and to adapt its CIAs to the business realities of the health care industry.

Providers that have successfully operated under a CIA, and that have continued to implement compliance measures after the CIA has expired, have found that the CIA is not a punitive mechanism, as it has sometimes been mischaracterized. Rather, it is a tool that assists the provider in focusing its attention on providing quality care, submitting claims that are free from error, and developing a business based on integrity. As the compliance officer for a California medical center explained, "Despite the difficulties of the task, implementing the [CIA] program was a positive opportunity for our healthcare system to not only gain valuable compliance knowledge, but also to enhance operational efficiency and improve patient care." (Mike Powers, Healthcarebusiness, September 2000, at 86.)

The Impact of Integrity Efforts on the Medicare Program

The OIG's enforcement efforts and the joint Government/industry compliance initiatives have helped to improve Medicare's financial outlook. Over the last 5 years, the OIG audit of the fee-for-service part of the Medicare program has shown that the rate of improper payments has been cut in half. For Fiscal Year 1996, improper payments totaled about $23 billion (14 percent of program expenditures), and by Fiscal Year 2000, improper payments had dropped to about $12 billion (7 percent of program expenditures).

Another indicator is the drop in the Medicare "inflation rate." The Congressional Budget Office (CBO) reports that from 1991 to 1996, the inflation rate averaged 10.9 percent per year, but the rate has dropped to an average of 3.2 percent since then. According to the CBO, "Most of the decline can be explained by a strong effort to ensure compliance with payment rules." (CBO Budget Report, January 2001).

Most significantly, over the last 5 years the Trustees of the Medicare Part A trust fund have extended their estimate of the financial life of the trust fund by 30 years, from 1999 until the year 2029. One of the primary contributing factors cited by the Trustees

has been, "the continuing efforts to combat fraud and abuse." (Trustees Annual Report, 1999).

Conclusion

The OIG is committed to protecting the integrity of the Federal health care programs and will continue to work with health care providers to achieve this mission. Our enforcement efforts will continue to focus on those providers who have engaged in fraudulent conduct. We also will continue to collaborate with the vast majority of providers and assist their efforts to comply with program requirements. We appreciate the strong support we have received from the Congress and your continued interest in this critically important subject.

Thank you for the opportunity to testify today. I would be pleased to answer any questions.

The CHAIRMAN. Thank you all very much for your testimony and your presentations.

Do you all have a memorandum of understanding between Justice and OIG as far as how you operate, where you overlap, and how you work together? Is there some kind of policy that you have, or is everybody on their own?

Mr. MORRIS. In one particular area, there is actually a statutory insurance that we do not overlap. When we bring civil monetary penalty actions, which are administrative actions, to pursue false or fraudulent conduct, we need to get the approval of the Department of Justice before we can go forward with that action. That ensures that we do not have overlapping enforcement efforts.

In addition to that, we have a series of work groups, both an executive level work group as well as individual working groups focusing on particular national initiatives, where we discuss both the underlying rules and regulations that we are looking into and also ensure that there will be a consistent application of our enforcement efforts across the country.

The CHAIRMAN. I would imagine that hospitals and providers will probably say that they do not know who they have to deal with—on the one hand, they are worried about Justice, and on the other hand, they are worried about OIG. What can we tell them to alleviate that concern? It seems like in some areas, the OIG is involved in enforcement or investigation, and in other areas, Justice is pursuing a criminal prosecution.

Is there anything we can say to providers to give them some confidence that there is no overlap in these areas?

Mr. SCHIFFER. Most of our cases, Mr. Chairman, are resolved on three fronts—any criminal investigation that has taken place; consideration of civil remedies; and the administrative sanctions or remedies that Mr. Morris testified about.

I do not think there is a consistent problem. To some extent, we have to have separation between the criminal and civil sides just to provide compliance with the ethical rules and matters such as limits on the extent to which grand jury information can be shared. But I do not think there are recurrent situations where a provider does not know whether to talk to the IG or the Justice Department, since in a typical case, we are working together, and the provider can frankly deal with either side of the house.

The CHAIRMAN. Thank you.

The American Hospital Association in their testimony coming up, I think, will basically recommend that Congress give hospitals a specific opportunity to challenge decisions made by HHS and the Medicare program that they feel would be legally questionable. Can you comment on that? I take it they would like to have an opportunity to go to court and try to challenge some of these policy decisions rather than go through some kind of administrative process to appeal these decisions. Would that have any effect on enforcement from your standpoint?

Mr. SCHIFFER. I think it could. I am reluctant to speak at length about proposals that we have not seen specifically. I think two things are separate. On one hand, I think providers need to be able to obtain clear guidance and to make sure they are not trapped by complex procedures. On the other hand, unlike some of my col-

leagues in private practice who will be testifying for the hospital associations, we have more business than we need, and the Federal courts certainly have more business than they need, and I think there is always a risk in bringing premature challenges when you are not operating with specific fact patterns where there really is a need for Federal courts to address these issues.

So I would far prefer to see things simplified on the administrative side so that such guidance can be obtained, as opposed to encouraging yet more litigation in the Federal courts.

The CHAIRMAN. Can anybody give me some kind of idea of how much of the improper payments are pursued under the False Claims Act versus other means of pursuing these improper payments? Is the bulk of it under False Claims Act, or is the bulk of it through internal OIG efforts? How do we do it? When we have problems with improper payments, how do we pursue them most of the time? Is there some kind of balance here?

Mr. SCHIFFER. Of course, the False Claims Act is only directed at payments that are fraudulent in nature—payments that constitute knowing presentation of false claims—and I am not sure that I——

The CHAIRMAN. In other words, to pursue an action under the False Claims Act, you have to show intent to defraud as opposed to just a mistake?

Mr. SCHIFFER. Not so much as a criminal intent, but at least a knowledgeable submission of a false claim. I am not sure that I can do any better than Mr. Scully did in estimating what percentage of improper claims are fraudulent as opposed to——

The CHAIRMAN. Is there ever a case where an intent to submit a false claim would not be criminal?

Mr. SCHIFFER. I am sorry?

The CHAIRMAN. Is there ever a case where an intent to submit a false claim would not be criminal?

Mr. SCHIFFER. No—typically, those would be criminal cases. What I am saying is that I am not sure I can give you an exact dichotomy in terms of estimating percentage of claims that are simply the result of erroneous submissions and those that are fraudulent. I am not sure if Mr. Morris can do any better—but we do not bring under the False Claims Act cases where we have reason to believe these are negligent mistakes or simple overpayments.

The CHAIRMAN. If you do proceed in that fashion and you find out that this was not an intent to defraud but sloppy bookkeeping or an honest mistake, do you kick it over to somewhere else for collection?

Mr. SCHIFFER. We would do that, or we would attempt, in conjunction with the agency, to collect the amount of the overpayment—certainly not to collect penalties or multiple damages.

The CHAIRMAN. Mr. Morris.

Mr. MORRIS. That is exactly right, and if I could just elaborate that I think the vast majority of billing errors are dealt with at the contractor level, and whether it is a hospital or a physician, there is a frequent exchange of information back and forth to reconcile the books. I think Mr. Scully referenced the great familiarity that hospitals will have with their contractors because of that.

As Mr. Schiffer said, the only types of cases that either OIG or the Department of Justice get involved in is where there is evidence of fraud; and if, during the investigation of that allegation, it appears that there was not a knowing submission of false claims, but in fact there were simply billing errors, perhaps as a result of miscommunication of information by the contractor, that ends the case from a fraud standpoint. Now, the program is still owed money. If there had been overpayments due to billing for unnecessary services or otherwise taking money that the provider is not entitled to, it is important that the trust fund get that money back, but that is not the job of law enforcement, that is the job of the program.

The CHAIRMAN. Thank you.

I have other questions, but I want to recognize Senator Ensign. Just one comment, Ms. Aronovitz. You talked about the GAO doing spot-checks with telephone calls to the various centers and that you got only an 85 percent satisfactory response from those calls to the centers. I am surprised you got that high a percentage when you identified yourself as being from the Federal Government—"I am from the GAO, and I would like to ask you a few questions." I am sure the poor person on the other end probably went crazy trying to figure out how to answer the question. It is like "I am from the IRS and I would like to ask you a few questions." I am not sure I could answer the questions straight, without being scared to death. [Laughter.]

Ms. ARONOVITZ. Well, maybe they were scared to death, or maybe they were paralyzed, because in fact our results were that only 15 percent of the time did they answer accurately and completely.

The CHAIRMAN. Oh, it is 15 percent—85 percent incorrect.

Ms. ARONOVITZ. That is correct.

The CHAIRMAN. I would bet that if you had not told them where you were from, you would have gotten a higher rate of compliance.

Senator Ensign.

Senator ENSIGN. Thank you, Mr. Chairman.

I do not know how well you are going to be able to answer these questions, but I am just tossing it out from an enforcement standpoint. I spent 4 years in the House of Representatives and was on the Health Subcommittee of Ways and Means, so I was very involved in a lot of these issues involving Medicare. When I would have town hall meetings with our seniors—and I know that every Senator or Member of Congress who has ever had a town hall meeting would agree—it seems like every time you have seniors who stand up and talk about how Medicare is being ripped off and so on. My question is asked in light of trying to get feedback from you to help us improve the regulations that we have put into place. In doing my research, most of the cases that the seniors think are fraud and abuse are just confusing regulation, because the State may require something different than the Federal Government that is different from what private insurance requires. And because of the DRGs and various other things, it actually has nothing to do with what is provided, yet the hospitals have to list out what was provided.

In your investigations or requests for investigations, do you know what percentage of investigations are due to cases like that? In other words, they are not really cases of fraud and abuse that you are able to dismiss. Do you keep track of those kinds of things?

Mr. MORRIS. Perhaps I can answer it this way. The Office of Inspector General runs a hotline which receives hundreds of thousands of calls from senior citizens and their families, because we encourage seniors to take a look at their bills; we urge them to think of it like a VISA bill—if there is a charge on there that you do not understand, ask someone. We, with the AARP and others, have urged that it be a three-step process. If you do not understand the bill, first ask the doctor, because it may well be that you do not recognize the name of the radiologist, but you got the x-ray. If you are not satisfied with that explanation, talk to the Government contractor, the carrier, who may explain, as you just elaborated that, "Well, it is a DRG bill, and that is the way it works."

If you are still not satisfied after having asked those questions, call our hotline. Of the folks who call our hotline, a significant proportion of them—I daresay a majority—are along the lines that you are raising. They are not fraud issues. They are either misunderstandings of the rules; it is a duplicate claim, but there is a reason for it, and it was caught and not paid, and so on. Those matters are referred to the contractors for clarification. They are not fraud.

But there are allegations that come through our hotline as well as through *qui tam* relaters and other sources which represent genuine intent to defraud our program.

Senator ENSIGN. Yes, and I have no doubt that any business, I do not care what it is, whether it is a retail business, whether it is the gaming business—most of the time when you catch people stealing or ripping off, it is because the public gives you the input. All the security measures in the world that you have are not nearly as effective as if you have just honest, ordinary citizens saying, "Hey, I think there is something wrong here." I think it is great that we continue that. But my question to you—because I think it is critical, because you are on the front lines seeing why the confusion is happening—is it just something that Tom Scully has to write new regulations, or whether we need to pass laws to try to clear up some of that confusion. If you are having the same things leading to the confusion every time perhaps your front line workers are saying, "The reason why this keeps happening is because these regulations are stupid; they do not keep less fraud from happening, but they lead to so much confusion among seniors that we get a lot of these phone calls—" which take up resources on your hotline and various other things then we need to do something. I guess that is the purpose for my questions.

Ms. ARONOVITZ. I would just throw in that I am not sure how much is attributed to this, but I think part of the confusion on the part of seniors is a result of the complex nature of health care today. I know that when my mother would come to me with her explanation of Medicare benefits, she would get confused because she would have lab tests that would have a different organization name—it would be the laboratory—that she had never heard of; or she would go to a provider whose billing office was in a different location, and she would insist that she did not go to a provider at

that location. There are many entities that are organized in a manner that results in bills from different locations, and the time periods are sometimes very confusing.

Also, sometimes she would literally just forget that she had gone to two appointments in the same day for two unrelated matters.

I think those are some of the typical things that do get very confusing in just trying to use the health care system. Despite this, I know that the Office of Inspector General occasionally gets some pretty good leads, from alert seniors who are perfectly correct.

Senator ENSIGN. And once again, we want to continue that. We held a lot of hearings, and I remember the numbers back in 1977, I think, about the $23 billion in fraud and abuse, and 90 percent of it turned out to be clerical errors—not even that the services had not been provided; it was just that the form might not have been filled out, or maybe a signature, or whatever.

The bottom line, I guess, when we are having to look at these things is that we need feedback from you to help streamline some of this stuff so the confusion is out of it. However, we have also got to look at cost-benefit analysis of what we are saving. We always hear these numbers, that every dollar in investigation saves Medicare three dollars, or whatever the numbers are. Most of the time, however, those dollar estimates do not take into account the huge regulatory burden that is put on all the providers and the extra people that they have to hire. That is only the cost to the Government; that is not necessarily the cost to the entire health care system. We spend way too much money in our health care system on administrative costs at all levels—private sector, public sector, every level—and that money does not get to proper health care, and that is I think what we should all be about.

Mr. MORRIS. Perhaps I can try to answer this question, and it is an excellent question. It is a source of a lot of concern for us in the OIG as we work to put together compliance measures to make sure that they are cost effective and that we are not shifting money to paperwork and not being able to provide better care.

It has been our experience—and this is now being borne out by empirical studies, and the GAO also did some work in this area—that providers that implement an effective compliance program, train their people on proper coding, do internal audits to make sure that the claims going out are correct, make available vehicles so that if people have concerns, they can bring them to the attention of management—all the aspects of what we say represent an effective compliance program—are not only doing the right thing by the program, which is important, but they are also finding that it is reducing the number of billing errors, it is reducing the number of undercodings—claims which should actually be billed at a higher level, legitimately, but because the billing folks did not understand the rules, they inappropriately undercoded it. When the GAO went out and talked to hospitals that were implementing compliance programs, they asked them whether they thought this effort was cost-effective, and if I could, I would like to read from a report that the GAO issued back in 1999—and we would be pleased to put it in the record.

"Almost all the hospitals in our study believed that their liability under the fraud and abuse statute would be reduced as a result of

their compliance programs. For most of them, the reduction in improper payments and they attendant liability is a benefit that exceeds the cost of their compliance programs." And it goes on to talk about the other benefits.

I also mention that there was other empirical work being done. A recent study published in one of the journals reports on work done at St. Louis University Hospital, where clinicians studied the rates of billing errors, underutilized codes, and the like before and after a compliance program was put into particular departments. They found that there was a reduction in the number of billing errors, a reduction in the undercoding, and an actual increase in revenues to the hospital as a result of implementing the compliance program.

One reason why we worked so hard with the industry to build these voluntary compliance programs is because we think they not only protect the integrity of the trust fund, but they are also good business.

Ms. ARONOVITZ. Since Mr. Morris did refer to our report, I would like to add this. He is completely correct—I think the hospitals that we went to were convinced that having a compliance program for them was the right thing to do for a lot of reasons.

However, while we tried to do a cost-benefit analysis to see the cost of implementing all of the different elements in their plans versus the benefit to those institutions. It was impossible to get the costs associated with implementing a lot of compliance plans for many reasons.

The costs associated with Corporate Integrity Agreements are sunk costs; they are ones that are typically not revenue-producing. They are things like having better training, having a corporate compliance officer who is responsible for overseeing the program, having a hotline, conducting different activities to assure that employees inside the organization could report any instances of questionable behavior. Those are activities that the organization would not typically want the board of directors to know they are spending relatively large amounts of money on.

So, it was difficult, and I think it should be stated that although hospitals were convinced that the money they invested in compliance programs was definitely worthwhile, we could not also say that it was cost-beneficial to do this.

Senator ENSIGN. Thank you.

The CHAIRMAN. Thank you, Senator Ensign.

Senator Craig.

Senator CRAIG. Mr. Chairman, thank you very much, and let me apologize to the witnesses for having to step out. The good news is that one of my staff people is going to be serving in the administration, and I wanted to be there to introduce him before the committee that is hearing him. The bad news is that it took me away from this hearing which, as I mentioned in my opening comments, I am very interested in.

Mr. Chairman, I know that you are going to hold the record open, and I will refrain from asking Mr. Scully any questions and will submit questions to him in writing that we can build the committee record on.

The CHAIRMAN. Yes, without objection.

Senator CRAIG. I thank you for that.

Let me turn to you first if I may, Leslie. I am interested in the report that your office issued on DOJ compliance with guidelines related, of course, to the national civil enforcement initiatives.

What prompted Congress to ask the GAO to review DOJ's effectiveness in implementing its own civil guidelines? What was the essence of that.

Ms. ARONOVITZ. Several years ago, the Department of Justice and the Office of Inspector General received money through the Medicare Integrity Program and through HIPAA to properly fund and more aggressively pursue health care fraud control activities. I think the provider community became much more aware and concerned about some of these activities.

There was a lot of discussion at that time, and there was a decision made by the Department of Justice that it should elaborate on its own guidelines for performing investigations for health care matters under the False Claims Act. My understanding is that this Deputy Attorney General guidance was in effect all the time, and it was something that had always supposedly been followed, but it was a restatement of what the policies were.

I think Congress was very concerned and very interested in whether these two organizations might be too aggressive in pursuing health care fraud activities, and we were asked to assure that the Department of Justice was following its own guidance—in other words, assuring the fairness of the Department of Justice's interactions with providers in pursuing the False Claims Act in regard to health care matters.

In fact, in our first year of overseeing the Department of Justice, we found that there was somewhat of a variation in the extent to which U.S. Attorneys' offices were following the guidance, but in subsequent years, we have been able to give the Department of Justice a clean bill of health.

Senator CRAIG. In what areas would you suggest there are still improvements to be made?

Ms. ARONOVITZ. Do you mean with CMS' enforcement activities?

Senator CRAIG. Yes.

Ms. ARONOVITZ. We have been very involved in looking at the way that CMS and its contractors are overseeing safeguard activities. There is more money devoted to assuring the integrity of the trust fund. And I think there has been in recent years, especially recently, a very strong emphasis on beneficiary education. I think the group that has really suffered has been in provider relations. When you talk about the discretionary budget of CMS and how limited CMS officials are in their ability to perform the many tasks they have to do, I think that provider relations has clearly lost out. This is an area that needs new focus, and I think this will happen, based on some of the comments that the administrator made this morning.

Senator CRAIG. In determining the intent in health fraud cases, it seems that it would be important for investigators to know what guidance the health care provider received from CMS and its contractors. Has your office taken a look at the level of coordination that occurs between CMS, OIG, and DOJ in conducting health fraud investigations?

Ms. ARONOVITZ. We have not looked at that specifically and in specific cases, but we are aware that the Department of Justice and OIG are very careful in terms of looking at the evidence before they pursue these cases.

We have not actually assessed the accuracy or the actual evidence that they have used in recent years on individual cases, so it might be that Mr. Morris or Mr. Schiffer could answer that better.

Senator CRAIG. Gentlemen?

Mr. SCHIFFER. Senator, I think some evidence of the care we take stems from whistleblower cases, so-called *qui tam* cases, under the False Claims Act, where we are under a statutory obligation to do at least some investigation of every one of those cases that is instituted in the first instance by a private party. And again, working in collaboration with the Inspector General's Office, we actually intervene in somewhere around one-fifth of those cases only—not always because there was absolutely no evidence of fraud, for example, but where we simply do not think evidence is sufficient for us to pursue cases.

So, as I said earlier, we do not need the business; we attempt to work collaboratively to make sure we are pursuing cases where actual fraud is present.

Mr. MORRIS. If I could elaborate, the OIG, of course, is the investigative arm in this process, and one of the standard steps that an investigator takes when building a case is to determine what is the requirement, and does the provider or the target of the investigation know what that rules is, because just from a practical standpoint as well as an equitable one, if we cannot show that there is a standard to be held to and the provider understood what the standard was, it is difficult to show that they knowingly chose to violate it. And regrettably, we have had cases where we thought we had a strong fraud case, and as the case developed, as we pulled data, as we interviewed witnesses, it became apparent that while what we were seeing was perhaps outrageous—the trust fund was losing great deals of money—we could not show that the provider had been told what the standard was, and we could not show that the provider then knowingly violated that standard. So that regrettably, in cases like that, we just have to walk away, and we do.

Senator CRAIG. And from your perspective, that was a result of failing to educate, failing to provide the necessary information to understand the effectiveness of that reg or the implementation of that reg?

Mr. MORRIS. That is right. We can only pursue fraud cases—and again, we have to stress that these are cases where the target knows that it is committing fraud or is recklessly indifferent to the truth of its dealings with us—if there is a standard that we can show that they are aware of. As I said, we have unfortunately had cases where the information provided by the contractor is sometimes inconsistent, or other information that comes to the provider leaves open the question of whether they really clearly understood the rules.

Senator CRAIG. I see my time is up. I have some more questions, but I will come back.

The CHAIRMAN. We will come back for another round.

Mr. Morris, the Hospital Association will argue that these Corporate Integrity Agreements should be used only in cases of fraud versus mistakes that are not intentional. What is your position?

Mr. MORRIS. I absolutely agree. The Corporate Integrity Agreement is implemented in cases where we in the Department of Justice are resolving false claims. The Congress has given to the Secretary, and the Secretary has delegated to us, responsibility for deciding whether to exclude providers that we have determined are untrustworthy, such as those submitting fraudulent claims.

In those cases where we have some discretion, where we are not mandated to exclude, we have to ask ourselves whether there are ways to ensure that that provider's fraudulent behavior will not recur and thus cause the trust funds to lose even more money.

So the cases in which we sit down with a provider to talk about implementing a Corporate Integrity Agreement are cases where they are facing potential exposure to exclusion for their fraudulent conduct, and they are also cases where the Department of Justice or U.S. Attorneys' offices are going to be settling a False Claims Act liability.

We do not pursue Corporate Integrity Agreement cases with providers who just make innocent billing errors. We have plenty of work without those.

Mr. SCHIFFER. I would only add, Mr. Chairman, that there is a distinction between cases where HHS or Government agencies have a right to insist on such agreements as a result of fraudulent activities, and in many instances, where providers on their own adopt compliance plans to ensure that their business is being operated in a proper manner. Obviously, the Government would never discourage such steps.

The CHAIRMAN. What would a Corporate Integrity Agreement consist of in addition to the way a well-run hospital would ordinarily conduct its business anyway?

Mr. MORRIS. There are only two elements that a Corporate Integrity Agreement requires that an effective compliance program would not have in place already. Those are, first, an annual report to the OIG which reports on all the activities that have been engaged in during the last year. It is really quite comparable to what you would expect a compliance department to report to the board of directors—here is the trending that we have done, here are the errors we found and what we have done about them, and so on.

The CHAIRMAN. But this report, instead of going to the board, goes to HHS or——

Mr. MORRIS. Yes, to my office, the Office of Inspector General. And we have a staff of attorneys and program analysts who review each one of those annual reports, and if they see questions or concerns, get back to the provider. We have a very active dialog with each provider under a CIA so that if we see issues or concerns developing, we can talk to them about them early.

The other aspect of the CIA that you would not find in a voluntary compliance program is our requirement that in some instances, the provider hire an independent review organization, or what we call an IRO, to conduct principally two functions. One is in the first year of the compliance agreement to assure us that all the elements that were set out in the contract have been met—do

they have a compliance officer, do they have a hotline—it is basically a checklist.

The CHAIRMAN. How many hospitals in the country are currently under CIA agreements?

Mr. MORRIS. The total number of CIAs that we have executed is about 700. There are about 400 CIAs in place right now, and I would say that the majority of those are with hospitals. That is largely because due to a number of national project initiatives we have done with the Department of Justice looking at the improper billing of outpatient lab services and so on, a large number of hospitals settled their False Claims Act liability and as a condition of that, we required them to put in certain compliance measures.

The CHAIRMAN. How long do they normally last?

Mr. MORRIS. The length of a CIA depends a little bit on the facts of the case. On average, I would say 5 years. For many of the cases where we have identified a more discrete problem, it would be 3 years. For cases where we are dealing with a provider that has settled fraud allegations in the hundreds of thousands, if not millions of dollars, and we are concerned that the integrity of the provider is so questionable, the CIA could last as long as 8 years. But on average, I would say 5 years, and a significant number of them, 3 years.

I should also mention that one of the things that we were very gratified by as we continued to work with the industry to promote voluntary compliance is that in the more recent years, providers with whom we negotiate CIAs have many of the compliance measures we want in place already, and we give them credit for that. We do not think it is wise to strip out what they already have in place and working and put something else in.

So we believe the CIAs are becoming less costly, less burdensome, and in many cases, we are able to eliminate perhaps the most costly aspect—the IRO—because the provider is able to demonstrate that it has an effective internal audit system.

The CHAIRMAN. Senator Ensign, do you have any follow-up?

Senator ENSIGN. Thank you, Mr. Chairman.

Just following up on my previous line of questioning, going more to the smaller providers, physicians' offices, and so on, what percentage of your claims are for the smaller providers?

Mr. MORRIS. In terms of dollars or volume?

Senator ENSIGN. Either one, or both.

Mr. MORRIS. I would first have to acknowledge that since the OIG does not run the program, the question is probably best put to Mr. Scully.

I would say—and we would be glad to get back to you with the hard numbers—that the dollar volume is, of course, highest with hospitals. I would suspect that physicians, because they do lots and lots of small dollar item services, may have the largest volume of claims.

Senator ENSIGN. Do you have any feedback—or maybe the GAO does—in your investigations, for the small provider, obviously, you do not have as many people that you can put on for administration, you do not have the kind of expertise that maybe a hospital would have—what kind of feedback do you get from the providers on being able to comply with some of these things?

In other words, if you had a Corporate Integrity Agreement with a small provider, what kinds of financial difficulties do they have? Can they hire the lawyers to deal with you all? What kind of hardship, even if they just get investigated, especially when we were talking earlier that some of these are false investigations—if they get investigated for a false investigation, what kind of cost does that bring to them?

Ms. ARONOVITZ. I think Mr. Morris can address the issue of the False Claims Act allegation, but just in the manner of submitting claims and trying to obtain reimbursement on a daily basis—I am talking now more just about participating in the program generally—we have anecdotal information. We do not have a sense for sure about small providers versus large ones. But the small providers we do talk to seem to be very concerned about the fact that they do not have the funds in their office to hire the clerks and the in-house counsel and other entities that can give them advice and assistance in terms of billing rules.

In our work, we found that one of the major ways that a small practice was learning about the rules was through hard copy but also through using a website; and during our study, the practice lost its internet provider in this rural community, felt that it was at a disadvantage because they could not get on the website and get questions answered that way.

What we find to some extent is that in the larger practices, some of the regulatory burden is self-induced—in-house counsel—and it might be because they are very concerned about the rules, and they want to make sure they follow the rules—sometimes some of the burden is a result of in-house counsel requiring the providers to do certain things. It might not even be the statute, or CMS, or OIG, or anyone else, but maybe just common practice in an entity. In a very small practice, it gets more difficult to be able to incur those costs.

Mr. MORRIS. I think I can answer in three ways. As to physicians, we recognize that they have limited resources and huge demands on their time for patient care. We have done a number of things in the IG to try to address those concerns.

First, we put out a compliance guidance, a voluntary guidance, for physicians and small group practices that lays out the various steps that they should implement, but we stress that they need to take into account the resources—that this is not do it all at once, or do not do it at all—that they should integrate these efforts into their program.

The most important component of that compliance is training—having your billing people understand what the rules are—and the contractors provide much of this training for free. There are also consultants out there that will charge quite a great deal of money, and we have concerns about that.

In addition, we thought we should talk to physicians directly. It is one thing to post a guidance and another to actually hear what people are saying. To that end, my staff and other parts of the OIG go out and speak frequently to medical societies, to trade groups, and explain what our vision of integrity is, and we get a great deal of feedback. The speech may be 45 minutes, but the follow-up is another 2 hours.

We also held a roundtable last summer here in Washington and invited physicians from around the country—rural practitioners, practitioners in big institutions—to come in and basically give us a piece of their mind, and they spent a full day doing that. They had lots of great suggestions on how we could make our ideas, our compliance efforts, more accessible and more usable. We actually wrote up a white paper on their suggestions and put it on our website to encourage physicians to give us even more ideas.

And finally to your question about Corporate Integrity Agreements—and we do have Integrity Agreements with practitioners, with physicians—recognizing that they cannot afford compliance officers and all the elaborate bells and whistles that perhaps a Columbia HCA can afford, we really focus on training. The most important thing we want them to do is get their billing people and those responsible for the business end of dealing with us to understand the rules.

So we are very mindful of the cost, and we have worked very hard to tailor the compliance obligations to the reality that patients should come first.

Senator ENSIGN. And I realize that all of you are basically on the enforcement end, but we as policymakers really have to take a hard look at what we have to those—it is one thing to do them at the hospitals where, with some of our regulations, we are running up costs that should not necessarily be there; but for these small practitioners, when people are telling me that in small practices, they are hiring two and three people just to help them comply with these new regulations. A couple physician friends of mine are no longer taking Medicare patients just because of the compliance aspects of it.

So we have got to be very careful, in the name of going after fraud and abuse, that we do not end up really hurting the system in the long run and having people not getting the medical care that they need.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Ensign.

Without objection, I will put in the record a letter from Ms. Janet Rehnquist, who is the nominee for Inspector General at HHS, responding to a question from Senator Chuck Grassley on the False Claims Act at her confirmation hearing. I think it would be helpful to have that as part of our record, in which she speaks to the importance of the False Claims Act.

We will also include a statement from Senator Grassley, who is on this committee, as part of the record.

[Statement of Senator Grassley and Letter from Ms. Rehnquist follows:]

UNITED STATES SENATOR • IOWA
CHUCK GRASSLEY
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Statement of Senator Chuck Grassley, of Iowa
Senate Special Committee on Aging
Hearing on Medicare Enforcement Actions: Federal Government Anti-Fraud Efforts
Thursday, July 26, 2001

Mr. Chairman and Ranking Member, thank you for holding this hearing on Medicare enforcement actions. As you know, I chaired this committee for the last two congresses and appreciate the importance of the work it does.

Since 1986, when Congress passed amendments that I sponsored to toughen the law, more than $4 billion has been recovered through the False Claims Act. Hundreds of billions more in fraud have been saved through the deterrent effect that this law has upon those who would betray the public's interest. In recent years, the False Claims Act has been under attack from industries targeted by the government's anti-fraud efforts. I am pleased that the President's nominee to be Inspector General at the Department of Health and Human Services agrees with me that: "Its use is essential to protect the Federal health care programs from those individuals who knowingly defraud them." Janet Rehnquist also said: "it is vital that those charged with protecting the integrity and longevity of the Federal health programs support the False Claims Act against attempts to weaken it." I'm submitting for the committee record a copy of Ms. Rehnquist's letter in response to a questions from me.

In addition to the recovery of money and the deterrent effect of this law, the False Claims Act is important for another, perhaps, more important reason. The fact is that the False Claims Act is being used, day after day, by prosecutors to maintain the integrity of countless federal programs funded by American taxpayers. For example, the False Claims Act is being used in the health care industry to ensure that nursing home residents receive quality care.

During the early 1980s, our defense budget was rising rapidly to counter the Soviet threat. It rose so rapidly, in fact, that it was beyond our ability to manage the money properly. As one defense official said, it was as if we opened up the money bags at both ends, laid them on the doorstep of the Pentagon, and told the contractors to come and get it.

Not coincidentally, that is the year Congress restored the teeth to the False Claims Act that were removed some 40 years earlier. It was in 1986 that I sponsored, along with Howard Berman of the House of Representatives, amendments to the False Claims Act intended to put the bite back in the statute. Since that time, the law has been a tremendous success. It has recovered more than $4 billion for the taxpayers, and continues to deter fraud in amounts estimated in the hundreds of

billions.

Since passage of the 1986 amendments to the False Claims Act, private industry has been plotting to gut the law. Even before the amendments were passed, a major effort was underway by the defense and other industries to undermine passage. Even supporters of my amendments suddenly turned against my bill. In the final analysis, the public's concern about fraud prevailed. My amendments passed and the False Claims Act has demonstrated itself to be one of the most powerful tools in the war against fraud.

Early in 1998, the American Hospital Association began an official and public challenge to the False Claims Act that continues today. The AHA's concerns then were not with the language of the False Claims Act, but with the Justice Department's implementation of that law. The AHA's position was that the Justice Department was heavy-handed in its implementation of the law and was not separating innocent billing errors from actual fraud.

In 1998, the AHA's position was countered by an audit report released by the Office of Inspector General at the Department of Health and Human Services. This report revealed that a staggering $20 billion was improperly paid through Medicare in 1997. That's 20 billion reasons to defend the False Claims Act. The audit is proof of why the False Claims Act is the law of the land and should remain the law of the land. Indeed, the False Claims Act helps maintain the integrity of Medicare for our nation's senior citizens. It helps maintain the standards we want for our seniors with respect to the quality of health care. The False Claims Act is even beginning to be used successfully by U.S. Attorneys to improve the quality of care provided to nursing home residents.

In July of 1998, the Department of Justice issued written guidance on the appropriate use of the False Claims Act in health care matters. This guidance was issued in response to concerns relating to the Justice Department's enforcement strategies in national health care projects. The guidelines were seen as an appropriate non-legislative solution and the attacks on the False Claims Act were quelled. Subsequently, the General Accounting Office performed a review of these guidelines. The GAO found that the guidelines were being properly implemented by the Department of Justice and US Attorneys.

If innocent mistakes are resulting in penalties, it has nothing to do with the Act. It has to do with process issues only. A failure to recognize this could lead to the public misperception that Members are going "soft" on fraud. After visiting with the Iowa Hospital Association and listening to their concerns, it seemed to me that the examples which the AHA has publicized speak more to some isolated problems with the implementation of the law, not problems with the law itself. I approached the Justice Department and began a dialogue between DoJ, the AHA, other Members of Congress, and myself. The goal was to examine the evidence, to see where the problems were occurring and why, and to fix any and all real problems with the implementation of the law.

After much examination and discussion, I, and others, determined that there were some legitimate concerns with the tone of the pre-litigation contacts between DoJ and some hospitals. In response, the Justice Department refined the process by which it initiates and pursues national initiatives under the umbrella of the False Claims Act. In fact, the Justice Department said that it will NOT use demand letters in national projects. In addition, DoJ has created working groups to enhance centralized coordination and to ensure that a sufficient factual and legal basis exists before any matter is pursued. Reason prevailed.

I knew then, that it would only be a matter of time before the medical industry would mount yet another challenge on the False Claims Act. It is for that reason I have come to be ever vigilant. There are many citizen groups around the country that have joined me in this vigil. They have the taxpayers' best interests in mind, because the False Claims Act is the final and most effective line of defense, protecting each taxpayer's hard-earned money. Since my amendments in 1986, the Act has been used to return more than $4 billion, fraudulently taken, back to the taxpayers. Nearly $2 billion of that is from the health care industry. So far, the Act has deterred somewhere between $150 and 300 billion of potential fraud.

The Act is a tool against fraud. It was not designed to be used, and is not used, against innocent mistakes. There is clearly an agenda to remove the taxpayers' most effective weapon in the government's arsenal against fraud. It is being pushed by some in an industry that has been ravaged by those who have committed fraud. Of course, there is no question that the vast majority of hospitals and hospital employees in this country are honest, civic-minded, and true public servants. Many are absolute heroes. But, those in the industry who defraud the government tarnish the industry's upright reputation.

Again, Mr. Chairman and Ranking Member thank you for hold a hearing on this important issue.

JANET REHNQUIST – NOMINEE FOR INSPECTOR GENERAL AT HHS
RESPONSE TO QUESTIONS FROM SENATOR GRASSLEY ON FALSE CLAIMS ACT

July 25, 2001

Mr. Dean Zerbe
United States Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

RE: False Claims Act Questions

Dear Mr. Zerbe:

Here are the responses to the questions you faxed to my attention yesterday.

1. **Is it your experience, as an Assistant United States Attorney, that the False Claims Act is a successful and useful tool to fight against fraud in the health care programs administered by the Department of Health and Human Services?**

As an Assistant United States Attorney in the Eastern District of Virginia, I had the opportunity to participate first hand in enforcing the Federal fraud and abuse statutes. That experience reinforced my belief that the False Claims Act is a highly effective remedy for health care fraud. Its use is essential to protect the Federal health care programs from those individuals who knowingly defraud them.

The success of the False Claims Act in fighting health care fraud can be measured in two ways. The first is the recovery of fraudulently claimed dollars from health care providers. Last year alone, the Government was able to recover over $1.2 billion from health care providers due to the Government's enforcement of the False Claims Act. Second, the penalty provisions of the False Claims Act constitute a crucial deterrent to those who may be tempted to commit fraud. The fact that a provider is subject to substantial penalties as a result knowingly committing fraud (as opposed to mere repayment of the fraudulently obtained dollars) results in a great incentive for the provider not to engage in such unlawful conduct

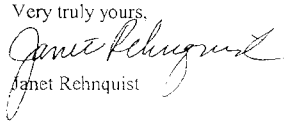
2. **Is it your experience, as an Assistant United States Attorney, that the False Claims Act needs to be watered down, limited in scope or weakened in any way?**

It is vital that those charged with protecting the integrity and longevity of the Federal health care programs support the False Claims Act against attempts to weaken it. As an Assistant U.S. Attorney, I fully understand and appreciate the importance of the False Claims Act as an anti-fraud tool. If confirmed as Inspector General, I would work to maintain the full remedial power of this statute while also ensuring that it is used fairly

and judiciously.

Please contact Carrie Loy at 202.690.6047 if I can be of further assistance.

Very truly yours,



Janet Rehnquist

The CHAIRMAN. I recognize Senator Craig for any questions.

Senator CRAIG. Mr. Chairman, thank you.

I have a couple more questions that I think need to be asked, because what Senator Ensign has just said is of course of great concern as we balance this effort so that we do not run the provider away from the very people that they want to provide health care for.

Let me, Stuart, speak to you for a moment if I could.

Mr. SCHIFFER. I have been enjoying the dialog on both sides of me, Senator, but I would be glad to.

Senator CRAIG. GAO says that you are doing a better job of implementing guidelines on the conduct of civil health fraud investigations. Does DOJ have similar guidelines in regard to how they conduct criminal investigations involving alleged fraud?

Mr. SCHIFFER. The Department has long had in place broad sets of prosecutorial guidelines. I am not personally familiar, I must confess, with whether there were specific guidelines directed to health care——

Senator CRAIG. I am specifically concerned about the search and seizure side of this as it relates to guidelines, involving doctors' offices and hospitals where patients might be receiving care at the time.

Mr. SCHIFFER. Again, I do not know specifically if we have search and seizure guidelines in the health care fraud area. There are certainly guidelines applicable to search and seizure.

The guidelines about which the General Accounting Office has testified were adopted largely in response to some specific instances that had been brought to the Department's attention by both industry and by Members of Congress where predicate procedures had not properly been followed in certain so-called national projects. We did not think we were breaking new ground with those guidelines, but we did believe and we were told that it was important to put in writing procedures which have long existed and to form working groups to oversee these guidelines.

Senator CRAIG. That is civil; right?

Mr. SCHIFFER. Yes, sir.

Senator CRAIG. But not criminal.

Mr. SCHIFFER. Not criminal.

Senator CRAIG. You cannot answer that.

Mr. SCHIFFER. I would be glad to get you a response in writing, Senator.

Senator CRAIG. Would you do that, please?

Mr. SCHIFFER. Surely.

Senator CRAIG. And I would like to know if you have those kinds of guidelines. That is an important part of all of this, ultimately, where you are involved in the criminal investigation as it relates to how those are conducted in those situations.

I think that would be tremendously important.

I see that in your testimony, you mentioned the future use of advanced technologies so that no provider is prosecuted or penalized for simply unintentional billing errors or mistakes lacking any evidence of intent to defraud.

You also announced that CMS and DOJ are launching new interagency efforts to enhance the use of technology and high-tech tools.

I like the idea of making these determinations of intent as accurate as possible—obviously, we all do. Could you tell us more about these efforts and your timetable for implementing the new technologies?

Mr. SCHIFFER. I am somewhat concerned, Senator, and worried about laughter that may come from the back of the room from my colleagues who are here, since I am one of the few remaining computer-illiterates in the Department of Justice.

Mr. Morris is certainly here to answer questions on technology——

Senator CRAIG. Stuart, I talk a good line, too, about computers, but I lack knowledge.

Mr. SCHIFFER. I could only fit a computer or a television set into my office, and I opted for the latter so I could use C-SPAN and many of these hearings.

We talk about occurrences in the past, for example, where people would look at a single spreadsheet and see billing for a particular code of pneumonia, let us say, and would leap from that to a conclusion that there must be fraud. We are now looking for matches, we are looking for many more complicated systems that will give us true indicia of fraud as opposed to simply pursuing honest mistakes.

But my computer friend over here is about to answer the question.

Mr. MORRIS. Thanks.

One of the reasons I went to law school was so I would not have to understand this stuff—but perhaps I can give you an example of how "data-mining" as it is often called, taking the huge amount of information that comes through the Medicare program and using technology, can help us.

Mr. Schiffer just referenced pneumonia. One of the national projects that we have under way is looking at hospitals that bill for a higher-coded level of pneumonia treatment than we believe was appropriate. One reason why this was brought to our attention was that by doing this data-mining, we came to see that there were some hospitals for whom the use of this particular pneumonia code was so disproportionate to demand we do something more. In fact, in one case, a hospital in Tennessee was using this higher-reimbursed code 93 percent of the time, when the Centers for Disease Control would tell us that we should see incidence of that type of pneumonia about 2.4 percent of the time.

What I want to stress here is that technology identifies a potential problem. What we need to do then and what we did do in all of these cases was to go onsite and pull medical records to see if there was some other explanation—was there an epidemic of pneumonia in that part of Tennessee, for example.

As it turned out in that case, medical experts looked at the charts and found no documentation or justification for the billing—and what is more, we discovered that consultants had been out, marketing these billing maximization schemes and that what was really going on here was not an epidemic of illness but an epidemic of fraud.

So we use technology to identify potential problems, but a lot of what we do requires shoe leather.

Senator CRAIG. In that instance of billing, I am assuming there was a variety of categories——

Mr. MORRIS. Yes, sir.

Senator CRAIG [continuing.] Or levels of severity, or whatever that would ultimately measure. So it was your determination that this was an intent to defraud?

Mr. MORRIS. Well, we relied on medical experts to look at the physician and the nurses' documentation in the charts, and we start with the premise that the doctor knows what he or she is ordering and accurately reflects that in the charts. When we go to chart after chart, and we find no tests to confirm the diagnosis as billed, when we actually find contraindicated information that there was a less serious pneumonia, and when we see this not once, not twice, but 93 percent of the time, and when we add to that the presence of consultants or others who have seen comparable schemes take place in other hospitals—when you link all that together, as well as interviews with people at the hospital, all of that put together gives us evidence that they knowingly engaged in fraud.

Senator CRAIG. Well, there are a good many more questions that we would like to ask, and we are going to hold the record open, so you may receive some in writing.

We thank this panel very much for your presence today.

Senator Craig [presiding.] Let us turn to our third and last panel. Senator Breaux has had to step away for a few moments, but I think he plans to return.

On the final panel, we have Robert Charrow, with Crowell and Moring, a law firm here in Washington; Joseph diGenova, special counsel to the American Hospital Association; and Jim Moorman, representing Taxpayers Against Fraud.

Robert, we will start with you.

STATEMENT OF ROBERT P. CHARROW, CROWELL AND MORING, WASHINGTON, DC

Mr. CHARROW. Thank you very much, Senator Craig, for giving me this opportunity to appear here.

For the record, although I am a partner at Crowell and Moring, I am not appearing on behalf of any client. I was asked by the committee to share some of my perceptions as someone who, as a prior political appointee, is partially responsible and shares some of the blame for the mess that we are dealing with today.

Medicare is perhaps the single most complex Federal program and it affects more Americans than any other program. I brought with me a copy of the Social Security Act, which is the organic legislation that has given rise to 1,300 pages of regulations in The Code of Federal Regulations, and over 100,000 pages of issuances, notices, and other documents published by CMS and its carriers and intermediaries.

I would like to follow up on a theme raised by, Senator Craig and his colleagues as well by Mr. Scully namely we are all attempting to strike the proper balance between, on the one hand, enforcement, and on the other hand, fairness.

One of the concerns that I have with the current system is that its complexity makes it very difficult for anyone to function prop-

erly. For example, when a physician calls me because he or she has just received a letter or a visit from the government, I ask "Who paid you the visit?" or "Whom did the letter come from?" and they invariably say, "Inspector General."

And I said, "Really? The Inspector General of HHS?"

And they say, "Well, no, but it was somebody."

And when you stop and talk to them and look at the materials, if they were smart enough to have gotten the card, it turns out it is someone from the carrier or intermediary as the case may be, depending on whether it is a hospital or a physician. And frequently, there is no distinction drawn, especially by small providers, between the carrier and fiscal intermediary on the one hand, the regional office of the Health Care Financing Administration—or, the CMS now—the central office, the IG, or the FBI. They are all viewed as "them"—and then there is "us"—and that is unhealthy.

The second point is that part of the reason why we see this fear in the community—and there is really fear in the community—of enforcement is not only because of the complexity and, at times, erratic enforcement posture of the various Federal agencies, but also the total lack of accountability. Medicare is the only significant program lacking in effective judicial review. There is no way for a provider to get into court effectively.

The DRG system is not subject to judicial review. RBRVS system, which is the fee schedule system, is not subject to judicial review. The system by which wage index rates are set for hospitals also is not subject to judicial review. And the most astonishing thing is that as a result of a recent Supreme Court decision, regulations issued by the Department of Health and Human Services that govern CMS are no longer subject to meaningful judicial review. That means that if you believe the agency issued a rule in contravention of the Administrative Procedure Act, it failed to solicit comments when it should have, the basic tenets of the APA have been violated—you cannot get into court, effectively. You have to go through a labyrinth-like appeals process that could take anywhere from 2 to 10 years before you are eligible to see the inside of a Federal district court. Most providers simply do not have the wherewithal to undertake such a litigation.

If you are a regulator, it is much easier to issue rules if there is no judicial review. If Congress makes one change, it should be to uncouple the judicial review procedures that govern HHS and CMS from the Social Security Act, Section 205(h). That uncoupling would go a long way toward creating accountability and easing the fear at relatively modest cost to the Government.

Thank you very much.

Senator CRAIG. Thank you very much for that testimony.

[The prepared statement of Mr. Charrow follows:]

STATEMENT OF ROBERT P. CHARROW, ESQ.

BEFORE

THE UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

JULY 26, 2001

Statement of Robert P. Charrow, Esq.

Crowell & Moring LLP

Former Principal Deputy General Counsel of Health and Human Services

July 26, 2001

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I am deeply honored at being asked to share some of my experiences, perspectives, and thoughts with the Committee. Health care—the way it is provided, the way it is regulated, and the way it is funded—is of critical importance to most Americans. As our population ages, concerns about the quality, availability, and affordability of health care will only grow. These concerns with attendant political and societal pressures will focus primarily on Medicare—a system designed in 1965 and largely modeled after the way medicine was practiced in that era.[1] Our attitudes towards medicine and government, our demographics, and even the way medicine is practiced—both scientifically and structurally, are remarkably different now than they were three decades ago.

Notwithstanding these changes, structurally, Medicare has remained fundamentally unaltered. Indeed, many would argue that while the private sector has achieved greater efficiency, Medicare has gone in precisely the

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1 The Medicare and Medicaid programs were enacted in 1965 as Titles XVIII and XIX of the Social Security Act, respectively, and began

opposite direction. The dissonance between what we demand from a medical system and the way Medicare operates has given rise to regulatory burdens and inefficiencies that frustrate all—hospital administrators, family physicians, and Medicare beneficiaries alike.

I am here to share my perceptions about Medicare and some of the troubles that it faces and the issues that need to be addressed. I am also here as a penitent, someone who is partly responsible for those troubles. It is a responsibility that I share with many in this room and with many—indeed virtually all—political appointees at HHS of both political persuasions who had responsibility over HCFA or CMS, as it is now known.

I would like to focus on three highly inter-related areas—complexity, enforcement, and accountability. I believe that the system has become too complex, enforcement too arbitrary, and accountability too lacking. As a result, providers, out of fear, are spending significant sums on administrative expenses that are not cost justified and those administrative costs ultimately mean that less money is spent on health care. This is good for lawyers and accountants; it is decidedly not good for those in need of quality health care.

I. Medicare is Too Complex for Mere Mortals to Comprehend

The Medicare statute is more than 400 pages long and is not a model of clarity. In theory, HCFA is supposed to issue regulations to give life to the

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operation on July 1, 1966. *See* Title I, Social Security Act Amendments

statute. The regulatory process, though, takes years, and usually what you end up with is a rule that is comprehensible and accessible only to lawyers. Medicare's regulations take up about 1,300 pages in the Code of Federal Regulations. But that's only the beginning. On top of the statute and regulations—all of which are accessible to the public, but essentially unreadable—are Medicare issuances, publications, program memoranda, manuals, Inspector General Alerts, advisory opinions, local medical review policies, coverage decisions, Departmental Appeals Board rulings, and so on. All told, the 400-page statute has given birth to more than 100,000 pages of secondary Medicare laws, guidelines, issuances, and the like. All of these affect the level of services and how they are delivered. Yet, little of this information is readily available or easily understandable. No beneficiary and no small provider has any hope of understanding most of these materials. Many federal judges have, at one time or another, labeled Medicare as "arcane" and "incomprehensible." The Medicare system is simply collapsing under its own regulatory weight.

Because the system is so difficult to navigate, doctors have to employ a bevy of staff solely to file claims, double check to make sure that they are using just the right code, and then follow-up with the carrier. Any time a physician wants to do anything out of the ordinary, he or she must call an attorney. This costs money; these costs are eventually passed on to Medicare.

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of 1965, Pub. L. No. 89-97, 79 Stat. 286.

How much does the systems' complexity cost? We have no idea and that is a sad irony.

Before the government buys a new $2 billion weapons system, it tests the system for years and requires the contractor to make necessary design and manufacturing changes. Before Congress passes amendments to Medicare, or before HCFA implements a regulatory initiative that could cost significantly more than $1 billion and will affect hundreds of thousands of providers and millions of beneficiaries, does either do any "testing?" The answer is usually "no." In short, we are making changes to a $200 billion system without first testing the impact of those changes.

II. Medicare's Enforcement Scheme Vests Too Much Authority in the Executive Branch

The system is extraordinarily complex. That, in itself, costs money. However, the amount spent by providers on administration may be out of proportion to what is required. Why is that the case? In large measure, I believe that these potentially large administrative costs are amplified—and some would say driven—out of a belief that if a provider errs then he, she, or it will be severely punished.

This fear of punishment—whether realistic or not—has a rational basis. Owing to linguistic lapses on the Congress, far too much authority has been vested in the Executive Branch—on two levels. First, broadly speaking, Congress in the Inspector General Act, authorized the IGs to ferret out

"fraud" and "waste," and by implication, abuse."[2] Second, many of the enforcement statutes, *e.g.*, anti-kickback, are so amorphous that they effectively vest extraordinary authority in OIG and HHS.

Everyone would agree that fraud is evil, is criminal, and should be punished decisively. Moreover, fraud is relatively easy to define. We not only know it when we see it, but we can articulate why some conduct is fraudulent and other conduct is not. For example, the hospital chain that billed Medicare for treating patients who were never hospitalized was committing fraud. Or the physician who bills Medicare for a long office visit, when in fact he saw the patient for less than three minutes is also committing fraud. The federal laws prohibiting fraud apply across the board from defense contractors to universities to hospitals, physicians, clinical laboratories and even beneficiaries. Interestingly enough, although we have been led to believe that healthcare is rife with fraud, in fact the numbers indicate to the contrary. The Inspector General, for instance, reports having recovered less than $500 million on account of all types of improper conduct; when compared to the about $400 billion spent on Medicare and Medicaid, the actual percentage of measurable fraud is relatively small—medicine is about 99 and 44 one-hundredths percent pure; so far, so good.

But what is "waste and abuse." Those are not legal terms. They do not differentiate between what is legal and what is illegal. Rather, they

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[2] *See* section 2 of the Inspector General Act of 1978, Pub. L. No. 95-452,

differentiate between one administration's necessarily fleeting views of what is good and what is not good. This is especially the case in health insurance programs—including Medicare--where one man's "waste and abuse" is another man's "medical necessity." It seems rather ironic that as both Houses prepare to enact some form of a Patients' Bill of Rights which would give doctors and patients greater latitude in deciding what is "medically necessary," the largest insurer—Medicare—is doing just the opposite.

Second, a number of Medicare-specific laws are too broad. In one case, that breadth is due more to a failure of language than anything else. I am talking about Medicare's unique anti-kickback law.

Like fraud, most of us consider that kickbacks should also be outlawed. The physician who accepts a 20% kickback in exchange for ordering a specific battery of tests from a specific clinical lab should be treated no differently than the defense contractor that gets secret kickbacks from its subcontractors. Kickbacks in Medicare are bad—they promote overpayment and over-utilization and inappropriately interject financial considerations into medical decisionmaking. The anti-kickback law that governs federal healthcare programs, though, is far broader and procedurally distinct from the one that applies to the other sectors of the government. In fact, these laws are so expansive that they prohibit conduct that is perfectly legitimate in other settings.

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§ 2, 92 Stat. 110.

Under the anti-kickback statute as written, for example, it is illegal for a physician to sell his practice if the sale includes "goodwill." No arrangement—whether it is a complex merger, acquisition, joint venture, or a simple purchase of hospital or medical office equipment—can be seriously considered without evaluating its anti-kickback implications. Moreover, the healthcare anti-kickback laws vest extraordinary discretion in the Office of Inspector General to modify, to interpret and to apply these already broad laws. The law effectively has transferred significant healthcare policy decisionmaking from the Congress and the political appointees to career OIG attorneys with no formal training in medicine and little in developing or testing cogent policy.

How did all of this happen? Congress first enacted an anti-kickback law for Medicare in 1972;[3] that law, however, was somewhat ambiguous. To eliminate that ambiguity, Congress in 1977 amended the law and broadened its coverage.[4]

The new law went beyond prohibiting kickbacks and other forms of fraud, and sought to use the threat of prosecution as way of regulating

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[3] *See* section 242(b), Social Security Amendments of 1972, Pub. L. No. 92-602, 86 Stat. 1419-1420.

[4] *See* Medicare-Medicaid Antifraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-1181 (1977). In lieu of the phrase "kickback or bribe," as used in the 1972 law, the amended version banned "<u>any remuneration</u> (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce a referral. 42 U.S.C. § 1396h(b)(1)(1977)(emphasis supplied).

"abuse" and "waste," terms that—as we noted above—have no real legal meaning. Not unexpectedly, the new law proved to be too broad, effectively outlawing all sorts of legitimate business arrangements: a physician could not sell his practice, a physician could not sublease space in his office to another physician if that sublessee referred patients to the owner and so on. To cure this problem, Congress in 1987, enacted legislation that authorized the Secretary of Health and Human Services, with the approval of the Attorney General, to develop so-called "safe harbors."[5] The theory was individuals who a person who conformed their arrangements to the conditions of the safe harbor would not be prosecuted even though the arrangement technically violated the anti-kickback law. In 1991, the Secretary issued the first ten "safe harbors." Today, there are more than twenty "safe harbors," the last group having been issued in November 1999.[6] There are safe harbors for renting office space, for receiving a discount on the purchase of equipment, for obtaining a warranty and for a variety of other normally straightforward business arrangements.

The anti-kickback law has been recodified as section 1128B(b), Social Security Act, 42 U.S.C. § 1320a-7b(b).

5 *See* section 14, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93.

6 *See* 42 CFR § 1001.952; *see* 56 Fed. Reg. 35,799 (July 29, 1991); 57 Fed. Reg. 52,723 (Nov. 5, 1992); 59 Fed. Reg. 37,202 (July 21, 1994); 61 Fed. Reg. 2,122, 2,125 (Jan. 25, 1996); 63 Fed. Reg. 46,676 (Sept. 2, 1998); 64 Fed. Reg. 63,503 (Nov. 19, 1999); and 64 Fed. Reg. 63,517 (Nov. 19, 1999).

The safe harbor system has its problems, however. The Inspector General had been reluctant to issue safe harbors and when she did, they tended to be extraordinary rigid. Moreover, it took years to issue a new safe harbor. Thus, as part of the Health Insurance Portability and Accountability Act of 1995, Congress required the IG to issue advisory opinions—these advisory opinions are essentially single transaction, one time safe harbors. In deciding whether to approve a proposed transaction, the OIG must consider, among other things, whether the proposed arrangement will cause over-utilization or adversely affect patient care. Should these types of policy decisions, requiring expertise in medical economics and medicine itself, be made by lawyers in the Inspector General's Office? I think not. Those whose training is law enforcement tend to see "waste" and "abuse" everywhere. Indeed, the IG has expressly noted that the advisory opinion process "permits this Office to protect specific arrangements that 'contain limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused.'" Advisory Opinion 98-14 (quoting from 62 Fed. Reg. 7350, 7351 (Feb. 19,1997).

Moreover, is it wise to effectively require people to seek governmental approval before entering into a normal business arrangement? The perils associated with violating the anti-kickback law are so great that even those who are providing free goods or services to health charities have sought advisory opinions first. Clearly, this is good for lawyers, since we draft the

advisory opinion requests. But is it good for medicine and health care and does it make sense?

The most interesting aspect of the anti-kickback saga is that a broad anti-kickback law may not make any sense today. Medicare payment has changed since 1977 so that over-utilization is far less of a problem than it was then. For example, in 1977, hospitals were reimbursed for their costs—the more they spent, the greater their reimbursement. If they paid kickbacks to suppliers, those kickbacks were passed through to the government. In such a setting a broad anti-kickback law made commercial sense. In 1983, however, Congress changed the way in which hospitals were paid so that they were no longer reimbursed for their expenses, but instead were paid a fixed fee for treating a given illness. If they paid kickbacks, the hospital, not the government, would eat the cost. Correspondingly, the introduction and quick spread of fee schedules and capitated payment arrangements in the late 1980s and early 1990s also shifted the cost of kickbacks from the government to private parties. In short, there is now a serious question as to whether this complex anti-kickback mechanism is even cost justified. Surprisingly, though, no one at HHS has indicated any interest in studying the problem or attempting to resolve it. The anti-kickback laws provide the government with a way to micromanage medical care and there does not seem to be any desire to give up that authority.

In short, we have an extraordinarily complex system—which is made only worse by the perception that rules are fluid and errors will be severely punished. This creates a climate of fear that leads providers to take costly precautions. Many of these precautions—such as corporate integrity programs and the like—may not make any economic, or indeed practical, sense. We just don't know.

III. Medicare Lacks Accountability

The fear that grips the provider community is further amplified by a vacuum of accountability: CMS and HHS are not subject to the normal rules that constrain and moderate other agencies. What do I mean? The actions of most other agencies are subject to judicial review. If the Environmental Protection Agency issues a rule that makes no scientific sense, folks can challenge that rule in court. If a government contractor feels that it has been underpaid, then there is a mechanism that allows it to challenge the payment decision in court. Access to court is essential if a system is going to be perceived as fair. While most government agencies have become more accountable through judicial review, Medicare has moved in the opposite direction.

Medicare has always attempted to prevent providers and beneficiaries from challenging its rules. At first, it claimed that the Administrative Procedure Act did not apply to it. When Congress threatened to amend the APA to lift any doubt, HHS begrudgingly acquiesced, but when it tried to

back-out of its promise, Congress amended the Medicare law to provide some review.[7] Even so, HCFA consistently has taken the position that a provider or beneficiary's ability to challenge a rule in court is severely constrained. As a result, most litigants spend far more money litigating whether they have the right to litigate than they do over the merits of the case.

While it was always difficult to sue HCFA, two terms ago, the Supreme Court, at HCFA's urging, made it far more difficult to do so. In *Shalala v. Illinois Council on Long Term Care, Inc.*,[8] the Court held that providers cannot attack a regulation until all administrative remedies have been exhausted even if the administrative process would prove futile and the attendant delay would impose undue hardship on the providers. In most cases, this means that the provider or beneficiary must go through a labyrinth-like process that is both costly and time-consuming before one can get into court. Once again, it seems ironic that as Congress is about to require that private insurers become accountable to patients and physicians, the government is moving in the opposite direction with respect to its own health insurance program.

There is a well-developed body of social science research that demonstrates that as people's control over a process decreases, the perceived fairness of the process also decreases. Thus, the Anglo-American adversarial system is perceived as being fairer than the European inquisitorial system.

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[7] *See* Section 1871 of the Social Security Act, 42 U.S.C. § 1395hh.

Litigants have far greater control over the course of the litigation under the adversarial system, than they do under the inquisitorial system. These perceptions are not only transnational, but also independent of whether the litigants won or lost. Since perceptions drive fear and fear drives costs, is it not about time that we change people's perceptions by giving them access to the courts?

Obviously, it is much easier to develop policies and to issue rules when you know that those who are being regulated will have little ability to challenge your decisions. However, our government is not designed for the convenience of the bureaucrats or political appointees, but rather for the benefit of the citizenry.

So What Does This All Mean?

Neither complexity nor regulation is free—the more regulation, the less that can be spent on health care. The real question is how much regulation is optimum, and for that we must be willing to conduct experiments or develop models to see how best to curtail regulation. There is certainly evidence, albeit anecdotal, to suggest that over-regulation adversely affects the quality of care by shifting resources from the medical treatment to paper pushing and compliance activities.

You might ask, how can this be? After all, HCFA constantly reminds us that Medicare's transaction costs are 80% less than those of private

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[8] 529 U.S. 1 (2000).

insurers. HCFA has achieved low government transaction costs by shifting those costs from the government to the private sector. For example, private insurers take on the responsibility for conducting compliance programs and auditing functions. Not so with Medicare; HHS expects providers to undertake those functions.

Many now believe that when you add in all the compliance activities and added administrative burdens associated with Medicare, its overall transaction costs far exceed those of the private insurers.
Given that providers—whether hospitals or physicians—are paid fixed fees, those extra transaction costs must be paid from somewhere and, in many cases, they are coming out of the treatment side of the office, rather than the administrative side. Given a choice, do we want our hospitals to hire more coding clerks and compliance officers, or more nurses and physicians? I am not advocating that we abandon regulation; nor am I suggesting that regulation is unnecessary. Rather, I am merely advocating that regulation is not free. We should at least determine empirically which regulations make sense and should be retained, and which are counter-productive and ought to be abandoned.

Correspondingly, the costs of regulation increase as those who are regulated fear prosecution, even if that fear is unfounded. Unfounded fear and perception of unfairness drives up costs. I believe that much of the fear is a function of the fact that HCFA is not immediately accountable.

Revitalized judicial review will go a long way toward improving the entire process and could save significant money in the long run.

Senator CRAIG. Now we turn to Joseph diGenova, special counsel to the American Hospital Association.

Joe, welcome before the committee.

STATEMENT OF JOSEPH DIGENOVA, SPECIAL COUNSEL, AMERICAN HOSPITAL ASSOCIATION, WASHINGTON, DC

Mr. DIGENOVA. Thank you, Mr. Chairman. I am delighted to be here.

I am Joseph diGenova, special counsel to the American Hospital Association. The AHA represents nearly 5,000 hospitals, health systems, networks, and other providers of care.

We absolutely, Mr. Chairman, appreciate the opportunity to testify on enforcement activities related to the Medicare program. It is a vital issue to providers in this country today and one that we are deeply grateful that the committee is addressing.

America's hospitals are committed to preventing, uncovering, and eliminating health care fraud and abuse. That is why hospitals across the Nation have voluntarily established programs to ensure compliance with Medicare's complex and confusing requirements—those two descriptions of it were attested to by almost all the witnesses here today.

Our experience reinforces the view that billing issues are usually billing mistakes. Fraud is the exception, and that too was testified to here by Government representatives today.

That is why we continue to urge that the starting point for any questions about a claim submitted by a hospital should be the administrative process. If and only if there is sufficient—and I underscore sufficient—indication of potential fraud should a referral be made to law enforcement authorities.

Our comments today will focus on the enforcement activities of the OIG and the need to provide hospitals with direct access to courts—a matter about which Mr. Charrow spoke at the end.

Hospitals are concerned with the way the OIG is exercising its enforcement authority with regard to Corporate Integrity Agreements as a condition of resolving billing issues and with regard to its investigation of matters previously investigated by the Department of Justice.

Our testimony today is in no way a challenge to the integrity or the honesty of anyone at the Office of Inspector General. We are talking about the open issues of how hospitals have to work in a complex and confusing network of billing, the most complex billing system in the world.

A Corporate Integrity Agreement, or a CIA as it is called, is used in settling investigations by the OIG, and in return for the OIG's agreement not to exclude someone as a provider for the Medicare program—the most draconian penalty that can befall any provider. It is viewed as a corrective action, and its imposition is viewed as a penalty.

The AHA's members repeatedly tell us that the OIG's insistence on a CIA impedes voluntary disclosures and the resolution of billing disputes. A CIA should only be used in the case of fraud, and indeed, Mr. Morris from the OIG's office has said that that is their standard.

We actually have a different view of how that standard is being applied, and it really becomes a question of how you define fraud, apparently, because we believe—and certainly the anecdotal evidence that we have seen leads us to believe—that these CIAs are being required where there was no fraud but rather billing mistakes.

If a hospital's own compliance program is insufficient to prevent future billing irregularities, it should be improved and requirements targeted to those specific areas—in other words, a targeted CIA, not one that covers a whole hospital where there are no problems in those other areas.

The imposition of a CIA imposes significant burdens and costs on hospitals. The biggest cost factor is the requirement that a hospital contract with an independent review organization to perform reviews of the hospital's billings and implementation of the CIA.

In addition to the compliance program issues, there are legal issues related to the heightened reporting accountability. For a provider, for example, who has not violated the law itself and committed fraud, if you sign a Corporate Integrity Agreement, there is a provision in there that says that if you violate the Corporate Integrity Agreement, you can be excluded from the Medicare program—a provision which the law does not require, but nonetheless it is in there, and of course, it is a burdensome threat that lives with the life of the CIA, which are generally 5-year agreements, which cost a lot of money to any organization, no matter how big.

The DOJ and the OIG have concurrent jurisdiction over fraudulent claims, which should provide flexibility to the agencies for allocating resources in an investigation. Instead, according to the evidence that we are gathering, it has permitted the Office of Inspector General to second-guess decisions of the Department of Justice. We are aware, for example, of a situation in which the OIG is pursuing a hospital and demanding hundreds of thousands of dollars in a hospital-wide Corporate Integrity Agreement under its authority to impose civil and monetary penalties.

The OIG is doing this despite an extensive and thorough investigation by DOJ of the very same issues, DOJ's dismissal of the case without taking any action whatsoever, and in spite of the OIG's active participation in the OIG investigation.

Direct access to court is essential to provide fundamental fairness for hospitals participating in the Medicare program. In Shalala versus Illinois Council, the Supreme Court held that claims related to the Medicare statute must go through an administrative process before being brought to court. Unfortunately for hospitals, that interpretation insulates HHS from legal accountability, as Mr. Charrow indicated earlier, for many of its actions and places hospitals in the position of having to violate a regulation in order to challenge the legality of HHS' decisions and policies. That means that the price of admission to the court for hospitals is termination from the Medicare program—or the risk of it—a price that no hospital or community can risk.

The Medicare statute needs to be clarified so that when a dispute challenges the legality of HHS' actions—not a specific payment or claim for reimbursement, but rather, the policy or a rule which has not necessarily followed a rulemaking proceeding—that that dis-

pute be brought to court for resolution—again, not the resolution of a specific payment claim, but the policy around that payment claim which determines whether or not it is a proper payment.

Hospitals also need access—just to review—when there is no process for resolving a dispute. The laboratory billing investigation is a very good example of that. Hospitals across the country were receiving demand letters from U.S. Attorneys effectively accusing them of fraud and threatening law enforcement proceedings.

As a special report commissioned by the AHA demonstrated, the foundation for the investigation was legally flawed. And indeed, as Mr. Schiffer testified to earlier, the Department specifically issued guidelines for this whole area, because it was concerned that the guidelines that it said had been verbal or known among professionals were not being followed by Assistant U.S. Attorneys all over the country. We have a report on that which I will submit for the record; I think it would be very helpful to the committee. And I want to give special credit to former Deputy Attorney General Eric Holder, who listened to the hospitals on this question, understood that there were major problems out in the field, which is not uncommon in these health care cases where regional offices and U.S. Attorneys offices know what is going on but decide they are going to do something differently from what is testified to here in Congress or what is directed to by an administrative agency.

When hospitals sought the court's protection in those particular cases, the Government attempted to dismiss them out of court, arguing that the hospitals had failed to go through an administrative process. The 6th Circuit Court of Appeals sided with the hospitals and held that the administrative process——

Senator CRAIG. Are you moving toward wrap-up, Mr. diGenova?

Mr. DIGENOVA. I am coming right to the end, Mr. Chairman.

Providers should be treated fairly, equitably, and in a civil manner and granted appropriate due process rights. To help hospitals achieve these rights we recommend the following, Mr. Chairman.

First, Congress should limit the OIG's use of CIAs to instances of intentional fraud. If a hospital's compliance program has deficiencies, they should be remedied, but the OIG should not be allowed to impose an overly burdensome and costly CIA.

Second, the OIG should be prohibited from second-guessing decisions made by DOJ and conducting duplicative investigations. This need not preclude, obviously, the payment of any overdue amounts. That can be handled through an administrative process.

Third, Congress should enact legislation to give hospitals and their providers a specific opportunity to challenge Medicare policy decisions made by HHS that are legally questionable.

Thank you.

Senator CRAIG. Thank you very much for that testimony.

[The prepared statement of Mr. diGenova follows:]

Testimony
of the
American Hospital Association
before the
United States Senate
Special Committee on Aging
on
Medicare Enforcement Actions: The Federal Government's Anti-Fraud Efforts

July 26, 2001

Mr. Chairman, I am Joseph diGenova, special counsel to the American Hospital Association (AHA). The AHA represents nearly 5,000 hospitals, health systems, networks, and other providers of care. We appreciate this opportunity to testify on an issue of great concern to the health care community and the general public: enforcement activities related to the Medicare program. Our comments will focus on the enforcement activities of HHS Office of Inspector General (OIG) and the need to provide hospitals with direct access to the courts.

BACKGROUND

America's hospitals and health systems are rooted in a tradition of ethics and caring. We're committed to preventing, uncovering, and eliminating health care fraud and abuse. Hospitals across the nation have voluntarily established programs to ensure compliance with Medicare's requirements - laws and regulations that are generally agreed to be complex and confusing. Each year, hospitals and health systems submit, on average, nearly 200,000 Medicare claims a day. To ensure the accuracy of those claims, the Mayo Foundation estimates that hospitals must

comply with 132,720 pages of rules that govern the Medicare and Medicaid programs – that's three times the size of the IRS Code and its federal tax regulations.

The AHA has a strong commitment to ensuring that hospitals have the information and tools they need to comply with the vast array of federal and state laws and regulations. As part of a compliance service offered by the AHA, we provide updates on guidance issued by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration. We have also instituted a formal process with CMS to obtain additional guidance on the "gray areas" that regularly arise when attempting to translate guidance into compliance.

Our experience with the compliance service and with assisting hospitals caught up in the web of government billing investigations reinforces our view that billing issues are usually billing mistakes. Fraud is the exception. That's why we continue to urge that the starting point for any questions about a claim submitted by a hospital should be the administrative process. That process is capable of dealing with any discrepancies in billings and should be the standard means of examining any questionable billings. If, and only if there is sufficient indication of potential fraud, should a referral be made to law enforcement authorities.

Recent experiences with several national law enforcement investigations demonstrate the importance of beginning with the administrative process. The AHA has commissioned reports on two of the major investigations undertaken by the government for the submission of allegedly fraudulent billings. The first was a response to the government's initial national billing investigation for outpatient laboratory billings. The second was a more recent investigation that examined pneumonia billings. In both instances, we found that the state of guidance on what

was required of hospitals was not as clear as the government asserted. In the lab matter, there was no legal duty for hospitals to bill as the government asserted there was. In fact, in many instances there were contrary instructions. As a result, the government significantly curtailed its national recovery efforts, withdrew its investigations in several states (and in one state actually refunded fines collected from hospitals); terminated compliance agreements that were imposed as part of settlements; and agreed to refer matters to the fiscal intermediary. In the pneumonia matter, guidance was ambiguous at best. These experiences with broad-based investigations demonstrate that treating billing issues as potential fraud is an unwarranted starting point.

ENFORCEMENT ACTIVITIES OF THE OIG

Hospitals are concerned with two ways the OIG is exercising its enforcement authority. We are seeing an insistence on hospital acceptance of an unnecessarily burdensome and costly corporate integrity agreement (CIA) as a condition for resolving billing issues, without regard to a hospital's own compliance program and the lack of any evidence of fraud. We have also seen disturbing evidence of the OIG using its enforcement authority to launch separate and duplicate investigations of matters previously investigated by the Department of Justice (DOJ) and resolved completely in favor of a hospital.

Corporate Integrity Agreements

A corporate integrity agreement (CIA) is the OIG's version of a compliance program that was designed for use in settling investigations, and in return for the OIG's agreement not to exclude a provider from the Medicare program. It was intended and is still viewed as a corrective action and its imposition a penalty. The AHA's members repeatedly tell us the OIG's insistence on a CIA impedes voluntary disclosures and the resolution of billing disputes. A CIA should only be

used in the case of fraud. If a hospital's own compliance program is insufficient to prevent future billing irregularities, it should be improved and requirements targeted to those specific areas. In the case of billing errors and honest billing mistakes, a CIA should not be required.

The imposition of a CIA imposes significant burdens and costs on hospitals. The biggest cost factor is the requirement that a hospital contract with an independent review organization to perform reviews of the hospital's billings and implementation of the CIA. Typically, CIA's require three types of review: a systems review, a billing review and a compliance review, each to be done by an outside organization. Instead of tying a systems review to a specific, identified systems problem, it has now become boilerplate. While the systems review is usually a one-time event, it is extremely costly and the benefits are not evident. The problem with the billing review is that the OIG's audit methodology requires that there be large samples, which has a direct bearing on the cost of the review. There is little flexibility on sampling issues, notwithstanding the impact on costs. Finally, the compliance review seems unnecessary in the absence of evidence that there is a specific problem with performance under the CIA. To the extent that these reviews are necessary, providers should be allowed to conduct them using internal resources unless there is some demonstrated reason to consider such review inadequate.

CIAs' training requirements are another cost issue. The agreements usually impose a mandatory minimum number of training hours per employee that creates a burden for conscientious providers because they may have to spend time and effort tracking down a handful of employees to ensure that there has been 100 percent participation. And the emphasis on hours does not ensure that the training is productive or meaningful. Hospitals should have the discretion to conduct training in ways that they consider optimal, which might include a Web-based tool as

opposed to a two-hour lecture. Also, CIAs require that the first wave of training take place within a fixed amount of time (usually 120 days) following entry into the agreement. This requirement is imposed even when the provider has had a compliance plan in operation and the underlying conduct occurred years before.

In addition to the compliance program issues, there are legal issues related to the heightened reporting accountability. For a provider that hasn't violated the law itself to learn that a later violation of the CIA may be grounds for termination from Medicare is extraordinary. As a result of their compliance efforts, providers are increasingly interested in disclosing billing errors. However, their effort to come forward over billing mistake issues that are not fraud then makes them subject to an investigation and a captive of the CIA.

Duplicate Investigations

DOJ and the OIG have concurrent jurisdiction over fraudulent claims: DOJ under the False Claims Act (FCA), and the OIG under the Civil Money Penalty (CMP) statute. Civil powers to pursue false or fraudulent claims are the same under the civil FCA for Justice as for the OIG under the CMP statute. Concurrent jurisdiction should provide flexibility to the agencies for allocating resources in an investigation. Instead, it has permitted the OIG to second-guess decisions of the DOJ. Attempts by the OIG to place a hospital under investigation for the very same issues examined and found to be without merit by DOJ, should not be permitted, and the OIG should be restrained from doing so.

We are aware of a situation in which the OIG is pursuing a hospital and demanding hundreds of thousands of dollars and a hospital-wide corporate integrity agreement under its authority to

impose CMPs. The OIG is doing this despite an extensive and thorough investigation by DOJ of the very same issues, DOJ's dismissal of the case without taking any action whatever, and in spite of the OIG's active participation in the DOJ investigation.

DIRECT ACCESS TO COURT

Direct access to court is essential to provide fundamental fairness for hospitals participating in the Medicare program. In Shalala v. Illinois Council on Long Term Care, the Supreme Court held that under section 205(h) of the Social Security Act, incorporated into the Medicare Act by section 1872, claims related to the Medicare statute must go through an administrative process before being brought to court. As a result of that decision and the government's expansive application of the holding, providers are being denied the ability to challenge the legality of actions by HHS that under other statutes would be immediately subject to review. In situations where no administrative process is available, the result could be no review of HHS's actions. The restrictions being placed on Medicare providers do not apply to many other regulated entities.

Unfortunately for hospitals, that interpretation effectively insulates HHS from legal accountability for many of its actions, and places hospitals in the position of having to violate a regulation in order to challenge the legality of HHS' decisions and policies. That means the price of admission to the court for hospitals is termination from the Medicare program - a price that no hospital or its community can risk.

The Medicare statute needs to be clarified so that when a dispute (unrelated to the specific situation of a provider or beneficiary) challenges the legality of HHS' actions, or any of the other

grounds for court review that currently exist under the Administrative Procedures Act, a hospital or other provider is entitled to bring an action in court. This clarification would not change the requirements that apply to anyone seeking relief in court, e.g., demonstration of standing and of a case or controversy. It would simply make clear that the HHS policy decisions are subject to the same level of judicial review as other federal regulatory agencies, such as the Food and Drug Administration and the Environmental Protection Agency.

In addition to needing access to court to challenge questionable HHS policy decisions without first being terminated from the Medicare program, hospitals need access to judicial review when there is no process for resolving a dispute. The laboratory billing investigation is a good example. Hospitals across the country were receiving demand letters from U.S. Attorneys effectively accusing them of fraud, demanding exorbitant amounts in repayment and penalties, and threatening law enforcement proceedings. As a special report commissioned by the AHA demonstrated, the foundation for the investigations was legally flawed. Hospitals were being accused of fraud for failing to follow alleged billing requirements that were never established through rulemaking, never issued as guidance by the agency, and actually contradicted in billing instructions from fiscal intermediaries.

Hospitals sought the court's protection. They were immediately confronted with the government's attempt to dismiss them out of court, arguing that the hospitals had failed to go through an administrative process. The 6th Circuit Court of Appeals sided with the hospitals and held that the administrative process provided no review at all for hospitals. However, the Supreme Court's decision in the Illinois Council case puts at risk the 6th Circuit's view that

hospitals have recourse to court when no administrative review is available. Congressional action is needed to ensure fundamental fairness for hospitalss.

CONCLUSION

Mr. Chairman, Medicare billing errors often result from confusing and conflicting regulations and instructions that are part of the Medicare reimbursement system. These are not intentional acts. Providers who make billing mistakes after attempting to comply with the complicated and frequently changing rules of Medicare payment should be treated in a fair, equitable and civil manner and granted appropriate due process rights -- rights that are guaranteed to all Americans.

To help hospitals achieve these rights, the AHA recommends the following improvements to the current administrative resolution and enforcement system:

Provide oversight of the OIG enforcement activities. The OIG plays a vital role in the government's anti-fraud efforts; however, its recent activities clearly indicate that the agency has overstepped its authority. First, Congress should limit the OIG's use of CIAs to instances of intentional fraud. If a hospital's compliance program has deficiencies, those should be remedied, but the OIG should not be allowed to impose an overly burdensome and costly CIA. Second, the OIG should be prohibited from second-guessing decisions made by DOJ and conducting duplicative investigations. The OIG's duplicative investigations are a waste of government and hospital resources.

Enable providers to challenge questionable policy action in court. Health care providers are required to exhaust all administrative processes and remedies before they can file suit against

HHS. However, when the issue is whether the department has exceeded its authority or failed in its duty, that is a matter for the courts. Congress should enact legislation to give hospitals and other providers a specific opportunity to challenge Medicare policy decisions made by HHS that are legally questionable.

The AHA is ready and willing to continue our work with HHS, CMS, DOJ and other agencies to ensure the integrity of the Medicare program. I thank the Committee again for the opportunity to describe the compliance difficulties hospitals face, and welcome any questions you may have.

Senator CRAIG. Now let us turn to James Moorman, Executive Director of Taxpayers Against Fraud.

Jim.

STATEMENT OF JAMES W. MOORMAN, EXECUTIVE DIRECTOR, TAXPAYERS AGAINST FRAUD, WASHINGTON, DC

Mr. MOORMAN. Thank you, Senator.

We very much appreciate being given this opportunity to testify. Taxpayers Against Fraud is a nonprofit public interest organization dedicated to combatting fraud against the Federal Government through the promotion of the False Claims Act and its *qui tam* provisions. Unlike the other organizations which have testified here today, we are a tiny organization and not so well-known.

The *qui tam* provisions of the False Claims Act are those provisions which allow whistleblowers with evidence of fraud involving the Federal Government to bring suits on behalf of the Government.

The False Claims Act is the primary tool of the Federal Government for fighting health care fraud. The Civil Division and the U.S. Attorneys Offices of the Department of Justice, working with the Inspector General's Office of HHS, have recovered billions of dollars in False Claims Act health care fraud cases. Most of these cases were initiated originally by whistleblowers as False Claims Act *qui tam* cases. When a whistleblower reveals a fraudulent scheme to the Government through a False Claims Act complaint, this permits the United States to then undertake an investigation, win back the money stolen, plus penalties, and deploy several other tools that enhance the effectiveness of the anti-fraud effort.

As I said, many of the Government's most fruitful False Claims Act investigations are based on information received from the whistleblowers. Overall False Claims Act actions since the Act was amended in 1986 have returned over $6 billion to the Federal Government, and a substantial amount of that has been in the health care fraud area.

Since September 30, 1986, the Government had recovered $2.83 billion from defendants in health care False Claims Act cases. This figure does not include the $745 million settlement with Columbia HCA in December of 2000 and other recent health-related settlements which pushed the healthcare recoveries well past $3.5 billion. In 2000, 80 percent of the Government's civil fraud recoveries were from *qui tam* cases.

There is evidence that the deterrent effect of the False Claims Act is one of the significant causes in the noticeable tapering off of the rise in Medicare costs in recent years. False Claims Act actions undoubtedly play a very large role in deterring fraud and saving the taxpayers money.

False Claims Act judgments have changed the attitude and actions of providers and encouraged Government efforts to correct systemic problems in the system and thus created additional cost savings. The indirect savings of deterrence and Government corrective activities are probably several times the amount actually recovered directly from case judgments and settlements. So, if you add the direct recoveries combined with the indirect savings attrib-

utable to False Claims Act deterrence, the taxpayers are receiving a very large benefit indeed.

In conclusion, the False Claims Act and its *qui tam* provisions are a vital component in any meaningful effort to curtail and deter fraudulent overbilling to Medicare and Medicaid. The fraudulent schemes uncovered by whistleblowers have saved the Government billions of dollars.

The majority of honest health care providers have nothing to fear from the False Claims Act, however, because the Act does not punish mere mistakes. But there is an important minority of bad actors in the health care industry who must be deterred by vigorous enforcement of the False Claims Act. It is our position that the Justice Department and OIG should do more and not less to be responsive to whistleblowers. The Department should join more *qui tam* cases and make a stronger effort to work closely and cooperatively with the whistleblowers, the people who bring them the bulk of their important health care fraud cases.

In summary, I urge the committee to continue the tradition established by Senator Grassley to encourage the Government to work with whistleblowers to uncover fraud and protect the public fisc.

Thank you, Senator.

[The prepared statement of Mr. Moorman follows:]

TAF
TAXPAYERS AGAINST FRAUD
THE FALSE CLAIMS ACT LEGAL CENTER

SUMMARY OF
TESTIMONY OF
JAMES W. MOORMAN, PRESIDENT
TAXPAYERS AGAINST FRAUD
THE FALSE CLAIMS ACT LEGAL CENTER
Before The
SENATE SPECIAL COMMITTEE ON AGING
JULY 26, 2001

Mr. Chairman and Members of the Committee, my name is Jim Moorman and I am appearing today on behalf of Taxpayers Against Fraud, The False Claims Act Legal Center ("TAF"). Taxpayers Against Fraud is a nonprofit public interest organization dedicated to combating fraud against the Federal Government through the promotion and use of the federal False Claims Act ("FCA") and its *qui tam* provisions. *Qui tam* is a legal mechanism that allows persons and entities with evidence of fraud involving federal programs or contracts to sue wrongdoers on behalf of the Government. The *qui tam* provisions include strong incentives both to report fraud against the Government and to participate in the resulting litigation.

The False Claims Act is the primary tool of the Federal Government for fighting healthcare fraud. The Civil Division and the U.S. Attorneys Offices of the Department of Justice, together with the Office of the Inspector General of the Department of Health and Human Services, have recovered billions of dollars in FCA health care fraud cases. Most of these cases have been initiated by whistleblowers as FCA *qui tam* cases. When a whistleblower reveals a fraudulent scheme to the government, this then permits the government to undertake an investigation, win back the money stolen, plus penalties, and to deploy several other tools that enhance the effectiveness of anti-fraud efforts.

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Many of the government's most fruitful FCA investigations are based on information received from private individuals (e.g., corporate whistleblowers or health program beneficiaries). Overall, *qui tam* actions have returned over $6 billion to the Federal Government since 1986, when the modern FCA was created by Amendments adopted that year. A very substantial share of these recoveries have come from perpetrators of health care fraud through FCA judgments. From September 30, 1986 through September 30, 2000, the government recovered $2.83 billion from defendants in health care related FCA cases. This figure does not include the $745 million settlement with Columbia/HCA in December of 2000, and other recent health-related settlement, which push the recovery number well past $3.5 billion. In 2000 80% of the government's civil fraud recoveries were from *qui tam* FCA cases.

There is evidence that the deterrent effect of the FCA is one of the significant causes in the noticeable tapering off of the rise in Medicare costs in recent years. FCA actions undoubtedly play a very large role in deterring fraud and saving the taxpayers money. FCA judgments change the attitude and actions of other providers, and encourage government efforts to correct systematic problems and thus create additional cost savings. The indirect savings of deterrence and government corrective activities are probably several times the amount recovered directly through case judgments and settlements. When direct FCA recoveries are combined with indirect cost savings attributable to the FCA, the taxpayers are receiving a very large benefit indeed.

Conclusion

The False Claims Act, and its *qui tam* provisions, are a vital component in any

meaningful effort to curtail and deter fraudulent overbilling to Medicare and Medicaid. The fraudulent schemes uncovered by whistleblowers have saved the government billions of dollars. The majority of honest health care providers have nothing to fear from the False Claims Act because the FCA does not punish mere mistakes. But there is an important minority of bad actors in the health care industry who must be deterred by vigorous enforcement of the FCA. It is TAF's position that the Justice Department and the OIG should be more, not less, to be responsive to whistleblowers. Justice should join more *qui tam* cases and make a stronger effort to work closely and cooperatively with the whistleblowers that bring them the bulk of their important health care fraud cases. In summary, I urge the Committee to continue the tradition established by Senator Grassley to encourage the government to work with whistleblowers to uncover fraud and protect the public fisc.

THE FALSE CLAIMS ACT LEGAL CENTER

TESTIMONY
of
JAMES W. MOORMAN, PRESIDENT
TAXPAYERS AGAINST FRAUD
THE FALSE CLAIMS ACT LEGAL CENTER
Before The
SENATE SPECIAL COMMITTEE ON AGING
JULY 26, 2001

I. Taxpayers Against Fraud

Taxpayers Against Fraud, The False Claims Act Legal Center ("TAF"), is a nonprofit public interest organization dedicated to combating fraud against the Federal Government through the promotion and use of the federal False Claims Act ("FCA") and its *qui tam* provisions. *Qui tam* is a legal mechanism that allows persons and entities with evidence of fraud involving federal programs or contracts to sue the wrongdoer on behalf of the Government. The *qui tam* provisions include strong incentives both to report fraud against the Government and to participate in the resulting litigation.

Under the False Claims Act, 31 U.S.C. §§ 3729-3733, those who knowingly submit or cause the submission of false or fraudulent claims for payment of government funds are liable for three times the dollar amount that the Government is defrauded (i.e. treble damages) and civil penalties of $5,000 to $10,000 for each false or fraudulent claim. If the FCA suit is filed by a private party under the *qui tam* provisions, that party can receive between 15 and 30 percent of the total recovery. A *qui tam* suit initially

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remains under seal for at least 60 days during which the Department of Justice investigates and decide whether to join in the action.

In general, the False Claims Act covers fraud involving any federally funded contract or program, with the exception of tax fraud. While many *qui tam* actions in the late 1980s and early 1990s involved Department of Defense contracts, in recent years the majority of *qui tam* actions have been used to fight Medicare fraud and fraud against other federally funded health care programs. A broad array of scenarios can constitute FCA violations. Examples include the following: a contractor falsifies test results or other information regarding the quality or cost of products it sells to the Government; a health care provider bills Medicare for services that were not performed or were unnecessary; or a grant recipient charges the Government for costs not related to the grant.

Overall, *qui tam* actions have returned over $6 billion to the Federal Government since 1986, when the modern FCA was created by Amendments adopted that year.

TAF's mission is to support and promote the FCA. Established in 1986, TAF serves to:

(1) Inform and educate the general public, the legal community, government officials, the media, and other interested groups about the False Claims Act and its *qui tam* provisions;
(2) Contribute to understanding of the Act's nature, workings, and critical importance to the public interest;
(3) Vigorously defend against any attempts to repeal or weaken the Act;
(4) Facilitate meritorious *qui tam* suits;
(5) Advance public, legislative, and government support for *qui tam*;
(6) Document the public policy value and the intellectual and legal foundation of the Act in general and the *qui tam* provisions in particular.

As part of its public outreach, TAF promotes and disseminates information concerning the False Claims Act and *qui tam*. TAF publishes the *False Claims Act and*

Qui Tam Quarterly Review, which provides an overview of case decisions, settlements, and other developments under the Act. TAF maintains a comprehensive FCA library open to the public by appointment, and TAF has an educational presence on the Internet. In addition, TAF has established an information network to assist counsel in their efforts to provide effective representation to *qui tam* plaintiffs.

TAF also files *amicus* briefs on important legal and policy issues in FCA cases, writes articles about the Act and *qui tam,* and has provided testimony to Congress. On a regular basis, TAF responds to inquiries from journalists and government officials as well as the general public.

II. Historical Overview

The FCA dates back to the Civil War. Reacting to allegations of fraud and corruption by private contractors selling supplies to the Union Army, Congress enacted this legislation to stem the frauds perpetuated against the government. It became law at the height of the civil War in March of 1863 at the urging of President Lincoln, and has often been referred to as the "Lincoln Law."

The original legislation subjected violators of the Act to double damages and an award to the government of $2,000 for each false or fraudulent claim submitted. It also contained *qui tam* provisions that allowed private citizens to file suit on behalf of the government. *Qui tam* is the abbreviation for the phrase "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*" which translates as "who sues on behalf of the king, as well as for himself." These private citizens or relators as they were called, originally

received 50 percent of the recovery. Republican Senator Charles Grassley, a co-sponsor of the 1986 Amendments to the Act, described the history and purpose of the inclusion of the *qui tam* provisions in the original legislation:

> Included in the anti-fraud arsenal of the False Claims Act was a provision called *qui tam*. *Qui tam* is a concept that dates back to feudal times. It allows private citizens who know of fraud against the taxpayer to bring a lawsuit against the perpetuators. In other words, the citizen acts as a partner with the government. As an incentive, the citizen shares in any monetary recovery to the U.S. treasury.

In one of the most important early cases considering the FCA, *United States v. Griswold* (1885), a federal district court stated its view with regard to the desirability of the *qui tam* provisions:

> The statute is a remedial one. It is intended to protect the Treasury against the hungry and unscrupulous host that encompasses it on every side, and should be construed accordingly. It was passed upon the theory, based on experience as old as modern civilization, that one of the least expensive and most effective means of preventing frauds on the Treasury is to make the perpetrators of them liable to actions by private persons acting, if you please, under the strong stimulus of personal ill will or the hope of gain. Prosecutions conducted by such

means compare with the ordinary methods as the enterprising privateer does to the slow-going public vessel.

In 1943, in the midst of the Second World War, congress amended the FCA again. The 1943 Amendments, unfortunately, erected substantial barriers to relators and the *qui tam* provisions of the FCA. As a consequence, the FCA fell into disuse.

However, in 1985 and 1986, there were numerous reports and publicity about widespread fraud against the government, especially in the area of defense contracting. The General Accounting Office, the Department of Defense and the Department of Justice produced various estimates of the cost of fraud to the American taxpayer — the highest approaching $50 billion per year. With the government seemingly unable to get inside information necessary to deal effectively with the problem, Congress saw the need to strengthen the FCA

In 1986, FCA Amendments were a bipartisan response to this "growing pervasiveness of fraud" in federal programs and procurement. The desire to strengthen the Act received broad support in Congress, and president Reagan signed the Act into law on October 27, 1986

Congress revitalized the *qui tam* provisions of the Act because it believed "only a coordinated effort of both the Government and the citizenry will decrease this wave of defrauding public funds." Senator Grassley described the purpose of reinvigorating the *qui tam* provisions:

> S. 1562 arises from a realization that the government needs help – lots of help – to adequately protect taxpayer funds from growing and increasingly sophisticated fraud. In the face of our current federal debt crisis, it is more important than ever that we maintain an efficient, fair, and most of all, effective enforcement system to protect our federal dollars from fraud and abuse . . .The expanded *qui tam* provisions in this bill will serve to establish a solid partnership between public law enforcers and private taxpayers in the fight against fraud.

The 1986 amendments to the *qui tam* provisions of the FCA aimed to strengthen these provisions. They guaranteed a role for the private citizen even if the government intervenes and they also increased the percentage of recovery for the relator that was severely reduced by the 1943 Amendments. In actions in which the government intervenes, a relator may now recover 15 to 25 percent of the proceeds of the action or settlement. If the government does not intervene, the relator may recover from 25 to 30 percent. It also provides whistleblowers with protections in the form of a federal cause of action for relators who are discriminated against by their employers for participation or involvement in a *qui tam* action.

The 1986 Amendments also updated other provisions of the Act. It clarified the level of intent necessary to establish a violation of the FCA. It made clear that one does not have to show specific intent to defraud the government. If one submits a false or fraudulent claim to the government with actual knowledge of the information, or acts in deliberate ignorance of the information, or acts in reckless disregard of the truth of

information, then one may be liable under the Act. It also established the burden of proof by which the government must prove its case as a "preponderance of the evidence." One very important aspect of the burden of proof is that mere mistakes are not a basis of liability under the FCA. Thus, those providers afflicted only with billing errors have no grounds for concern about the FCA.

III. The False Claims Act Role In Efforts to Suppress Fraud Against Health Care Programs

The False Claims Act is the primary tool of the Federal Government for fighting healthcare fraud. The Civil Division and the U.S. Attorneys Offices of the Department of Justice, together with the Office of the Inspector General of the Department of Health and Human Services, have recovered billions of dollars in FCA health care fraud cases. Most of these cases have been initiated by whistleblowers as FCA *qui tam* cases. Indeed, most FCA cases involve collaborative efforts of whistleblowers and government agencies in investigations, information sharing, litigation, and settlement activities.

Many of the government's most fruitful FCA investigations are based on information received from private individuals (e.g., corporate whistleblowers or health program beneficiaries). Following the collection of information from these individuals, the agencies typically uncover additional evidence of fraud through audits and investigations. The bulk of government' FCA investigations in the health care area are done by HHS/OIG. The cases are prosecuted by one of the seventy or so attorneys in the Civil Divisions or by one of the Justice Department's 94 U.S. Attorneys Offices. In most cases, where the government joins a *qui tam* case, there is a settlement. When

whistleblowers' cases are not joined by the government, however, whistleblowers are frequently required to go to trial.

IV. False Claims Cases Have A Major Deterrent Effect on Health Care Fraud

The FCA lies at the center of efforts to curb fraud against government health care programs. When a whistleblower reveals a fraudulent scheme to the government, this permits the government to undertake an investigation, to win back the money stolen, plus penalties, and to deploy several tools that enhance the effectiveness of anti-fraud efforts.

First: FCA cases facilitate criminal prosecution, where appropriate

Criminal investigations often derive from and benefit from civil FCA investigations and cases, as fraudulent activities can implicate both civil and criminal liability. As a result, FCA settlements with corporations often include additional criminal fines and/or criminal prosecutions of individuals (many of whom ultimately go to jail). As in most white-collar areas, criminal liability is a significant deterrent.

Second: FCA cases facilitate Corporate Integrity Agreements ("CIA's")

Most government settlements of FCA cases in the health care field now require healthcare providers to adopt Corporate Integrity Agreements, or CIA's. In general, CIA's mandate strict corporate compliance programs and extensive reporting requirements. CIA's, are typically monitored for five years, are tailored to each provider's situation and activities, and usually require a compliance officer, written standards and policies, a comprehensive employee-training program, audits of billings to federal health care programs, a confidential disclosure program, restrictions on employment of ineligible persons, and reports to the OIG.

As direct outgrowths of FCA investigations and case settlements, CIA's should be instrumental in deterring corporate fraud. The strict oversight inherent in CIA's should work to enhance compliance by the providers under such agreements. The imposition of CIA's should also have a spillover effect on other providers now that the details of CIA's have been widely publicized.

Third: The settlement of FCA cases against some nursing homes have resulted in greatly improved quality of care. This Committee is well known for its strong bipartisan concern about the quality of nursing home care purchased by Medicare and Medicaid with federal taxpayer dollars. This concern has been a priority of some United States Attorneys Offices, as well as the Office of Inspector General. Notably, the Eastern District of Pennsylvania, using the False Claims Act, has resolved a number of nursing home quality of care cases by negotiating settlements designed to improve the quality of the services for which Medicare and Medicaid are paying. For example, in a case settled last November involving federal payments to a nursing facility for the provision of allegedly inadequate nutrition and wound care, the nursing facility agreed (1) to spend $100,000 (from non-federal funds) over 2 years to improve the quality of life for residents, (2) to implement a weight monitoring program, (3) to adhere to clinical guidelines in the treatment of pressure ulcers, and (4) to retain at its expense a third-party monitor selected by the government to oversee its compliance with these requirements. Thus, as a result an FCA settlement, the quality of care at this facility will improve dramatically, to the benefit of federal taxpayers and the facility's patients.

Fourth: The Federal Government has recovered substantial money from perpetrators of health care fraud through FCA judgments. From September 30, 1986

through September 30, 2000, the government recovered $2.83 billion from defendants in health care related FCA cases. This figure does not include the $745 million settlement with Columbia/HCA in December of 2000, and other recent health-related settlements, which push the recovery number well past $3.5 billion.

These recoveries have virtually all come since 1993. From 1986 through 1992, health care FCA recoveries probably only totaled about $50 million. Since 1997, however, health care related recoveries have been particularly significant, representing the majority of FCA recoveries. Of particular importance are *qui tam* FCA cases initiated by whistleblowers. Since 1986, 48 percent of all FCA cases filed by whistleblowers have been healthcare cases. (32% have been defense contractor cases). *Qui tam* FCA cases now account for the overwhelming majority of FCA recoveries. Thus, in 2000 80% of the government's civil fraud recoveries were from *qui tam* FCA cases

Obviously, the large dollar amount of FCA judgments, coupled with ancillary CIA's and criminal liability, is having a powerful deterrent effect on the billing culture in the health care area. There is evidence that this effect is one of the significant causes in the noticeable tapering off of the rise in Medicare costs in recent years. The impact of FCA actions to increase compliance and deter fraud beyond actual monetary recoveries would be difficult to quantify. Nevertheless, FCA actions undoubtedly play a very large role in deterring fraud and saving the taxpayers money. FCA judgments change the attitude and actions of other providers, and encourage government efforts to correct systematic problems and thus create additional cost savings. Upon learning of fraud schemes revealed by whistleblowers, the government takes many initiatives to close the loopholes or government practices which facilitated fraud. The indirect savings of

deterrence and government corrective activities are probably several times the amounts recovered directly in case judgments and settlements. When direct recoveries are combined with indirect cost savings attributable to FCA actions, the taxpayers are receiving a very large benefit from the FCA indeed.

V. The Nature of Fraud in the Health Care Field

Because much has been said about the complexity of Medicare regulations, I believe it would be useful to invite the Committee's attention to the simplicity of health care fraud. More often than not, you don't have to understand much about regulations to understand the fraudulent schemes involved. A few examples will suffice.

- Corporate officials told their employees to charge twice the nursing hours to Medicare patients as to all others. To make this happens, "1s" on nurses' logs were altered to "4s" and "3s" to "8s".
- A kidney dialysis service company paid doctors to prescribe an intravenous dietary supplement to patients on dialysis, which it then charged Medicare, even though the supplement is medically unnecessary 85% of the time. (This case is an example of why the anti-kickback statute is important and illustrate how it meshes with the FCA to suppress fraud).
- A medical lab manipulated doctors into ordering blood tests they didn't want or need, then charged Medicare for the tests.
- A hospital charged Medicare for all its emergency room patients at the high end of a system of five codes graded for the severity of the emergency.
- A doctor charged for visits and consultations that never occurred.

In these, and many other schemes where dishonest health care providers have fraudulently deprived the taxpayers of large amounts of money, the basic idea behind the fraud is simple. Health care providers engaged in cheating frequently cloak their fraud in a cloud of confusion, citing bureaucratic rules, and claiming mistakes. But if these are just mistakes, you would think they would go both ways: against providers as often as against the government. Why is it that almost all the so-called mistakes cost taxpayers money? The truth is, we have been plagued by a cottage industry of consultants that have taught many in the health care industry how to game the Medicare system to increase cash flow at taxpayers expense. Far from being flummoxed by complex rules, they have learned the rules intimately for the purpose of manipulating them.

Conclusion

The False Claims Act, and its *qui tam* provisions, are a vital component in any meaningful effort to curtail and deter fraudulent overbilling to Medicare and Medicaid. The fraudulent schemes uncovered by whistleblowers have saved the government billions of dollars. The majority of honest health care providers have nothing to fear from the False Claims Act because the FCA does not punish mere mistakes. But there is an important minority of bad actors in health care who must be deterred by vigorous enforcement of the FCA. It is TAF's position that the Justice Department and the OIG should do more, not less, to be responsive to whistleblowers. The Justice should join more cases and make a stronger effort to work closely and cooperatively with the whistleblowers that bring them the bulk of their important health care fraud cases. In summary, I urge the Committee to

continue the tradition established by Senator Grassley to encourage the government to work with whistleblowers to uncover fraud and protect the public fisc.

TAF
TAXPAYERS AGAINST FRAUD
THE FALSE CLAIMS ACT LEGAL CENTER

The False Claims Act

- **History**
  - Enacted in 1863 at President Lincoln's request to fight fraud against the Union Army
  - Fell into disuse after a 1943 Amendment
  - Revived by the 1986 Amendments sponsored by Senator Grassley and Congressman Berman and signed into law by Ronald Reagan

- **Accomplishments**
  - $5 Billion recovered since 1986 Amendment
  - $1.5 Billion recovered in Fiscal Year 2000

- **How it works**
  - Whistleblowers (called "relators") file suit under seal, give their evidence to the Justice Department
  - DoJ and defrauded Agency investigate; DoJ may intervene and take over the case.
  - If the case is won, the defendant is liable for a civil penalty of $5,000 to $10,000 per false claim, plus treble the amount of the damages to the Federal Government
  - Whistleblowers are awarded from 15 to 30% of recoveries (average is 16.2%)

- **Areas of significant Activity**
  - Medicare, Medicaid and other health care fraud (60% of recoveries since 1986)
  - Defense contractor Fraud (about 30% of recoveries since 1986)

- **Types of Medicare Fraud Uncovered by Whistleblowers**
  - Billing Medicare for unallowable costs by disguising them as allowable costs
  - Billing Medicare for laboratory tests not ordered by physicians
  - Billing Medicare for services more expensive than those actually provided ("upcoding")

- **Excluded from the Act**
  - Tax Fraud
  - Actions by whistleblowers based upon allegations of fraud disclosed in the news media or in Congressional or administrative reports, hearings, audits or investigations, unless the whistleblower is an "original source" (as defined by the statute)

1220 19th Street, NW Suite 501 Washington, DC 20036 phone (202) 296-4826 fax (202) 296-4838
internet: http://www.taf.org or taf-info@taf.org

THE FALSE CLAIMS ACT LEGAL CENTER

Taxpayers Against Fraud

The False Claims Act Legal Center

Mission

- To combat fraud against the Federal Government through the use of the False Claims Act
- To facilitate whistleblowers' use of the qui tam provisions of the False Claims Act
- To defend the False Claims Act against weakening amendments
- To promote public understanding of the False Claims Act

Activities

- Publishes reports and other matereials about the False Claims Act
- Tracks litigation involving the False Claims Act
- Maintains a library of False Claims Act materials and cases
- Provides technical, litigation, and other assistance to whistleblowers' attorneys

About TAF

- A non-profit public interest organization (501 (c)(4) tax exempt status)
- James W. Moorman, President and Chief Executive officer
- For further information, see TAF's website www.taf.org

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THE FALSE CLAIMS ACT LEGAL CENTER

JAMES MOORMAN

President and CEO
Taxpayers Against Fraud:
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Mr. Moorman was appointed to head Taxpayers Against Fraud ("TAF") in January of 2000. TAF was founded in 1986 shortly after Congress enacted amendments To strengthen the False Claims Act. The Act enables ordinary citizens to file suits Concerning fraud and abuse against Medicare and other Federal programs, and to Share in the recovery of public funds. These citizens are generally considered as "whistleblowers." TAF provides information and assistance to whistleblowers and their lawyers. TAF also seeks to educate the public and the legal community about the Act, documenting public policy values of the False Claims Act approach and building a constituency to support the law.

As President and CEO of TAF, Mr. Moorman is responsible for the organization's various programs, including government affairs, press relations, publications, and policy studies, all of which relate to the promotion and well-being of the FCA. He is also responsible for fundraising and the various activities of TAF directed to the support of whistleblowers and their attorneys.

Prior to assuming his duties at TAF, Mr. Moorman was a partner in the Washington, D.C. office of Cadwalader, Wickersham and Taft. At Cadwalader, Mr. Moorman served as the head of the firms environmental law practice, with a widely varied practice of national scope. Mr. Moorman's matters literally encompassed the nation from Northern Alaska to Southern Florida.

Prior to his service at Cadwalader, Mr. Moorman served as an Assistant Attorney General of the United States Department of Justice in charge of the Land and Natural Resources Division (1977-1980). In that capacity, Mr. Moorman was responsible for the division's 26,000 plus cases on behalf of EPA, the Departments of the Interior, Agriculture, Energy, and Army, and virtually every other department and agency of the United States Government.

At an earlier period in his career Mr. Moorman served as a Staff Attorney in the General Litigation Section of the Lands And Natural Resources Division (1966-1969). At that time Mr. Moorman's practice emphasized water resource cases, mostly in California, Colorado, and Nevada.

From the years 1971-1977 Mr. Moorman served as Staff Attorney and Executive Director of the Sierra Club Legal Defense Fund in San Francisco and from 1969-1971 as a Staff Attorney at the Center for Law and Social Policy in Washington, D.C. At SCLDF and the Center Mr. Moorman was involved in a number of landmark case, including one that led to the ban of DDT.

Mr. Moorman attended Duke University as an undergraduate and as a law student. In law school he served on the Board of Editors of the Duke Law Journal. After graduating from Duke School of Law in 1962, Mr. Moorman served a brief term in the Army, then three years at the New York firm of Davis, Polk, Wardwell, Sunderland & Kiendel (1993-1995).

Senator CRAIG. Jim, thank you very much.

Gentlemen, let me thank you all for your testimony. I do have several questions that I would like to ask of you.

Mr. Charrow, in your opinion, is there merit to the assertion that health care providers are paying substantial monetary penalties for innocent mistakes?

Mr. CHARROW. In the form of settlements, yes. Most health care providers who are subject to prosecution civilly under either the False Claims Act or its administrative counterpart at HHS cannot afford in many cases to go through the litigation process, either because of the risks or the costs of the litigation are too great they settle, even though many of them believe, and their attorneys believe, that they did nothing other than make an honest error.

Bear in mind that at the administrative level as opposed to in court which is under the False Claims Act, the standard of proof is much closer to actual negligence than it is under the False Claims Act. So the OIG can make out a case administratively where the OIG might not have been able to make out that case in court under the False Claims Act.

So, yes, in answer to your question.

Senator CRAIG. From your experience working inside HHS and in private practice—and maybe you have just given me the answer, but let me finish asking the question—why do you think the OIG is pursuing cases that DOJ is walking away from?

Mr. CHARROW. Different standards.

Senator CRAIG. Different standards.

Mr. CHARROW. Different standards—an easier standard administratively. It does not have a jury to deal with, it does not have a Federal judge to deal with. The calculus is very different.

Senator CRAIG. What do you think of the proposed compliance education efforts for providers described by Administrator Scully?

Mr. CHARROW. When I was a law professor, I had difficulty teaching law studies to comprehend what was in a couple of hundred pages. I do not know how Mr. Scully is going to teach providers what is in 100,000 pages—especially when much of what is in there is not written in a language that has been discernible by any known linguist and frequently is at-odds with some other materials in the same compendium.

Senator CRAIG. Well, I guess you have answered the balance of the follow-up questions as it relates to efforts to deal with the serious problem. That is one of the things that I most often hear from providers is a clear attempt to understand what is meant. And one of the great difficulties inside this beltway is the bureaucratic ease that ultimately makes it to the regulation that really is not very applicable or does not make a lot of sense on the ground, and you literally have to go through an educational process to comprehend—and now with the volume that we have.

Senator CRAIG. What do you think it costs on average in a typical case in terms of attorneys' fees to defend against allegations that a provider has engaged in fraudulent billing practices? Do you have any indication of that?

Mr. CHARROW. If the provider is lucky, in the low six figures. If we are talking about a small provider and a small case, in the low

six figures. If it is a large provider, a hospital, it could be in the millions.

Senator CRAIG. Mr. diGenova, in the rare instance where criminal enforcement actions occur involving providers, what do you think needs to be in DOJ's guidelines related to the issuance of search warrants involving hospitals that is not there already?

Mr. DIGENOVA. Mr. Chairman, thank you for the opportunity to answer that question. First of all, our opposition to certain enforcement actions by OIG and even by DOJ under the False Claims Act several years ago was related to civil cases.

With regard to criminal cases, obviously, there is a higher standard of evidence that is necessary, and probable cause for a search warrant means that there is some evidence of fraud, and therefore the warrant has to be issued by a judge.

What we would like to see and I think is absolutely necessary particularly in light of HIPAA, which has underscored the absolute importance of the privacy of medical records of all types, is that the Justice Department have some form of written guidelines for searches of health care facilities so that they do not interfere with patient treatment during the execution of the warrant, and second, that they do not unnecessarily compromise confidential patient information in medical records.

As you know, the Justice Department has guidelines for the issuance of search warrants for lawyers' offices. That is because of the nature of the attorney-client relationship and the 6th Amendment right to counsel.

We think it would probably be a very good idea for the Department to study and hopefully issue guidelines for the issuance of search warrants and their execution at health care facilities to protect privacy rights under HIPAA, to protect generic privacy rights under the Constitution, and certainly to protect confidential information relative to the doctor-patient privilege.

Senator CRAIG. You have expressed reservations in the past about arming inspector generals. Is there any instance where you think it would be justifiable to arm investigators in a health care matter?

Mr. DIGENOVA. Mr. Chairman, I do not. I have been a critic for some time of the basic issue of having OIGs throughout the Government, not just in HHS, being permitted to carry weapons. As you know, this practice was permitted a number of years ago, sometime within the last 8 years, when the Deputy Attorney General issued a memorandum essentially deputizing inspector generals as deputy U.S. Marshals, thus giving them the right to carry a weapon.

In matters involving fraud investigation, if it is a criminal case, the FBI should be there anyway, and they have guns, they are trained, they know how to use them; and I think the fewer law enforcement people who have guns, especially those who are not regularly using them and trained to, the better off we all are.

I would like to see that memorandum from the Deputy Attorney General rescinded, a study of the policy of arming OIGs throughout the Government conducted, and a determination made by Congress as to whether or not such a policy of arming OIGs is a good idea for policy reasons, because as you know, Senator, the wearing of a

weapon in certain circumstances has a coercive impact. If it is done during an audit having nothing to do with a criminal case or anything else, it is not exactly the best way I think to establish relationships between individuals trying to engage in a partnership to clean up any problems in the health care billing system.

Senator CRAIG. Maybe a question of both you and Mr. Charrow. Mr. Morris of OIG asserted that OIG's efforts only concerned true fraud and not matters involving innocence or negligent error. In your experience, is this an actual description of how the system actually works?

Mr. CHARROW. All you have to do is read a semiannual report. The Office of Inspector General is charged with examining much more than merely fraud. It is charged with examining fraud, waste, and mismanagement—the generic term is "fraud, waste, and abuse."

Waste and abuse is not a legal concept. It is in the eye of the beholder. One person's waste and abuse is another person's medical necessity.

Fraud, on the other hand, is a discrete legal concept, but there, too, reasonable minds can differ, and I have seen cases where the IG has thought this is a case of fraud, and I have concluded, no, this is not a case of fraud.

So there are disagreements. It is not as clear-cut or as black-and-white as Lew would lead you to believe.

Senator CRAIG. Mr. Moorman, I have heard it mentioned that unless the Government joins in *qui tam* lawsuits, a majority of them fail. Is this a true assertion, and if so, why is this the case? I would ask that of you or anyone else on the panel who might like to elaborate.

Mr. MOORMAN. That is basically correct, Senator. When the Government joins the case, the case is successful most of the time. When the Government does not join the case, it is an uphill battle for the whistleblower.

The Justice Department obviously has an ability to put a lot of resources and energy and the prestige of the Government into a case that an individual whistleblower and his lawyer could equal.

Because the Justice Department has not joined a case does not mean it is not a good case, but let us face it, some whistleblower cases are not good cases. So those cases tend to fall by the wayside. But there is a definite advantage—a huge advantage—for a whistleblower to have the Justice Department on its side. In fact, most whistleblowers' lawyers will tell you that the single most important thing that happens in their False Claims Act case is the decision of the Justice Department to join or not join the case.

Senator CRAIG. Yes?

Mr. DIGENOVA. Senator, the reason for that, of course, is if someone files a private lawsuit under *qui tam* as a relater, they want the Government to take over the case, because the Government will pay for the case. Once the Government decides not to take the case, a private relater is not going to fund the litigation, except in the rarest of instances, because the discovery that would be involved would be exceptionally costly. As Mr. Charrow has testified to, these cases can cost millions of dollars, and only the Government really has those resources.

But I want to commend the Government for refusing to intercede in *qui tam* cases where they are not warranted. I think the Government should be very careful about whether or not it chooses to put its name behind the allegations of a private citizen where the incentive for the private citizen is 30 percent of the recovery against somebody—not that that is bad per se, but certainly the Government ought to be very careful—and I think they are, and the Department is to be commended—before it takes over one of these cases, because we also know that many of these allegations are totally unfounded, and that some people are trying to extort settlements from hospitals and other health care providers. And the Department of Justice has been very good at figuring out which ones those are. I think their 5 percent intervention number looks pretty good to me, and I think it shows professionalism on the part of the Department.

Mr. MOORMAN. May I correct something? The intervention rate is about 20 or 21 percent and——

Mr. DIGENOVA. I was quoting Mr. Schiffer's number.

Mr. MOORMAN. That was his number.

Mr. DIGENOVA. I thought he said 5 percent. I apologize if it is 20 percent.

Mr. MOORMAN. And the average whistleblower award in *qui tam* cases is 16 percent, Senator.

Senator CRAIG. Does that include attorneys' fees—total award?

Mr. MOORMAN. No. That is the whistleblower's average share of the judgement. Also, some attorneys' fees are awarded in addition to the relater's share, but that is usually a much smaller number than what the relaters get.

Senator CRAIG. Mr. Charrow, do you wish to comment?

Mr. CHARROW. I think the name of the game for the relator is getting the Department of Justice to intervene. The unfortunate aspect of the process is that frequently, it drags on in some cases for up to 2 or 3 years. There are *qui tam* cases still under seal where no decision has been made by the Department of Justice, and those cases have been going on for 2 or 3 years in the health care area.

Mr. MOORMAN. I agree with Mr. Charrow that sometimes the investigations take far too long.

I would say with regard to the resources that whistleblowers put into these cases, it is a very inconsistent thing. Sometimes the Justice Department encourages the whistleblowers to participate very actively in the case, and they put a lot of work into it. Sometimes the Justice Department does not want the whistleblower's attorney to put much effort into it, and they do not put much into it. But many whistleblowers and their attorneys spend a huge amount of money to pursue these cases. So it is not at all a question of just turning the cases over to the Government, sir.

Senator CRAIG. Well, gentlemen, we thank you very much for your time here today and your testimony.

The chairman intends to leave the record open for 2 weeks for additional information and for questions that we may wish to submit to you for additional comment.

Your testimony has been extremely valuable today as we sort through all of this. I think that clearly, the intent of Congress and our Government is to provide a health care system that functions

and functions well, certainly for the recipient of it but also for those who are the providers of it.

I have been on both sides of this for a good many years in the sense that I once tried to read Government regulations, and I oftentimes found out that they were very difficult to read, and now, in this area, I understand, of course, that they are phenomenally complicated. So there does have to be a balance here, and we have to try to strike that in doing so. At the same time, shame on us if we provide a system that allows an effort to defraud to do just that and to take valuable tax dollars away from the citizens who might otherwise be delivered health care because of it.

That is clearly the intent of this committee and our efforts as we review these, as we know that we are moving toward a time when there could well be a comprehensive overview of Medicare and working with the new administration as they try to reshape the new HCFA and the new CMS.

Thank you all very much for being with us today.

The committee will stand adjourned.

[Whereupon, at 12:27 p.m., the committee was adjourned.]

APPENDIX

Answers for the Record
In Response to Questions from Senator Larry Craig
From the
Senate Special Committee on Aging Hearing
on
Medicare Enforcement Actions: The Federal Government's Anti-Fraud Efforts
July 26, 2001

Q1: What are the most serious problems within the current regulatory and enforcement system involving CMS, Office of the Inspector General, and Department of Justice? What specific recommendations, with respect to each of these agencies, does CMS propose to address these problems?

A: One of the greatest challenges facing the Centers for Medicare & Medicaid Services (CMS) within the current regulatory and enforcement system is the perception among physicians and other providers that past efforts to protect and preserve the Medicare Trust Funds unfairly targeted honest providers for making honest mistakes and errors. I am committed to addressing this and know that the vast majority of providers are honest and law-abiding individuals who want nothing more than to provide the best care possible to their Medicare patients. I firmly believe that no provider should be targeted or prosecuted for an innocent billing mistake.

I am committed to working with our law enforcement partners to ensure that our enforcement activities are sharply focused on the bad actors that are knowingly -- and with intent -- seeking to defraud the Medicare program, and not on honest providers. I am taking steps to improve the way the Agency communicates with providers. We need to make sure our rules are clear and sensible and we need to make sure that providers understand them so they can bill the program correctly in the first place. We also are working with our contractors, who provide a great deal of educational information to providers, to ensure that they are correctly and appropriately sharing information. Finally, I am committed to bringing a culture of responsiveness to CMS. I have initiated a new "open-door" policy and have created health care sector working groups, led by senior-level CMS staff, that will serve as important avenues for providers to ask questions, share their concerns, and receive straight answers from the Agency.

Q2: What steps can CMS take to enhance the effectiveness and efficiency of investigative collaborations between CMS, OIG, and DoJ in cases of alleged fraud?

A: We are committed to working with OIG and DOJ to improve the effectiveness and efficiency of our collaborative efforts. We have taken several steps to open the lines of communication with our law enforcement partners. For example, we regularly attend and participate in meetings with the national health care fraud and managed care fraud workgroups. We also participate in senior level interagency meetings and maintain ongoing staff liaison relationships with DOJ and OIG.

In addition, we are working to encourage cooperative relationships and ensure consistency in communications between law enforcement field offices and the contractors. Many contractors hold regional and local health care fraud task force meetings, monthly conference calls to discuss pending cases or potential referrals, and many have daily informal contacts with law enforcement. These open lines of communication allow contractors and law enforcement personnel to learn from each other and help ensure that investigations are focused appropriately on the most egregious of providers. We also are proactively educating law enforcement on complex Medicare coverage and payment issues in order to enhance their case development and ensure that the targets of their investigations warrant increased scrutiny.

Q3: According to a recent GAO report, roughly half of the claims appealed by providers are resolved in favor of the provider. Providers say the percentage is higher when appeals are heard before an Administrative Law Judge (ALJ). What can be done to increase the accuracy of CMS's determinations prior to an administrative appeals hearing?

A: Medicare processes approximately one billion claims each year from over one million Medicare providers. Our goal is to pay every claim appropriately, every time. Today, ninety-five percent of clean claims submitted to Medicare are automatically processed and paid without a human ever looking at them. Given the volume of claims we process, there are bound to be some errors, and there is always room for improvement. I certainly understand your concern and agree that providers should not have to go through the hassle and the expense of appealing determinations that were wrong in the first place. I am committed to reducing these errors and working to ensure that our initial payment determinations are as accurate as possible.

It is critical to keep several factors in mind, when considering the substantial percentage of appeals that ultimately are resolved in favor of the provider. First, the number of appealed claims represents only a very small proportion, about 3.5 percent, of Medicare claims denials. For example, we process about 740 million Part B claims each year and only about 200,000 are appealed to an Administrative Law Judge (ALJ). The overturn rate may even demonstrate that the system is working to catch and correct errors. Second, at the fair hearing level and the ALJ level, providers frequently introduce additional documentation, which supports payment of the claim that was not presented during the contractor's initial determination to deny payment. We currently are examining legislative and regulatory changes to require full and early presentation of this type of evidence. This type of change should help reduce the number of incorrect payment denials at the outset.

As you indicate, there is a relatively high reversal rate at the ALJ level. The ALJs reverse (in whole or in part) about 50 percent of the claims denials, made at the Medicare contractor level, that are appealed. The high reversal rate at the ALJ level is likely due to the fact that contractors and ALJs use different criteria when ruling on coverage and payment matters. In making determinations, the ALJs are bound <u>only</u> by statute,

regulations, and national coverage determinations. In contrast, when our contractors make decisions, they are bound by statute, regulations, and national coverage determinations, as well as CMS manual instructions and local medical review policies. Therefore, if an ALJ disagrees with, or simply is unaware of manual instructions or local medical review policies, their ruling could easily differ from the contractor's initial decision. There also are other factors that contribute to the frequent differences between contractors' decisions and ALJ rulings. For example, CMS does not have "party" status at ALJ hearings and is precluded from routinely defending its payment decisions before ALJs. Also, ALJs are relatively unfamiliar with Medicare policy and issues. In addition, there is no systematic dissemination of ALJ decisions on Medicare cases and the decisions generally lack precedential value.

There are several administrative actions we are considering for improving the current situation. We are working to improve and expand the notices that our contractors give providers when their claims are denied, so that they include a more thorough explanation of why a particular claim is being denied. We believe that this additional information will improve providers' understanding of the contractor's reasoning and may ultimately reduce the likelihood of a provider appealing a decision because they understand more fully why the denial was made in the first place. In addition, as I mentioned above, we are exploring the possibility of requiring providers to provide claims documentation in support of their position earlier in the process. This should help cut down the number of appeals reversals and result in more consistent decisions between our contractors and the ALJs.

Q4: Providers have voiced concerns about the current Medicare practice of withholding a provider's future Medicare payments as recovery of alleged overpayments, even while those alleged overpayments are being appealed. In light of the current high rate at which Medicare contractor overpayment determinations are reversed on appeal at the ALJ level, are there any CMS plans to change this practice administratively?

A: I certainly understand your concern and that of providers regarding the withholding of future Medicare payments from providers when an overpayment is discovered. I agree with some of the concerns expressed by providers on this matter and I am prepared to work with Congress on possible legislative alternatives. Current law, however, requires CMS to immediately collect overpayments from providers once an overpayment has been determined, even if the provider decides to appeal, but I do share providers' concerns and welcome your legislative suggestions.

Answer for the Record
In Response to a Question from Senator Susan Collins
From the
Senate Special Committee on Aging Hearing
on
Medicare Enforcement Actions: The Federal Government's Anti-Fraud Efforts
July 26, 2001

Q: I want to commend you for the initiatives that you and Secretary Thompson are undertaking to make the Centers for Medicare & Medicaid Services more efficient and streamlined for providers.

One area that has been of particular concern to me has been the burdensome and excessive paperwork requirements imposed on home health nurses, which has greatly detracted from their ability to provide quality care to their patients. In fact, I am told that the actual amount of time that a nurse provides medical care during an average home health visit is approximately 45 minutes, only 30 percent of the average 2.5 hours of a nurse's time during the admission visit. According to Price Waterhouse Cooper, every hour of patient care time requires 48 minutes of paperwork time for hospital-owned home health agencies.

I recently joined with my colleague Russ Feingold in introducing legislation, the Home Health Nurse and Patient Act of 2001, S.1169, which would significantly alleviate the burdens that the Outcomes and Assessment Information Set (OASIS), the claims process for patients who are enrolled in both Medicare and Medicaid, and certain audit and medical review processes have had on home health providers. For example, we believe that OASIS can be simplified by reducing the number of questions per assessment and the number of assessments per 60-day episode of care without compromising quality of care for patients. In addition, the bill makes optional the requirement to collect OASIS data from non-Medicare/Medicaid patients because private insurance typically requires separate patient assessments that are more appropriate for that patient population. A more streamlined and effective OASIS regulation would not only alleviate the burden on nurses, but would abbreviate the time that patients, who are often weak from surgery or other medical treatments, must spend answering numerous questions, many of which are not clinically significant.

It is my understanding that many of the provisions of our bill could be implemented administratively. Has CMS taken a look at these issues? Is this something that you would be willing to work on with our staffs?

A: I share your concern about the need to reduce the amount of paperwork home health agencies are required to complete. I am committed to reviewing and simplifying Medicare's assessment instruments, including the Outcome Assessment and Information Set (OASIS). We are currently evaluating the extent to which the volume of items

required by OASIS, and the frequency with which they must be completed, are truly necessary; and we are convening a Technical Expert Panel to examine administrative options for simplifying OASIS. In addition, we are currently reviewing your legislation, S. 1169, the Home Health Nurse and Patient Act of 2001. We appreciate your invitation and welcome the opportunity to work with you and your staff in seeking positive solutions. And I am confident that we can arrive at a solution that provides the information we need to continue upholding the highest standards of care for our beneficiaries while also reducing unnecessary paperwork burdens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

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AUG 13 2001

The Honorable John Breaux
Chairman, Special Committee on Aging
United States Senate
Washington D.C. 20510

Dear Mr. Chairman:

This is in response to your letter of August 1, 2001, co-signed by the Honorable Larry Craig, requesting answers to several questions as a follow-up to the hearing held by the Senate Special Committee on Aging on July 26, 2001. This information was requested in order to complete the Committee Record. An identical letter is being sent to Senator Craig.

How many providers have had Corporate Integrity Agreements ("CIAs") or Civil Monetary Penalties ("CMPs") imposed by the OIG in the past ten years?

The OIG's records indicate that, in the context of settling cases under the False Claims Act ("FCA") and Civil Monetary Penalties Law ("CMPL"), the OIG has executed approximately 750 agreements with health care providers which either (1) contain specific integrity provisions, or (2) constitute separate CIAs.

With respect the OIG's imposition of civil monetary penalties, it may be helpful if we provide some background information. The CMPL, 42 U.S.C. § 1320a-7a, was enacted as an administrative alternative to criminal prosecution or initiation of a False Claims Act action. Under this authority, the OIG may impose a CMP, assessment, and program exclusion in cases involving the submission of false or fraudulent claims to a Federal health care program. The OIG is authorized to act under the CMPL only in fraud cases where the Department of Justice (DOJ) declines to initiate a criminal or civil FCA case.

We are only able to provide you with information about the OIG's fraud-based CMP cases from October 1996 to the present. Prior to October 1996, the OIG's records combined data on cases under the FCA and CMPL. Thus, we are unable to separate out

the number of individuals and entities subject to an OIG CMP action prior to FY 1997. Records maintained by the OIG Office of Investigations indicate that from October 1, 1996 to July 31, 2001, the OIG resolved 34 fraud-related CMP actions.

The American Hospital Association in its written testimony states that the government's initiatives on outpatient laboratory billings and pneumonia billings were not legal actions brought on clear grounds of fraud. How do you respond to that?

As noted on page 2 of our written testimony, health care providers are not subject to criminal or civil penalties for innocent errors, or even negligence. The primary civil enforcement remedies (the FCA and the CMPL) cover only offenses that are committed with *actual knowledge* of the falsity of the claim, or *reckless disregard or deliberate ignorance* of the falsity of the claim. These statutes do not sanction mistakes, errors, or negligence. For criminal penalties to be imposed, the legal standard is even higher, i.e., criminal intent to defraud must be proved beyond a reasonable doubt. Thus, our enforcement efforts have focused on health care providers who have clearly violated the law; not cases of honest mistakes or billing disputes.

The OIG coordinates its efforts to protect the integrity of the Medicare program with the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Investigation, and DOJ. These Federal agencies have responded to identified and widespread patterns of Medicare fraud by establishing national projects. The national projects target a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers. There are multiple objectives for each of the national projects, including obtaining restitution to the Medicare program, protecting program beneficiaries and ensuring the provision of quality care, sanctioning providers who have submitted false claims with knowledge of their falsity, and imposing appropriate integrity measures to deter future misconduct.

You inquired about two national projects, i.e., those addressing hospital upcoding of Medicare claims for treating patients with pneumonia and hospital outpatient laboratory billing. With respect to both of these national projects, we believe that a strong legal basis exists for pursuing these types of false or fraudulent claims.

The pneumonia upcoding national project is based on a determination that in many instances hospitals misrepresented patients' medical conditions as more complex by claiming a higher code in order to receive greater Medicare payments. Medical expert review of hospital claims for treating pneumonia cases revealed significant over-

utilization of higher codes in order to receive enhanced Medicare payments. As was noted in my oral testimony, in one case a hospital used the higher reimbursed code for pneumonia treatment in 93.5% of its claims, as compared to a national average of 2.4%.

The hospital outpatient laboratory billing national project was based on findings that multiple automated laboratory tests were performed simultaneously with one piece of equipment, but were billed as if they were performed separately. The result was that hospitals received more Medicare reimbursement than they were entitled to.

The pursuit of specific cases under these national projects is assessed under criteria established by both the OIG and the DOJ. Attached are copies of the guidance issued by both the OIG and DOJ with respect to the handling of national project cases. Again, cases are pursued under these guidelines only where there is evidence of fraud. In cases where there is evidence of improper Medicare claims that do not amount to fraud, referrals are made to CMS for potential collection of overpayments.

How do you address the AHA's concern that CIAs are imposed when hospitals voluntarily disclose overpayments and lack intentional fraud?

CIAs are only developed for cases where there is clear evidence of fraud. As outlined in our written testimony (pages 7-10), CIAs are developed and used by the OIG to give a "second chance" to providers who have been determined to have committed fraud.

To ensure the integrity of the Medicare program, the OIG implements the Secretary's authority to exclude wrongdoers from participation in Federal health care programs. Thus, in cases where individuals or entities are found to have engaged in fraud or abuse, the OIG must determine whether a program exclusion is warranted to protect the Federal health care programs and beneficiaries from future wrongdoing. In the context of settling civil False Claims Act cases in conjunction with the DOJ, the OIG has adopted certain criteria for deciding whether to exclude a provider determined to have committed fraud, or alternatively, allow them to continue to participate in Federal health care programs. In appropriate cases, the OIG will offer to waive a program exclusion in exchange for the provider entering into a CIA. Such an agreement, typically in effect for between three and five years, requires a provider to institute or maintain a series of internal controls to ensure future compliance with program requirements and protection of both the Medicare program and its beneficiaries.

Typically, a CIA is voluntarily negotiated and agreed to in settling a potential exclusion action as part of a "global settlement" including FCA liability. In cases of mistake or

error that may be voluntarily disclosed by providers who seek to resolve Medicare overpayments through contacting CMS and its contractors directly, CIAs are not a part of the process.

The OIG's annual report filed jointly with DOJ, dated January 2001 (Report Title: HHS and DOJ Health Fraud and Abuse Program - Annual Report for FY 2000), specifically cites that over $717 million were recovered under the categories of "Fraud and Abuse." What percentage of the total sum recovered falls under the category of "Fraud," and what percentage falls under the category of "Abuse"?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a Health Care Fraud and Abuse Control Program, under the direction of the Attorney General and Secretary of HHS (acting through the Inspector General), to coordinate Federal, state and local law enforcement activities with respect to health care fraud and abuse. For each fiscal year (FY), as required by law, a report is submitted to Congress detailing activities, recoveries, and disbursements under the Program. The report for FY 2000 summarized:

> In 2000, the Federal government won or negotiated more than $1.2 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the federal government in 2000 collected $717 million. More than $577 million of the funds collected and disbursed in 2000 were returned to the Medicare Trust Fund. An additional $27 million was recovered as the federal share of Medicaid restitution.

Annual Report of the Departments of Health and Human Services and Justice, Health Care Fraud and Abuse Control Program FY 2000, Page one.

The Report further specifies under various categories, as provided for in the law, the amounts that were obtained or recovered under the program in FY 2000, and states that, "as a result of the combined anti-fraud actions of the federal and state governments and others, the federal government collected $717 million in connection with health care fraud cases and matters." Page 5. The Fraud and Abuse Control Program does not distinguish between "Fraud" and "Abuse" in tracking recoveries or maintaining data related to the resolution of cases. However, the vast majority of the monies recovered are the result of cases brought under the civil False Claims Act, which is considered a "fraud" remedy.

Does the $717 million recovery figure include monetary sums in dispute (including overpayments recovered or future payments withheld) that are still pending administrative appeal? If so, what is the actual monetary sum of overpayments recovered, and future payments withheld, and future payments withheld, that are not in dispute?

To the best of our knowledge, the $717 million in reported recoveries does not include monetary sums in dispute that are still pending administrative appeal.

What are the OIG's recommendations to enhance the effectiveness of investigative collaborations between CMS, OIG and DOJ in cases of alleged fraud?

It essential that there be close coordination between all health care payer and enforcement agencies with respect to addressing fraud and abuse. As noted in the testimony of the Acting Assistant Attorney General Stuart E. Schiffer at the hearing on July 26, 2001, consistent with the objectives of HIPAA, a number of task forces and committees have been established between Federal and state agencies aimed at improving coordination and communication with respect to health care fraud enforcement activities. See pages 3-6. We believe that the collaboration between Federal and State agencies should continue and be enhanced in the future.

In addition, we believe that the establishment of the Medicare Integrity Program (MIP) in HIPAA, and the advent of Program Safeguard Contractors (PSCs), provides CMS with the opportunity to more effectively target resources at program integrity issues. As noted by the General Accounting Office in its testimony, "MIP saved the Medicare program more than $16 for each dollar spent in fiscal year 2000." (Page 4) However, the effectiveness of MIP can be enhanced by increased communications and coordination between CMS and its PSCs. In addition, the OIG is committed to working with the PSCs to identify vulnerabilities in the Medicare program and develop ways to address them.

Finally, we would note that CMS currently operates under significant statutory limitations with respect selection, payment, and retention of Medicare claims processing contractors. We believe that the current law restricting the selection, payment, responsibilities, evaluation, and termination of Medicare contractors is outdated and needs to be changed. It is our view that

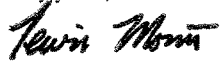
> CMS needs to be given greater flexibility in the methods it uses to select, organize and supervise the contractors who handle the day-to-day operations of the Medicare program. This includes authorities to use entities other than insurance

> companies, select them competitively, pay them on other than a cost basis, organize them according to functions or benefit area, and hold them accountable for performance.

Testimony of Acting Inspector General Michael Mangano before the Subcommittee on Oversight and Investigations and Subcommittee on Health, House Energy and Commerce Committee, June 28, 2001.

We hope that the information provided above is responsive to your questions. If you desire any further information, please contact either Helen Albert or Marcia Sayer in the OIG Office of External Affairs at (202) 260-8610.

Sincerely yours,



Lewis Morris
Assistant Inspector General for Legal Affairs

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date JUN - 3 1998

From /s/ June G. Brown
June Gibbs Brown
Inspector General

Subject National Project Protocols - Best Practice Guidelines

To Deputy Inspector General for Investigations
Deputy Inspector General for Audit Services
Assistant Inspector General for Legal Affairs

BACKGROUND

With increasing frequency, the Office of Inspector General (OIG) has coordinated with other agencies on so-called "national projects" aimed at targeting widespread patterns of misconduct among Medicare and Medicaid providers. At this time, I have decided to memorialize recommendations for "best practice" guidelines to be used by the OIG when developing and participating in national enforcement projects. These guidelines are generally applicable to national projects, but not every guideline listed below will necessarily be appropriate for all future enforcement initiatives. However, in the future, any deviation from these guidelines must be approved in advance by the Deputy Inspector General for Investigations in consultation with other components of the OIG, such as the Office of Counsel or Office of Audit Services, as appropriate.[1]

GUIDELINES

1. **Minimum Thresholds**

After considering and reviewing the statutes, regulations and Medicare and/or Medicaid program guidelines, as well as the applicable provider data, the OIG will set an appropriate minimum monetary threshold and/or percentage error rate for its participation in each national project. This minimum threshold will be used as a guideline for determining which health care providers the OIG will initially refer to the appropriate contractor (carrier or fiscal intermediary) for an overpayment recoupment (if any). Cases involving providers which exceed the project's threshold may be developed for potential referral to the Department of Justice (DOJ) or other appropriate enforcement agency (e.g., the Federal Bureau of Investigation) for consideration under

[1] Note: These Guidelines are for internal OIG use only. They are not intended to impinge on the exercise of legal authorities which are the responsibility of other agencies, nor do they confer rights in favor of any party.

a civil or criminal authority. Obviously, this minimum threshold will vary from project to project and will be based on a number of factors such as Medicare and/or Medicaid revenues, total health care revenues, prior audits and notice to the provider community, provider size, number of erroneous claims, and overpayment liability.

2. **Equitable Treatment of Providers**

The OIG supports the equitable treatment of providers in national projects, consistent with the prerogatives vested in the various United States Attorneys. Investigative protocols and settlement agreement terms should be consistently applied to minimize variations among judicial districts. Further, compliance or corporate integrity provisions should be uniform and consistently applied to providers targeted in a national project. It may be appropriate to establish a gradation of compliance measures based on objective criteria, such as the size of the provider and scope of the misconduct. If a matter is handled through means involving a criminal conviction or civil penalty, the OIG will develop and require appropriate and measured compliance obligations. Generally, when a matter is referred by the OIG to the contractors for an overpayment recoupment, no compliance obligations will be imposed by the OIG.

3. **Resource Allocation Considerations**

Prior to the referral of a national enforcement initiative to the DOJ or any other law enforcement agency, the OIG will undertake an assessment of the available investigative resources that it can commit to the national project. The OIG will communicate the results of this assessment to other involved law enforcement agencies with the referral of the national project information and data. The purpose of this assessment is to provide notice to our law enforcement partners of the resources the OIG is able to commit to an initiative.

4. **Provider Guidance and Communication**

Prior to the formal initiation of a national project, and as appropriate, the OIG will provide information to representatives of the affected health care industry or provider community regarding the project. This prior contact with the provider community will only occur with the concurrence of all appropriate law enforcement agencies. Similarly, the OIG will seek input from the Health Care Financing Administration regarding its views on the proposed national project in the appropriate circumstances and with the concurrence of all affected law enforcement agencies.

5. **Assess Legal Sufficiency of Theory Prior to Referral to Department of Justice**

Prior to the referral of any data or information concerning the development of a national project, the OIG will assess (including as appropriate, consultation with the Office of the General Counsel) the legal basis and sufficiency supporting the enforcement initiative. In its legal review, the OIG will consider, as necessary, applicable statutes, regulations, program guidance and communications, *de minimus* thresholds, sufficiency and availability of data, case law, statute of limitation issues, appropriate documentation, and burden of proof issues.

6. **Central Point of Contact**

The OIG will designate a central point of contact from each OIG component involved in a national project in order to coordinate responses on important questions or issues related to that project as they may arise. The OIG will inform the DOJ and any other law enforcement agency involved in the national project of these points of contact.

Office of the Deputy Attorney General
Washington, D.C. 20530

June 3, 1998

MEMORANDUM FOR: All United States Attorneys
All First Assistant United States Attorneys
All Civil Health Care Fraud Coordinators in the Offices of United States Attorneys
All Trial Attorneys in the Civil Division, Commercial Litigation Section

FROM: Eric H. Holder, Jr.
Deputy Attorney General

SUBJECT: Guidance on the Use of the False Claims Act in Civil Health Care Matters

One of the Department's most important tools in protecting the integrity of Medicare and other taxpayer-funded health care programs is the civil False Claims Act. While the broad reach and substantial damages and civil penalties under the Act make it one of the Department's most powerful tools, Departmental attorneys are obligated to use their authority under the Act in a fair and responsible manner. This is particularly important in the context of national initiatives, which can have a broad impact on health care providers across the country.

This guidance is being issued to emphasize the importance of pursuing civil False Claims Act cases against health care providers in a fair and even-handed manner, and to implement new procedures with respect to the development and implementation of national initiatives.

1. National Initiatives.

Generally, national initiatives deal with a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers. National initiatives must be handled in a manner (i) that promotes consistent adherence to the Department's policies on enforcement of the False Claims Act, as well as a consistent approach to overarching legal and factual issues, (ii) while avoiding any rigid approach that fails to recognize the particular facts and circumstances of an individual case.

To achieve these objectives, the Department has instituted the following procedures:

(A) Legal and Factual Predicates.

Before alleging violations of the False Claims Act, whether in connection with a national initiative or otherwise, Department attorneys must evaluate whether the provider: (i) submitted false claims to the government, and (ii) submitted false claims (or any false statements made to get the false claims paid) with "knowledge" of their falsity, as defined in the Act. These are separate inquiries. Department attorneys shall not allege a violation of the False Claims Act unless both of these inquiries lead to the conclusion that there is a sufficient legal and factual predicate for proceeding. The following issues, among other issues, shall be considered in these determinations:

(i) Do False Claims Exist?

a. Examine Relevant Statutory and Regulatory Provisions and Interpretive Guidance. Department attorneys shall examine relevant statutory and regulatory provisions, as well as any applicable guidance from the program agency or its agents, to determine whether the claims are false. In certain circumstances, such as when a rule is technical or complex, Department attorneys should communicate with knowledgeable personnel within the program agency (e.g., the Health Care Financing Administration, TRICARE, or Office of Personnel Management) concerning the meaning of the provision.

b. Verify the Data and Other Evidence. Department attorneys shall take appropriate steps to verify the accuracy of data upon which they are relying, either independently, or with the assistance of the fiscal intermediaries and carriers, the Department of Health and Human Services - Office of Inspector General, the Federal Bureau of Investigation, or another investigative agency.

c. Conduct the Necessary Investigative Steps. Department attorneys should conduct such investigative steps as are necessary under the circumstances, including where appropriate, the subpoenaing of documents and the interviewing of witnesses.

(ii) Did the Provider Knowingly Submit the False Claims?

In the event the claims are false, Department attorneys must also evaluate whether the health care provider "knowingly" submitted the false claims or "knowingly" made false statements to get the false claims paid. As set forth above, and before making this determination, Department attorneys should conduct such investigative steps as necessary under the circumstances, including where appropriate the subpoenaing of documents and the interviewing of witnesses. Under the False Claims Act, false claims and false statements are submitted "knowingly" if the provider had actual knowledge of their falsity, or acted with deliberate ignorance or reckless disregard as to their truth or falsity. While relevant factors will vary from case to case and the list below is not intended to be exhaustive, factors that must be considered are:

a. Notice to the Provider. Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?

b. The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?

c. The Pervasiveness and Magnitude of the False Claims. Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?

d. Compliance Plans and Other Steps to Comply with Billing Rules. Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?

e. Past Remedial Efforts. Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?

f. Guidance by the Program Agency or its Agents. Did the provider directly contact either the program agency (e.g., the Health Care Financing Administration) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?

g. Have There Been Prior Audits or other Notice to the Provider of the Same or Similar Billing Practices?

h. Any Other Information That Bears on the Provider's State of Mind in Submitting the False Claims.

(B) Oversight by National Initiative Working Groups.

For all current and future national initiatives, the Attorney General's Advisory Committee (AGAC) and the Civil Division shall establish a working group to coordinate the development and implementation of each initiative.

Working groups will be comprised of Assistant United States Attorneys and Civil Division attorneys with particular expertise in health care fraud. In accordance with the health care guidelines promulgated in January 1997, in appropriate instances each working group may also need to coordinate and plan the initiative with the Department's Criminal Division.

Each working group will (i) examine the initiative to ensure that a factual and legal predicate is present for the initiative prior to its implementation, (ii) prepare initiative-specific guidance and sample documents (such as legal analyses, summaries of audit data, contact letters, tolling agreements, compliance and settlement agreement language) for use in the initiative, and (iii) prepare a general investigative plan, setting forth

suggested investigative steps that each office should undertake prior to proceeding. Working groups shall be responsible for coordination with law enforcement agencies, the Health Care Financing Administration, and other appropriate entities.

While the working groups shall be responsible for coordinating the overall development and implementation of national initiatives, each matter against a specific provider must be evaluated on a case-by-case basis.

(C) Use of Contact Letters in National Initiatives.

As outlined above, Department attorneys participating in national initiatives shall, in general, make initial contacts with health care providers, to resolve a case, through the use of "contact" letters. The purpose of a contact letter is to notify a provider of their potential exposure under the False Claims Act and to offer the provider an opportunity to discuss the matter before a specific demand for payment is made. In limited circumstances, where the specific facts of a situation warrant a different approach, Department attorneys may make an initial contact through other legitimate means.

The use of contact letters to make initial contact with health care providers is in furtherance of Executive Order 12988, which obligates Department attorneys to make a reasonable effort to notify the opposing party about the nature of the allegations, and attempt to resolve the dispute without litigation if at all possible. The type of contact employed will depend on the nature of the allegations and the stage of the investigation. Regardless of the form of initial contact, Department attorneys must ensure that health care providers are afforded: (i) an adequate opportunity to discuss the matter before a demand for settlement is made, and (ii) an adequate time to respond. In addition, Department attorneys shall grant all reasonable requests for extensions of time to the extent that they do not jeopardize the government's claims. The use of statutory tolling agreements are strongly encouraged to allow providers time to respond without jeopardizing the government's claims.

2. Alternative Remedies.

After reviewing the legal and factual circumstances of a particular matter, Department attorneys shall consider other available remedies -- including administrative remedies such as recoupment of overpayments, program exclusions, and civil monetary penalties -- to determine what remedy, or combination of

remedies, would be the most suitable under the circumstances. Should the recoupment of an overpayment be the most appropriate remedy, Department attorneys shall consider referring the matter to the appropriate carrier/fiscal intermediary for appropriate action.

3. Ability to Pay Issues.

Attorneys shall consider any financial constraints identified by a provider in determining a fair, reasonable and feasible settlement between the parties. Hospitals and other health care providers citing an inability to pay a specific settlement amount should be asked to present documentation in support of their stated financial condition.

4. Rural and Community Health Care Provider Concerns -- Impact on Availability of Medical Services.

When dealing with rural and community hospitals and other health care providers, Department attorneys shall consider the impact an action may have on the community being served. In determining an appropriate resolution, or deciding whether to bring an action, care must be taken to consider the community's interest in access to adequate health care along with any other relevant concerns.

5. Hospitals and Other Health Care Providers Not Represented by Counsel.

Department attorneys shall pay special attention to contacts with hospitals and other providers that choose (due to financial constraints or otherwise) to resolve claims without legal representation. Department attorneys faced with this circumstance must carefully assess every action taken to avoid even an appearance of coercion or overreaching because of the absence of opposing counsel.

6. Minimizing Burdens Imposed on Providers During Investigations.

Department attorneys also should be mindful of the ways in which our investigations and audits can disrupt and burden the day-to-day operations of providers in both a financial and practical sense. In developing and implementing an investigative plan, we should do what we can do to minimize these adverse effects, while still meeting our obligation to diligently

investigate allegations of potential fraud. For example, while recognizing that certain circumstances might warrant different approaches, Department attorneys should consider a provider's request to accept the results of an audit of a sample of claims in lieu of a complete audit.

7. **Provider Assistance with the Investigation.**

In determining an appropriate settlement amount, Department attorneys should consider the extent to which a health care provider has cooperated with the audit or investigation of the relevant matter.

8. **Individualized Review.**

The proper determination as to the use and application of the False Claims Act or other appropriate remedy requires an individualized review of each case, ensuring that each of the above factors are given full consideration.

9. **Review of Guidance.**

In order to assure the fair and appropriate application of the False Claims Act, this guidance will be subject to review in six months.

10. **Additional Information.**

Questions regarding use of the False Claims Act should be referred to the Health Care Fraud Coordinator in your district, or to Robert Liles, Health Care Fraud Coordinator for the Executive Office for United States Attorneys (tel. no. 202-616-5136), or Shelley R. Slade, Health Care Fraud Coordinator for the Civil Division (tel. no. 202-307-0264).

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

October 9, 2001

The Honorable John Breaux
Chairman
Special Committee on Aging
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing in response to your correspondence of August 1, 2001, in which you pose additional questions as a follow-up to the testimony of Acting Assistant Attorney General Stuart E. Schiffer before the Senate Special Committee on Aging on July 26, 2001.

Questions from Senator Breaux:

1. **Does the Department of Justice have a Memorandum of Understanding (MOU) with the HHS Office of Inspector General? If so, please provide a copy of and briefly explain the memorandum.**

Answer: The various memoranda of understanding between the Department of Justice and the HHS Office of Inspector General (HHS/OIG) are attached. The 1983 MOU enclosed as Attachment A sets forth our policy that the HHS/OIG may not commence administrative proceedings against a provider until the case has been referred to the Department of Justice and the Department has had the opportunity to consider the merits of the case for potential criminal or civil action.

The 1995 MOU enclosed as Attachment B governs the imposition of civil money penalties ("CMPs") against skilled and other nursing facilities, and provides procedures that balance the needs of the Department to pursue criminal and civil remedies while permitting HHS and the Health Care Financing Administration (now the Centers of Medicare and Medicaid Services ("CMS")) to move swiftly to protect the health and safety of residents. Generally, this MOU requires that CMS provide notice to the Department before

seeking to impose CMPs, with the length of notice dictated by the degree of threat to public health.

In a 1994 MOU, the Department and HHS/OIG agreed on procedures allowing the Department access to information held by Medicare contractors (Attachment C). This MOU permits the Department and its components, including the Federal Bureau of Investigation, to directly request from Medicare contractors information pertinent to on-going investigations. While HHS/OIG approval is not required for such requests, the MOU requires that the HHS/OIG be notified of the requests in order to avoid duplication of investigative efforts.

2. How does the DOJ ensure that the technical assistance provided to AUSAs with regard to health care fraud cases is followed and adhered to?

Answer: The Department engages in extensive internal coordination to ensure that Department guidelines and policies are adhered to. For example, the Counsel to the Deputy Attorney General chairs a bi-weekly Component meeting that includes representatives from the Criminal Division Fraud Section, the Civil Division Commercial Litigation Branch, the FBI, the Executive Office of United States Attorneys - Office of Legal Programs, the Office of Legislative Affairs, the Nursing Home Initiative Coordinator, and the Justice Management Division. At this meeting, policies and actual case matters are discussed. In addition, health care fraud working groups and/or task forces meet in many of the 94 federal districts and are composed of representatives of the United States Attorneys' Offices, FBI, HHS/OIG, DCIS, and state and local officials charged with the task of coordinating health care fraud enforcement efforts.

As Mr. Schiffer indicated in his written testimony, in the past 18 months the Department's Office of Legal Education conducted 8 training courses related to health care fraud and use of the False Claims Act and trained over 600 Assistant United States Attorneys, Department trial attorneys, and auditors/investigators. This training takes place primarily at the Department's National Advocacy Center in Columbia, South Carolina, and includes lessons gleaned from past experiences in health care fraud cases and the types of allegations that are coming to the forefront.

In addition, the Deputy Attorney General on June 3, 1998, issued formal guidance to the United States Attorney community that memorialized existing policies requiring allegations of False Claims Act liability to be based on an adequate factual and legal

predicate, and instituted new procedures for "national projects," including coordination and oversight by working groups, and the use of "contact letters" that offer health care providers an opportunity to discuss the government's allegations before a demand for payment is made. This guidance was updated on February 3, 1999. These guidelines are enclosed as Attachments D and E, respectively.

The General Accounting Office ("GAO") has reported to Congress regularly on the compliance by the United States Attorney community with the Deputy's guidelines. In its most recent report to Congress in March, 2001, GAO specifically found that the Department has an evaluation process that provides meaningful assessment of compliance with the guidance, that United States Attorneys' Offices certify compliance with the guidance, and that interaction with the hospitals under investigation was consistent with the guidance. GAO found also that the Department has taken substantive steps to strengthen oversight of compliance with the guidance and that the two most recent national initiatives (PPS Transfer and the Pneumonia Upcoding projects) are being handled in a manner consistent with the guidance. GAO concluded that the Department "has demonstrated its continued commitment to promoting the importance of compliance with the False Claims Act guidance at its U.S. Attorneys' Offices."

3. **Are there reasons why, even if the case has merit, that the DOJ would not pursue it, thereby making it appropriate for HHS-OIG to pursue?**

Answer: There are reasons for such a result. In some instances, the HHS/OIG may have statutes better suited to redress the conduct at issue. For example, providers who conceal records from Medicare fiscal intermediaries but otherwise submit truthful claims seeking payment from the United States are subject to administrative sanctions for that action. While application of the False Claims Act in those circumstances may not be appropriate, it is nevertheless conduct that merits administrative review.

Many of the civil health care fraud allegations brought to the Department of Justice originate from so-called "qui tam," or whistleblower, suits filed under the False Claims Act. 31 U.S.C. §§ 3729-3733. The provisions of the Act permit the Department 60 days to investigate the allegations and make a decision to intervene, or take over, the whistleblower's suit. 31 U.S.C. § 3730(b)(2). Although the Department often is successful in obtaining court approval to extend this 60-day investigative period, courts increasingly are reluctant to grant extended time

to permit a thorough investigation of what often proves to be complex allegations. Accordingly, there are times when the Department is unable to timely perform the necessary initial investigation that would warrant intervention. On those occasions, the Department may well decline to intervene and the HHS/OIG may then elect to pursue administrative sanctions if the allegations have merit.

In other instances, the various investigative agencies that ordinarily would assist us in confirming allegations may lack sufficient resources to devote to a given case. This may be due to any number of factors independent of the merits, including the demands of other investigations or the geographic location of the target of the investigation. In those instances, the Department likely will be unable to ascertain whether the allegations have merit and may well defer to the HHS/OIG for administrative sanctions.

Lastly, the workload of the Assistant United States Attorneys and the Department's trial attorneys may require that other matters receive priority over particular allegations, and cause the attorneys to conclude that referral to the HHS/OIG for administrative sanctions is the most efficient use of government resources.

4. What is DOJ's response to so called "horror stories" of overzealous enforcement actions and improper use of the False Claims Act.

Answer: It is our understanding that in testimony before your Committee on July 26, representatives of the health care provider community did not make such allegations against the Department. The so-called "horror stories" now under investigation by the GAO and referenced in that hearing involve entities other than the Department of Justice, or so we have been advised by GAO. Further, as I indicated, the Department's enforcement activities have been closely scrutinized by the GAO which recently praised our efforts at promoting the importance of compliance with the False Claims Act guidance to the United States Attorney community.

5. Should health care providers be given direct access to the courts during the appeals process without first exhausting all administrative remedies available to them first?

Answer: The Department has very serious concerns with such a proposal, which threatens to involve already overburdened Federal courts in prematurely resolving controversies that, under

current law, could and in many instances would, be resolved at the administrative level. Given the enormous volume of Medicare claims, the potential increase in the courts' civil caseload would be significant. And, even for those cases not conclusively resolved at the administrative level, eliminating the exhaustion requirement would deprive the courts of a complete administrative record for the court to review in assessing the validity of the agency action that is the subject of the appeal, and would impair the courts' ability to utilize agency expertise in interpreting and applying the complex Medicare statute, regulations and published regulatory guidance in the context of specific disputes. This would result in many more lengthy and resource-intensive de novo proceedings in federal court.

Current law (*see* 42 U.S.C. §§ 405, 1395cc, 1395ii) prevents "overly casual or premature judicial intervention in an administrative system that processes millions [now, perhaps billions] of claims every year." Heckler v. Ringer, 466 U.S. 602, 627 (1984). This "channeling" of claims through the agency "assures the agency greater opportunity to apply, interpret, or revise, policies, regulations, or statute without possibly premature interference by different individual courts," Shalala v. Illinois Council on Long Term Care, 529 U.S. 1, 13 (2000). It is for these reasons that Congress has required exhaustion of administrative remedies under Medicare and why courts generally require exhaustion of administrative remedies even in the absence of express statutory requirements such as those contained in the Medicare Act.

I suggest that the resources necessary for the Department of Justice and the Judicial Branch to handle the increased burden that would stem from eliminating Medicare's exhaustion requirement as to providers would be vast and unwarranted. Furthermore, the required resources would be better devoted to the administrative process and systems at HHS.

6. How many hospitals have had criminal or civil settlements or judgments imposed in the past ten years by DOJ?

Answer: Department data bases do not differentiate among provider types when storing our case information. Hence, I am unable to respond more fully to the precise question you pose. Instead, I refer you to the various reports we have submitted to Congress in the past several years that detail our health care fraud enforcement activities. The most recent reports include The Health Care Fraud and Abuse Control Programs Report for fiscal years 1998, 1999, and 2000, and the Health Care Fraud Reports for fiscal years 1997 and 1998. These reports are available on our web page, but I will be glad to provide

your staff with copies if they are unable to access them.

Question from Senator Craig, Ranking Member

1. **Does DOJ have agency guidelines governing searches and seizures involving physicians' offices and hospitals, in criminal cases?**

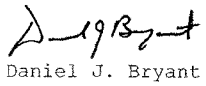
Answer: The Department is well aware of the sensitivity of conducting searches and seizures at physician offices and hospitals in criminal cases. The Department expects its employees to conduct such searches professionally and in a manner which minimizes the adverse impacts on patient care and on individuals present at the search location, consistent with the legitimate needs of the search and the safety of the law enforcement officers conducting the search.

The Department's "Guidelines on Methods of Obtaining Documentary Materials Held by Third Parties," published at 28 C.F.R. Part 59, includes specific guidelines which apply to searches for confidential patient information ". . . in the private possession of a disinterested third-party physician," and articulate the criteria which must be satisfied to obtain the necessary approval to seize such evidence. The Department's "Guidelines" also include general guidelines for planning and executing search warrants which apply equally to all searches of "disinterested third-parties," including those at physician offices and hospitals. In addition, the FBI has extensive general guidelines on planning and conducting all searches, which may be found in the FBI's "Legal Handbook for Special Agents" and in the FBI's "Manual of Investigative Operational Guidelines." Standard procedure requires that FBI agents prepare individual search plans, which can tailor the execution of each search to the unique circumstances present. All search plans are subject to supervisory review.

* * *

I hope that this information is responsive to your inquiry. Please contact us if you would like further information.

Sincerely,



Daniel J. Bryant
Assistant Attorney General

MEMORANDUM OF UNDERSTANDING BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE DEPARTMENT OF JUSTICE
REGARDING IMPLEMENTATION OF
SECTION 1128A OF THE SOCIAL SECURITY ACT

I. DEFINITIONS

For purposes of this memorandum:

1. "Attorney General" means the Attorney General of the United States, or his designee;

2. "Secretary" means the Secretary of the Department of Health and Human Services, or his designee;

3. "Department of Justice" means the United States Department of Justice or an Office of a United States Attorney;

4. "United States Attorney" means the United States Attorney who has jurisdiction of a case;

5. "Civil Division" means the Assistant Attorney General of the Civil Division of the Department of Justice, or any of his subordinates authorized to consider referrals under this memorandum;

6. "Criminal Division" means the Assistant Attorney General of the Criminal Division of the Department of Justice, or any of his subordinates authorized to consider referrals under this memorandum;

7. "administrative proceeding" means the procedure specified in section 1128A of the Social Security Act, and regulations promulgated thereunder, whereby the Secretary may assess a monetary penalty for the filing of a false claim;

8. "total assessment" means the total potential amount of a penalty which may be levied against a person in an administrative proceeding, including the amount of any fines and any amount permitted by law in lieu of damages; and

9. "the delegated authority of the United States Attorney" means the amount specified by the Attorney General, below which the merits of a case may be considered by the appropriate United States Attorney.

II. AUTHORIZATION PROCEDURES

A. IN GENERAL

The Secretary may not commence an administrative proceeding in any case until he has notified the Department of Justice of his intent, he has referred the case to the Department

ATTACHMENT A

of Justice, and the Department of Justice has had an opportunity to consider the merits of the case, in accordance with procedures set forth herein.

B. CASES IN WHICH THE TOTAL ASSESSMENT WOULD BE WITHIN THE DELEGATED AUTHORITY OF THE UNITED STATES ATTORNEY

The Secretary may not commence an administrative proceeding until the case has been referred to the United States Attorney and:

1. The United States Attorney declines both civil and criminal prosecution; or

2. The United States Attorney authorizes the Secretary to do so.

C. CASES IN WHICH THE TOTAL ASSESSMENT WOULD EXCEED THE DELEGATED AUTHORITY OF THE UNITED STATES ATTORNEY

The Secretary may not commence an administrative proceeding until:

1.(a) The case has been referred to the United States Attorney for criminal prosecution and (i) prosecution has been declined, or (ii) if prosecution has been accepted, all criminal processes have been completed; and

(b) (i) The case has been referred to the Civil Division for civil action, and civil action has been declined, or (ii) the Civil Division has been notified of the Secretary's intention to begin administrative proceedings, and the time period specified in section III.A. has expired;

or

2. The case has been referred under the two preceding paragraphs and both the United States Attorney and the Civil Division authorize the Secretary to commence an administrative proceeding.

III. MISCELLANEOUS PROVISIONS

A. TIME PERIOD FOR CONSIDERATION

The Civil Division will respond to notices of intention to proceed with administrative proceedings within 60 days of the date of receipt of a case under section II.C.1.(b)(ii). The Civil Division will send an acknowledgment to the

ary at the time each case is received. In any case criminal prosecution has been declined, or regarding criminal processing is complete, the Department may ice an administrative proceeding if: (1) the Secretary des the Civil Division a second notice of his intent oceed administratively 20 days in advance of the ation of the 60 day period; and (2) the Civil Division to notify the Secretary within the 60 day period of intent to proceed with civil litigation.

RECONSIDERATION

1. The Secretary shall have a continuing duty to revise and supplement the information furnished in a case referred pursuant to sections II.B. and II.C., upon discovery of any new information material to the case. The following information shall be deemed material: the addition of another person or persons as potential respondent(s) in the anticipated administrative proceeding; or the possibility of bribery, gratuities, conflict of interest, or other corruption or similar activity on the part of any officer, employee, or agent of the United States or any State.

2. Upon submission to the Secretary of a written determination by the Attorney General that the continuation of an administrative proceeding may adversely affect any pending or potential criminal judicial proceeding relating thereto, such administrative proceeding shall be immediately stayed and may be recommenced only upon written authoriza ion of the Attorney General.

C. EXPEDITED CONSIDERATION

If it appears to the Secretary that any circumstance compels expedited consideration of a referral, he may request authorization orally. Upon oral authorization by the Attorney General, the Secretary may immediately commence an administrative proceeding; in such instances, the Secretary shall provide relevant information pertaining to the case in writing to the Department of Justice within 10 days of the oral authorization.

D. CONTENT OF REFERRAL TO THE DEPARTMENT OF JUSTICE

The referral to the United States Attorney and the Civil Division (or, where applicable, to the Criminal Division) should be in writing and include the following information: name of all potential defendants including

business entities, amount of potential monetary loss, identity of Federal program or operation involved, description of fraudulent activity, identity and status of any pending criminal or civil investigation or litigation involving the same or related persons or entities, outline of any evidence or suspicion of corruption of a public official, date of claim, and any other data which would affect the Department of Justice decision to proceed criminally or civilly in district court.

E. REFERRALS TO THE CRIMINAL DIVISION

Nothing in this memorandum shall prevent the Secretary from referring a case for consideration of criminal prosecution to the Criminal Division rather than to the United States Attorney. Where a case is referred under this paragraph to the Criminal Division, the Criminal Division shall carry out the responsibilities of the United States Attorney, regarding consideration of criminal prosecution, which are described in paragraph B or paragraph C of section II.

F. REVIEW OF MEMORANDUM

The General Counsel and Inspector General of the Department of Health and Human Services will meet once a year with the Assistant Attorneys General of the Civil and Criminal Divisions to evaluate the effectiveness of the operations of the memorandum and any need for modifications.

J. Paul McGrath
Assistant Attorney General
Civil Division

2/2/83
Date

Ciwan A. del Real
General Counsel

JAN 24 1983
Date

D. Lowell Jensen
Assistant Attorney General
Criminal Division

February 15, 1983
Date

Richard P. Kusserow
Inspector General

JAN 24 1983
Date

B

MEMORANDUM OF UNDERSTANDING
BETWEEN THE U.S. DEPARTMENT OF JUSTICE
AND THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Purpose

This Memorandum of Understanding ("MOU") between the undersigned parties representing the U.S. Department of Justice ("DOJ") and the U.S. Department of Health and Human Services ("HHS") constitutes an agreement as to the terms and conditions necessary to implement § 1128A(c)(1) of the Social Security Act ("the Act"), 42 U.S.C. § 1320a-7a(c)(1). This section requires the imposition of civil money penalties ("CMP") only as authorized by the Attorney General pursuant to procedures agreed upon by the Attorney General and the Secretary. This MOU governs only the imposition of CMPs by HHS that may be assessed against skilled nursing facilities and nursing facilities as authorized by §§ 1819(h)(2)(B) and 1919(h)(3) of the Act, 42 U.S.C. §§ 1395i-3(h)(2)(B) and 1396r(h)(3). CMPs under these provisions became available to the Secretary on July 1, 1995 pursuant to rules that became effective on that date.

II. Objectives

A. It is the objective of the DOJ to be able to preserve its interest in pursuing investigations of fraud and abuse that may occur in nursing homes without facing potential interference that might be caused by a parallel administrative proceeding.

B. It is the objective of HHS, and the Health Care Financing Administration ("HCFA"), to be able to move swiftly, through the imposition of CMPs and other remedies, to protect the health and safety of residents residing in nursing homes that participate in the Medicare and Medicaid programs when nursing home providers violate requirements at §§ 1819 and 1919 of the Act, 42 U.S.C. §§ 1395i-3 and 1396r.

III. Procedures

A. Acting as HCFA's agent, States conduct surveys of nursing homes to determine if they comply with Federal requirements for participation in the Medicare program. Where a State survey agency identifies noncompliance in facilities that participate in the Medicare program, or both the Medicare and Medicaid programs, the State survey agency may recommend to HCFA that certain remedies be imposed, including CMPs. For such facilities, only HCFA, through its Regional Offices, may impose CMPs. The contact person for such actions is the Associate Regional Administrator for Health Standards and Quality in the appropriate HCFA Regional Office or the person indicated on the notification by HCFA to the United States Attorney ("USAO") of the specific CMP action. Within thirty (30) days of the signing of this MOU, HCFA will furnish to DOJ a list identifying each Associate Regional Administrator having the authority to impose CMPs on nursing

ATTACHMENT B

homes. Within thirty (30) days of the signing of this MOU, DOJ will provide to HCFA the names of the appropriate persons in the USAO to whom notification shall be made of HCFA CMP actions.

B. Poor performing facility CMP cases. In those cases where HCFA seeks to impose a CMP on a poor performing facility, HCFA will send a notice to the noncompliant facility advising it that a CMP is being imposed. The definition of "poor performing facility" appears in HCFA's State Operations Manual, and has been furnished to DOJ. Should HCFA revise the definition at any time, HCFA shall promptly advise DOJ of that fact and furnish to the USAOs a copy of the revised definition. Simultaneous with HCFA's notification to a facility that it is imposing a CMP, HCFA will provide to the USAO, or its designated representative, for the District in which the facility is located, by hard copy and/or electronic transmission, a copy of the notice it has sent to the facility along with a copy of the Statement of Deficiencies (Form 2567) upon which the CMP is based. The USAO will have fourteen (14) days from receipt of this information to advise HCFA that it ought not proceed further with the CMP, and in no case may HCFA seek to collect, or accept payment of, the CMP before the USAO has had its fourteen (14) day opportunity to review the matter. Should the USAO advise HCFA not to proceed with the CMP in a manner consistent with the procedures set forth in section IV of this MOU, HCFA will rescind the CMP.

C. Immediate jeopardy cases. In those cases of immediate jeopardy (as defined in 59 Fed. Reg. 56238 (1994) [to be codified at 42 C.F.R. § 488.301]), where HCFA seeks to impose a CMP, HCFA will send a notice to the noncompliant facility advising it that a CMP is being imposed. Simultaneous with HCFA's notification to a facility that it is imposing a CMP, HCFA will provide to the USAO, or its designated representative, for the District in which the facility is located, by hard copy and/or electronic transmission, a copy of the notice it has sent to the facility along with a copy of the Statement of Deficiencies (Form 2567) upon which the CMP is based. The USAO will have fourteen (14) days from receipt of this information to advise HCFA that it ought not proceed further with the CMP, and in no case may HCFA seek to collect, or accept payment of, the CMP before the USAO has had its fourteen (14) day opportunity to review the matter. Should the USAO advise HCFA not to proceed with the CMP in a manner consistent with the procedures set forth in section IV of this MOU, HCFA will rescind the CMP.

D. All other cases. In all other cases of facility noncompliance, when HCFA seeks to impose a CMP it will advise the facility of the possibility that this remedy may be imposed. Simultaneous with the time that HCFA sends such a notice to the facility, but in no case less than fourteen (14) days before the imposition of a CMP, HCFA shall send a copy of the notice, by hard copy and/or electronic transmission, to the USAO, or its designated representative, for the District in which the facility is located. Along with a copy of the notice, HCFA will be

responsible for assuring that the USAO receives a copy of the Statement of Deficiencies (Form 2567) upon which the CMP would be based. In no case under this subsection may HCFA seek to impose, collect, or accept payment of, a CMP before the USAO has had its fourteen (14) day opportunity to review the matter. Unless the USAO advises HCFA within fourteen (14) days of its receipt of the notice that the CMP should not be imposed, HCFA may assess the CMP as indicated in the notice to the facility. If the USAO concludes its review in less than fourteen (14) days, and advises HCFA that it may proceed with the CMP, HCFA will be free to impose, collect, and accept payment of the CMP at that time. Should the USAO advise HCFA not to proceed with the CMP in a manner consistent with the procedures set forth in section IV of this MOU, HCFA shall not impose, collect or accept payment of the CMP.

E. In all notifications by HCFA to the USAO of CMPs proposed or imposed pursuant to paragraphs III B., C., and D. of this MOU, HCFA will provide to the USAO, to the extent that it is readily available to HCFA, the following information:

1. the number of residents affected by the deficiency;
2. an estimate of how long the deficiency has existed;
3. the identity of the owners and managers of the facility in question;
4. the names and addresses of other facilities owned or managed by the same individuals or entities; and
5. an estimate of the actual damage which was caused by the deficiency (i.e. injury, death, additional medication or treatment).

F. Consistent with law enforcement needs and limitations on permissible disclosure of such information, the USAO shall advise HCFA of any investigations it is pursuing against a nursing provider certified for participation under the Medicare or Medicaid programs where the USAO has information that might have a bearing on the health and safety of residents in those facilities in order to enable HCFA to undertake its statutory obligations to protect those residents' interests.

G. The procedures set forth herein shall be reviewed by HCFA and DOJ within one year of the date of this MOU to evaluate its effectiveness and any need for modification.

IV. <u>Intent of the Parties</u>

It is the parties' intent that the procedures set forth above by which the USAO may cause HCFA not to proceed with a CMP, will be used where the USAO has a good faith basis to request that a CMP not be pursued. Where the USAO has no ongoing investigation, but intends to initiate one only after receiving notice of HCFA's imposition of (or intent to impose) a CMP, the USAO and HCFA

shall discuss possible ways to allow HCFA to proceed with the CMP in a manner that accommodates the interests of both HCFA and the USAO. Where the USAO believes that a CMP imposed by HCFA may interfere with an ongoing investigation of that facility, the USAO shall make every effort, consistent with law enforcement needs and limitations on permissible disclosure of such information, to contact HCFA to determine if the CMP may proceed.

Gerald Stern
Special Counsel for Health Care Fraud
U.S. Department of Justice

Date:

Bruce C. Vladeck, Administrator
Health Care Financing Administration
U.S. Department of Health and Human Services

Date: AUG 31 1995

MCU – 5/17/94

DEPARTMENT OF JUSTICE ACCESS TO MEDICARE CONTRACTOR INFORMATION

Combatting Medicare fraud is a goal shared by the Department of Justice ("DOJ"), Department of Health and Human Services Office of the Inspector General ("OIG"), and the Health Care Financing Administration ("HCFA"). Investigating and prosecuting such cases typically requires access to information and documents from Medicare contractors. To ensure that law enforcement's need for this information is met consistent with Medicare contractors' other responsibilities, DOJ, OIG, and HCFA agree to the following procedures:

1. DOJ can request in writing information and documents related to an ongoing civil or criminal health care fraud investigation or prosecution directly from a Medicare contractor. DOJ includes personnel at the Federal Bureau of Investigation ("FBI"), United States Attorneys Offices and the Department of Justice in Washington, D.C., including but not limited to the Criminal Division and Civil Division.

2. When DOJ requests information from a Medicare contractor, it must notify the Regional OIG in writing.

OIG approval is not necessary for DOJ requests for information from a Medicare contractor. OIG notification is intended to prevent duplication in investigative efforts.

3. HCFA approval is not necessary before a Medicare contractor can provide information requested to DOJ.

4. It is presumed that a Medicare contractor will furnish DOJ officials with information and documents related to a civil or criminal health care fraud investigation or prosecution in a timely fashion. However, if a Medicare contractor objects to the request on the basis that it is unduly burdensome in terms of the volume of information requested, the timing of the request, or the format in which DOJ seeks the information, the Medicare contractor may take the following steps:

a. Contact the requesting DOJ official to explain the basis of the objection. All parties agree to make good faith efforts to reach a resolution which accommodates DOJ's legitimate law enforcement needs and the Medicare contractor's budgetary constraints or other needs.

Legitimate requests include but are not limited to requests for the following documents:

(1) information contained on claim forms and other records maintained on individual providers or suppliers;
(2) billing procedure updates and other Medicare publications furnished to providers or suppliers;
(3) contractor correspondence to and from providers/suppliers;
(4) billing history of beneficiaries;

ATTACHMENT C

(5) analysis performed by Fraud and Abuse Units;
(6) data analysis routinely done by Medicare contractors such as utilization reviews.

DOJ recognizes that general data analysis is typically the prerogative of the Medicare contractor and HCFA and therefore, agrees to limit requests for data analysis not otherwise performed by the Medicare contractor. HCFA recognizes that OIG and DOJ may have legitimate law enforcement needs for data analysis in ongoing investigations and proceedings. Where DOJ requests data analysis not otherwise performed by the contractor, DOJ should discuss the request with the Medicare contractor to explain the need for such analysis and to determine whether there is an alternative format for a contractor to provide the information.

b. Where the FBI has sought the information, the FBI may involve in the resolution a representative of the United States Attorney's Office, DOJ's Criminal Division or Civil Division.

c. If the Medicare contractor and the requesting DOJ official cannot reach an accommodation, then they may seek the intervention of HCFA's Associate Regional Administrator. It is anticipated that such an appeal will be a rare occurrence prevented by reasonable requests and timely and comprehensive responses.

5. Periodic meetings between DOJ, OIG, HCFA regional officials, and the Medicare contractors should be held at the local levels. Similar meetings between DOJ, OIG and HCFA should be held at the national levels. Such meetings offer an opportunity to discuss trends in fraudulent practices; to devise possible solutions to stopping ongoing fraud; to report the status of DOJ health care fraud cases – consistent with DOJ's enforcement needs and limitations on permissible disclosure of such information; to resolve problems, if any, concerning requests for information; and generally, to foster cooperation among law enforcement, HCFA and Medicare contractors.

6. DOJ, OIG, and HCFA agree to conduct training which familiarize their respective personnel on the activities and needs of the others.

7. DOJ will handle the information and documents obtained from Medicare contractors consistent with existing statutory and regulatory provisions protecting confidentiality of patient records including, but not limited to, the Privacy Act of 1974.

8. Contractors requiring further instructions or clarification regarding any aspect of this policy, including the application of any statute or regulation, may contact the appropriate Associate Regional Administrator.

This policy will be revisited six months from the date of its adoption.

GERALD M. STERN
Special Counsel for Health Care Fraud
Department of Justice

JUNE GIBBS BROWN
Inspector General
Department of Health and Human Services

BRUCE VLADECK
Administrator
Health Care Financing Administration

4/29/94
DATE

Office of the Deputy Attorney General
Washington, D.C. 20530

June 3, 1998

MEMORANDUM FOR: All United States Attorneys
All First Assistant United States Attorneys
All Civil Health Care Fraud Coordinators in the Offices of United States Attorneys
All Trial Attorneys in the Civil Division, Commercial Litigation Section

FROM: Eric H. Holder, Jr.
Deputy Attorney General

SUBJECT: Guidance on the Use of the False Claims Act in Civil Health Care Matters

One of the Department's most important tools in protecting the integrity of Medicare and other taxpayer-funded health care programs is the civil False Claims Act. While the broad reach and substantial damages and civil penalties under the Act make it one of the Department's most powerful tools, Departmental attorneys are obligated to use their authority under the Act in a fair and responsible manner. This is particularly important in the context of national initiatives, which can have a broad impact on health care providers across the country.

This guidance is being issued to emphasize the importance of pursuing civil False Claims Act cases against health care providers in a fair and even-handed manner, and to implement new procedures with respect to the development and implementation of national initiatives.

1. **National Initiatives.**

Generally, national initiatives deal with a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers. National initiatives must be handled in a manner (i) that promotes consistent adherence to the Department's policies on enforcement of the False Claims Act, as well as a consistent approach to overarching legal and factual issues, (ii) while avoiding any rigid approach that fails to recognize the particular facts and circumstances of an individual case.

ATTACHMENT D

To achieve these objectives, the Department has instituted the following procedures:

(A) Legal and Factual Predicates.

Before alleging violations of the False Claims Act, whether in connection with a national initiative or otherwise, Department attorneys must evaluate whether the provider: (i) submitted false claims to the government, and (ii) submitted false claims (or any false statements made to get the false claims paid) with "knowledge" of their falsity, as defined in the Act. These are separate inquiries. Department attorneys shall not allege a violation of the False Claims Act unless both of these inquiries lead to the conclusion that there is a sufficient legal and factual predicate for proceeding. The following issues, among other issues, shall be considered in these determinations:

(i) Do False Claims Exist?

a. Examine Relevant Statutory and Regulatory Provisions and Interpretive Guidance. Department attorneys shall examine relevant statutory and regulatory provisions, as well as any applicable guidance from the program agency or its agents, to determine whether the claims are false. In certain circumstances, such as when a rule is technical or complex, Department attorneys should communicate with knowledgeable personnel within the program agency (e.g., the Health Care Financing Administration, TRICARE, or Office of Personnel Management) concerning the meaning of the provision.

b. Verify the Data and Other Evidence. Department attorneys shall take appropriate steps to verify the accuracy of data upon which they are relying, either independently, or with the assistance of the fiscal intermediaries and carriers, the Department of Health and Human Services - Office of Inspector General, the Federal Bureau of Investigation, or another investigative agency.

c. Conduct the Necessary Investigative Steps. Department attorneys should conduct such investigative steps as are necessary under the circumstances, including where appropriate, the subpoenaing of documents and the interviewing of witnesses.

(ii) Did the Provider Knowingly Submit the False Claims?

In the event the claims are false, Department attorneys must also evaluate whether the health care provider "knowingly" submitted the false claims or "knowingly" made false statements to get the false claims paid. As set forth above, and before making this determination, Department attorneys should conduct such investigative steps as necessary under the circumstances, including where appropriate the subpoenaing of documents and the interviewing of witnesses. Under the False Claims Act, false claims and false statements are submitted "knowingly" if the provider had actual knowledge of their falsity, or acted with deliberate ignorance or reckless disregard as to their truth or falsity. While relevant factors will vary from case to case and the list below is not intended to be exhaustive, factors that must be considered are:

FACTORS

a. Notice to the Provider. Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?

b. The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?

c. The Pervasiveness and Magnitude of the False Claims. Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?

d. Compliance Plans and Other Steps to Comply with Billing Rules. Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?

e. Past Remedial Efforts. Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?

did it yet

f. Guidance by the Program Agency or its Agents. Did the provider directly contact either the program agency (e.g., the Health Care Financing Administration) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?

g. Have There Been Prior Audits or other Notice to the Provider of the Same or Similar Billing Practices?

h. Any Other Information That Bears on the Provider's State of Mind in Submitting the False Claims.

(B) Oversight by National Initiative Working Groups.

For all current and future national initiatives, the Attorney General's Advisory Committee (AGAC) and the Civil Division shall establish a working group to coordinate the development and implementation of each initiative.

Working groups will be comprised of Assistant United States Attorneys and Civil Division attorneys with particular expertise in health care fraud. In accordance with the health care guidelines promulgated in January 1997, in appropriate instances each working group may also need to coordinate and plan the initiative with the Department's Criminal Division.

Each working group will (i) examine the initiative to ensure that a factual and legal predicate is present for the initiative prior to its implementation, (ii) prepare initiative-specific guidance and sample documents (such as legal analyses, summaries of audit data, contact letters, tolling agreements, compliance and settlement agreement language) for use in the initiative, and (iii) prepare a general investigative plan, setting forth

suggested investigative steps that each office should undertake prior to proceeding. Working groups shall be responsible for coordination with law enforcement agencies, the Health Care Financing Administration, and other appropriate entities.

While the working groups shall be responsible for coordinating the overall development and implementation of national initiatives, each matter against a specific provider must be evaluated on a case-by-case basis.

(C) Use of Contact Letters in National Initiatives.

As outlined above, Department attorneys participating in national initiatives shall, in general, make initial contacts with health care providers, to resolve a case, through the use of "contact" letters. The purpose of a contact letter is to notify a provider of their potential exposure under the False Claims Act and to offer the provider an opportunity to discuss the matter before a specific demand for payment is made. In limited circumstances, where the specific facts of a situation warrant a different approach, Department attorneys may make an initial contact through other legitimate means.

The use of contact letters to make initial contact with health care providers is in furtherance of Executive Order 12988, which obligates Department attorneys to make a reasonable effort to notify the opposing party about the nature of the allegations, and attempt to resolve the dispute without litigation if at all possible. The type of contact employed will depend on the nature of the allegations and the stage of the investigation. Regardless of the form of initial contact, Department attorneys must ensure that health care providers are afforded: (i) an adequate opportunity to discuss the matter before a demand for settlement is made, and (ii) an adequate time to respond. In addition, Department attorneys shall grant all reasonable requests for extensions of time to the extent that they do not jeopardize the government's claims. The use of statutory tolling agreements are strongly encouraged to allow providers time to respond without jeopardizing the government's claims.

2. **Alternative Remedies.**

After reviewing the legal and factual circumstances of a particular matter, Department attorneys shall consider other available remedies -- including administrative remedies such as recoupment of overpayments, program exclusions, and civil monetary penalties -- to determine what remedy, or combination of

remedies, would be the most suitable under the circumstances. Should the recoupment of an overpayment be the most appropriate remedy, Department attorneys shall consider referring the matter to the appropriate carrier/fiscal intermediary for appropriate action.

3. **Ability to Pay Issues.**

Attorneys shall consider any financial constraints identified by a provider in determining a fair, reasonable and feasible settlement between the parties. Hospitals and other health care providers citing an inability to pay a specific settlement amount should be asked to present documentation in support of their stated financial condition.

4. **Rural and Community Health Care Provider Concerns -- Impact on Availability of Medical Services.**

When dealing with rural and community hospitals and other health care providers, Department attorneys shall consider the impact an action may have on the community being served. In determining an appropriate resolution, or deciding whether to bring an action, care must be taken to consider the community's interest in access to adequate health care along with any other relevant concerns.

5. **Hospitals and Other Health Care Providers Not Represented by Counsel.**

Department attorneys shall pay special attention to contacts with hospitals and other providers that choose (due to financial constraints or otherwise) to resolve claims without legal representation. Department attorneys faced with this circumstance must carefully assess every action taken to avoid even an appearance of coercion or overreaching because of the absence of opposing counsel.

6. **Minimizing Burdens Imposed on Providers During Investigations.**

Department attorneys also should be mindful of the ways in which our investigations and audits can disrupt and burden the day-to-day operations of providers in both a financial and practical sense. In developing and implementing an investigative plan, we should do what we can do to minimize these adverse effects, while still meeting our obligation to diligently

investigate allegations of potential fraud. For example, while recognizing that certain circumstances might warrant different approaches, Department attorneys should consider a provider's request to accept the results of an audit of a sample of claims in lieu of a complete audit.

7. **Provider Assistance with the Investigation.**

In determining an appropriate settlement amount, Department attorneys should consider the extent to which a health care provider has cooperated with the audit or investigation of the relevant matter.

8. **Individualized Review.**

The proper determination as to the use and application of the False Claims Act or other appropriate remedy requires an individualized review of each case, ensuring that each of the above factors are given full consideration.

9. **Review of Guidance.**

In order to assure the fair and appropriate application of the False Claims Act, this guidance will be subject to review in six months.

10. **Additional Information.**

Questions regarding use of the False Claims Act should be referred to the Health Care Fraud Coordinator in your district, or to Robert Liles, Health Care Fraud Coordinator for the Executive Office for United States Attorneys (tel. no. 202-616-5136), or Shelley R. Slade, Health Care Fraud Coordinator for the Civil Division (tel. no. 202-307-0264).

U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

February 3, 1999

MEMORANDUM FOR: All United States Attorneys
All First Assistant United States Attorneys
All Civil Health Care Fraud Coordinators in the Offices of United States Attorneys
All Civil Division Fraud Attorneys

FROM: Eric H. Holder, Jr.

SUBJECT: Review of June 3, 1998, Guidance on the Use of the False Claims Act in Civil Health Care Fraud Matters

On June 3, 1998, I issued a Memorandum ("Guidance Memorandum") to all United States Attorneys' offices and the Civil Division providing guidance on the use of the False Claims Act in civil health care matters. The Guidance Memorandum was issued to emphasize the importance of using our anti-fraud and abuse tools, particularly the False Claims Act, in a fair and even-handed manner. The Guidance Memorandum also established new procedures for the development and implementation of national enforcement initiatives. The Guidance Memorandum further provided that it would be subject to review within a six-month period.

The six-month review process is now complete. Department officials have held separate meetings with the chairpersons of the national initiative working groups and senior representatives from the Commercial Litigation Branch, Civil Division, to discuss the application of the procedures outlined in the Guidance Memorandum and to solicit their suggestions on possible changes or clarifications. In addition, Department officials have met with representatives from several of the largest health care industry organizations to discuss the Guidance Memorandum. The Department also received written comments from one health care industry organization. Finally, comments were solicited from the Health Care Fraud Coordinators in all United States Attorneys' offices.

Based on the comments received to date, I believe the Guidance Memorandum - and the policies and procedures contained therein - has been extremely effective and that major revisions are not necessary at this time. This supplemental memorandum is being issued to clarify a number of issues that were raised during the review process.

ATTACHMENT E

1. Application and Scope.

The Guidance Memorandum applies to all civil health care fraud and abuse matters involving the use of the civil False Claims Act. In addition, all Department attorneys are expected to comply with the policies and procedures contained in the Guidance Memorandum. Specifically, sections 1(B) and (C) of the Guidance Memorandum (national initiative working groups and contact letters) establish new policies for national initiatives. Section 1(A) (factual and legal predicate) and Sections 2 through 8 emphasize long-standing policies and procedures applicable to all civil health care matters involving the use of the False Claims Act.

2. Compliance.

All Department attorneys handling civil health care matters are to comply with the Guidance Memorandum to ensure that the False Claims Act is applied in a fair and even-handed manner. Providers or their counsel with concerns about compliance with the Guidance Memorandum should bring their concerns to the Assistant United States Attorney or Trial Attorney handling the matter or, if necessary, to appropriate supervisory personnel in the United States Attorneys' office or the Civil Division in Washington, D.C. While the Guidance sets forth these internal procedures and safeguards, it does not establish enforceable rights of health care providers.

3. Allegations of False Claims Violations.

Section 1(A) of the Guidance Memorandum provides that Department attorneys should not "allege a violation of the False Claims Act" unless they conclude there is a sufficient legal and factual predicate for proceeding. The purpose of this requirement is to ensure that Department attorneys undertake an adequate, case-by-case factual and legal inquiry before alleging a violation of the False Claims Act. This requirement does not prohibit Department attorneys from taking appropriate steps to investigate a matter or undertaking other preliminary steps (e.g., requesting that a provider sign a statutory tolling agreement) before deciding whether to allege violations of the False Claims Act.

4. National Initiatives.

The Guidance Memorandum established new procedures for all current and future national initiatives. The term "national initiative" refers, generally, to projects involving a national investigation stemming from an analysis of national claims data, indicating that numerous similarly-situated health care providers have engaged in similar conduct to improperly bill government health care programs. In consultation with the Civil Division and the Health Care Fraud Subcommittee of the Attorney General's Advisory Committee, the Department will determine whether particular investigations of national scope should be designated as "national initiatives." Once such a designation is made, the Department will establish a working group to develop and implement the national initiative pursuant to the Guidance Memorandum and will notify United States Attorneys' Offices of such designation.

5. Coordination.

Working groups for new national projects shall establish formal liaison with the Office of Inspector General, Department of Health and Human Services, and/or other appropriate investigative agencies and with the Health Care Financing Administration and/or other programmatic agencies. The views of these agencies shall be solicited and considered by working groups in connection with their coordination and oversight of national initiatives.

* * * * *

Questions regarding the Guidance Memorandum, the clarifications outlined above, or other matters involving the use of the civil False Claims Act in health care fraud and abuse matters should be referred to the Health Care Fraud Coordinator in your district or to Robert Liles, Health Care Fraud Coordinator for the Executive Office for United States Attorneys, (202) 616-5136, or Shelley Slade, Senior Counsel for Health Care Fraud, Civil Division, (202) 307-0264.

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August 22, 2001

Honorable John Breaux, Chairman
Honorable Larry E. Craig, Ranking Member
Senate Special Committee on Aging
Dirksen Senate Office Building, Room G31
Washington, DC 20510

Dear Senators Breaux and Craig:

Regarding your letter of August 1 to Joseph DiGenova, requesting additional information from the American Hospital Association (AHA) in connection with your July 26, 2001 hearing on Medicare Enforcement Actions: The Federal Government's Anti-Fraud Efforts, we are pleased to submit the following responses to your questions.

1) The American Hospital Association is asking Congress to enact legislation to give hospitals and other providers the opportunity to challenge Medicare policy decisions and fraud cases under the False Claims Act without exhausting its administrative remedies. Are there any other classes of people or business that have been exempted from exhausting administrative remedies?

The AHA is proposing that the Department of Health and Human Services (HHS) be placed on an equal footing with other agencies. As currently interpreted, HHS is uniquely insulated from legal accountability for its decisions and actions under the Medicare Act. The AHA's proposal would not exempt hospitals from exhausting administrative remedies. We agree that in certain instances administrative review is appropriate. The proposal would remove the legal impediment, unique to the Medicare Act, which prevents hospitals from challenging actions of HHS that, if taken by other agencies, would be subject to judicial review.

The Administrative Procedures Act provides for court review of agency actions under a variety of circumstances. There are also a variety of laws that provide direct access to court to challenge agency rulemaking (e.g., The Clean Air Act, The Clean Water Act, the Resource Conservation and Recovery Act, and The Food Drug and Cosmetic Act). It is our understanding that the Defense and Energy departments also oversee laws under which there is direct access to court.

AHA agrees that disputes between a beneficiary or provider and HHS that are specific to an individual's eligibility, coverage, or amount of payment are subject to the administrative review process. These are the types of disputes for which the administrative process that the Medicare statute adopted from the Old Age, Survivors, and Disability Act was designed. In contrast, the

AHA proposal would provide direct access to court when a dispute challenges the underlying authority for or legality of HHS's action, or on any of the grounds on which court review of agency action is permitted under the Administrative Procedures Act.

As we stated in our testimony, under the current interpretations, a provider is effectively being denied access to court. For some types of disputes there is no administrative process available (e.g., fraud investigations that are legally flawed). For others, the prerequisite for initiating administrative review makes it unavailable (e.g., a hospital must violate a rule and be terminated from the Medicare program).

2) Proposals to give medical providers direct access to federal court have been discussed for some time, at least since 1998. Has any legislation been introduced to further these proposals?

A number of legislative proposals have been introduced since 1998 that would provide direct access to federal court. For example, in 2000, former Senator Spencer Abraham (R-MI) introduced S. 2999, the "Health Care Provider Bill of Rights", that would have allowed for direct access to court to challenge specific regulatory mandates. More recently, H.R. 868 and S. 452, the "Medicare Education and Regulatory Fairness Act of 2001", introduced by Rep. Patrick A. Toomey (R-PA) and Sen. Frank Murkowski (R-AK), would also address this issue, among others.

3) What data do you have that supports the conclusion that hospital billing mistakes are generally unintentional errors? Isn't the intent to commit fraud a determination for prosecutors to make?

The best evidence that billing errors are unintentional, not fraudulent, is from the government. The testimony from the Office of Inspector General (OIG) before the Committee makes clear that violations of the law are the exceptions. Reports from the General Accounting Office (GAO) have documented that investigations under the False Claims Act were launched without any legal basis. In the lab unbundling investigations, hundreds of hospitals were sent demand letters and coerced into settlement agreements. As the legal deficiencies in those investigations were made public, Assistant U.S. Attorneys dropped similar investigations, dissolved settlement agreements and corporate integrity agreements (CIAs), and, in some instances, returned money that hospitals had been coerced into repaying. Recognizing the need for direction and oversight of investigations, the Department of Justice (DOJ) issued guidelines for U.S. Attorneys' use of the False Claims Act.

General agreement on the complexity and confusion of the billing requirements is further evidence that billing mistakes are unintentional error. Again, GAO reports document the situation. In addition, two reports commissioned by the AHA, one in connection with the lab unbundling investigations and the other in connection with the pneumonia coding investigations,

demonstrate the kind of complexity, confusion and contradiction that defy any effort to characterize the errors as an intent to defraud. A copy of each report is attached.Another example involves discrepancies in guidance on billing requirements for services involving medical residents (i.e., the Physicians at Teaching Hospitals (PATH) audits). The problems with guidance to teaching hospitals regarding billing for services involving residents are well documented. Indeed, in July 1997 the general counsel for HHS wrote a letter acknowledging the conflicting and inconsistent guidance regarding these issues. This history belies any suggestion that the PATH settlements, all of which involved imposition of integrity agreements, reflected some type of fraud finding.

The problem with relying on prosecutors to make judgments about fraud is that prosecutors now face a conflict in their disposition of health care cases. Offices and prosecutors are evaluated on the basis of their financial recoveries. Given the tremendous leverage that they enjoy in these matters, there is an incentive to push dubious cases with the full knowledge that providers will pay to avoid the threat of ruin. This leverage inevitably clouds the exercise of discretion. In almost none of the investigations launched by the government has there been a court finding of fraud. Practically all are, at most, allegations of fraud or assertions of potential fraud by the government. It is the government's discretion to decide whether to initiate a prosecution. It is not the ultimate decision-maker on whether fraud occurred.

4) In your statement, you indicate that the HHS uses its enforcement authority to launch separate investigations and duplicate DOJ investigations previously resolved "completely" in favor of the hospital. Do you have specific examples of this? Please supply these for the record.

We are aware of a specific situation in which this has occurred and anecdotal information indicates there are other similar situations. A brief summary of the specific example is attached.

5) Couldn't DOJ have a variety of reasons for not pursuing a case that would not preclude the HHS-IG from pursuing remedies under its statutes?

There are circumstances in which DOJ could defer to the OIG and refer a matter to the OIG for handling. That type of situation is not our concern. Our concern is when DOJ has reached a decision on the merits in favor of a hospital, does not refer the matter to OIG, and OIG begins a separate, independent and duplicative investigation.

6) Please provide statistics on the number of CIAs imposed where there was no fraud and voluntary disclosure. Please provide specific instances, including names of providers that face imposition of a CIA with no showing of fraud.

To the best of our knowledge, there are only a few instances in which a CIA has been imposed following a court determination of fraud or a guilty plea. In all other instances they are imposed in the settlement of investigations or following a voluntary disclosure. Good examples of the use

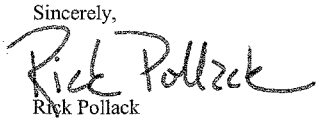
of CIAs in the absence of fraud are the lab and PATH investigations. Hospitals across the country were coerced into settlements that included CIAs, with the government subsequently acknowledging that grounds for asserting fraud did not exist. While the OIG's testimony indicates that they only impose CIAs in situations involving fraud, in the absence of a court determination or guilty plea it is hard to see the basis for this assertion. The OIG alleges fraud, and then settles matters without proving in a court of law or administrative proceeding that fraud has occurred. OIG's characterization of matters as fraud reinforces the concern of hospitals that the judgment of law enforcement authorities is being influenced by their financial interest in "fraud recoveries."

7) List all instances where hospital providers were subjected to armed raids or seizures by HHS-IG staff. Indicate whether the FBI was involved.

In response to a question from the Committee, the AHA reported on concerns about OIG coming into hospitals while carrying guns. The information provided was based on reports from our members. We have attached several news articles reporting on situations of such raids. However, the OIG and FBI would be the best sources to provide data on these types of raids because the records they maintain could identify the specifics of where and when the armed raids or seizures occurred, and who was involved.

We appreciated the opportunity to testify before the Committee and would be pleased to provide additional information at your request.

Sincerely,



Rick Pollack
Executive Vice President

Attachments

Attachment: Question 3

SPECIAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION

DEVELOPMENT OF GOVERNMENT GUIDELINES FOR HOSPITAL OUTPATIENT LABORATORY REIMBURSEMENT

MARCH 1998

Prepared by Jones, Day, Reavis & Pogue

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INTRODUCTION

Medicare reimbursement for outpatient laboratory tests is not based on a fixed amount. Rather, Medicare reimburses claims for two or more outpatient laboratory tests at the lowest amount of the sum of the individual tests performed, the panel or profile fee, or the National Limitation Amount. Multiple tests performed individually and later combined for either billing or payment purposes are considered "bundled" tests. Bundling of outpatient laboratory tests either can be performed by hospitals, before they submit Medicare bills to Fiscal Intermediaries ("Intermediaries"), or by Intermediaries, before they reimburse the hospitals. In either event, the legal responsibility to determine the payment amount rests with the Medicare Intermediaries.

Beginning in 1997, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), in conjunction with the Department of Justice and United States Attorneys' Offices (collectively, "DOJ"), began to threaten hospitals that have submitted unbundled claims with severe criminal, civil, and administrative sanctions. The investigations target claims for outpatient laboratory tests submitted as early as 1990. The premise of the federal enforcement effort is that certain hospitals have violated the False Claims Act by submitting unbundled claims for tests actually performed to Medicare in violation of Health Care Financing Administration ("HCFA") guidelines.

In an effort to understand the legal basis of the enforcement actions being taken against hospitals by the federal government, the American Hospital Association directed Jones, Day, Reavis & Pogue to identify the statutory or regulatory requirements that make "bundling" the legal responsibility of hospitals. The resulting report chronicles numerous ambiguous and sometimes conflicting "bundling" pronouncements of the various agencies involved in Medicare reimbursement -- OIG, HCFA, Intermediaries, and Carriers -- from 1984 to 1998.

The report is perhaps most striking for what it did not find -- any statutory provisions or duly promulgated regulations placing the burden on hospitals to bundle their claims. Instead, the report shows that, until quite recently, HCFA guidelines concerning outpatient laboratory tests were *payment* guidelines directed toward Intermediaries and Carriers, not *billing* guidelines directed toward hospitals.

Until recently, HCFA directed Intermediaries to bundle claims submitted by hospitals in unbundled fashion and pay the lower amount of the bundled or unbundled tests. Furthermore, Intermediaries informed hospitals that they would bundle for payment any claims submitted by hospitals in unbundled fashion. HCFA even required Intermediaries to put computer edits in place to automatically bundle tests for reimbursement purposes. Moreover, the OIG itself

repeatedly declared that hospitals were not obligated to bundle. In the OIG's 1995, 1996, and 1997-98 Red Books, the OIG stated that "Medicare policies are not sufficient to control the billing of profile tests because there is no requirement that the tests ordered as a panel by the physician be billed only as a panel."

In an abrupt departure from that view, in 1997, the OIG began characterizing bills that contain unbundled outpatient laboratory tests as potential false claims warranting severe penalties. Apparently frustrated with Intermediaries continuing to reimburse for unbundled outpatient laboratory tests, the OIG shifted its focus from the reimbursement methods of Intermediaries and Carriers, HCFA's payment agents, to the billing practices of hospitals. In 1998, the OIG expressly declared that unbundling was an "illegal" practice. The OIG's new position, however, did not coincide with the promulgation of any legally binding pronouncements from HHS or HCFA concerning laboratory billing.

Finally, the report demonstrates that neither the OIG nor the DOJ can point to any legal authority requiring *bundling* of laboratory test claims that has been violated by AHA member hospitals.

EXECUTIVE SUMMARY

Scope of Report

The following report is a synopsis of significant government payment and billing guidelines for hospital outpatient laboratory tests from 1965 to the present. The overall report is arranged chronologically and, within each year, the report, as appropriate, addresses the following:

- The sections entitled "Federal Laws and Regulations" discuss relevant laws enacted by the United States Congress and regulations promulgated by the Secretary of Health and Human Services ("Secretary"). Supporting documents for this section are contained in Appendix A.

- The sections entitled "HCFA Guidelines" discuss relevant provisions of the Intermediary, Carrier, and Hospital Manuals of the Health Care Financing Administration ("HCFA"), an agency of the Department of Health and Human Services charged with administering the Medicare program. Also discussed are relevant Program Memoranda from HCFA to Fiscal Intermediaries ("Intermediaries") and Carriers. Supporting documents for this section are contained in Appendix B.

- The sections entitled "Intermediary and Carrier Newsletters" outline relevant instructions from Intermediaries to hospitals and from Carriers[1] to independent laboratories. Supporting documents for this section are contained in Appendix C.

- The sections entitled "Office of the Inspector General" summarize relevant pronouncements of the Office of the Inspector General ("OIG"), an agency of the Department of Health and Human Services. Supporting documents for this section are contained in Appendix D.

Federal Laws and Regulations

Congress has enacted legislation and the Secretary has authority to promulgate regulations to

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[1] Generally, Intermediaries administer inpatient hospital services under Part A of the Medicare program, and Carriers administer physician and independent laboratory services under Part B of the Medicare program. Notwithstanding, hospitals are instructed to submit claims for outpatient laboratory tests to Intermediaries rather than Carriers. Therefore, hospitals routinely look to the Intermediary Manual and the Hospital Manual, but because hospitals may have access to the Carrier Manual, all three Manuals are discussed in this report.

govern Medicare payments for outpatient laboratory tests. Congressional enactments establish a framework for payment of outpatient services, but do not provide a comprehensive procedure for submitting and processing hospital bills for outpatient laboratory tests. Moreover, the Secretary has not filled this void by promulgating regulations establishing a comprehensive framework for submission and processing of provider bills for outpatient laboratory tests. Remarkably, while the Secretary first proposed such regulations in 1993, as of the date of this report, no regulations have been promulgated despite congressional directives to do so.

In 1984, Congress instructed the Secretary to: (1) create a fee schedule for outpatient laboratory tests; and (2) establish a system for determining the appropriate amount of payment for such tests based either on a negotiated rate or based on 80 percent of the lesser of: (a) the fee schedule; (b) the limitation amount for the test; or (c) the amount of the charge billed for the test. In 1986, Congress instructed Intermediaries to require the use of HCPCS by providers as a condition of payment for outpatient laboratory tests. With these two requirements, Congress established the payment amount and the payment method for outpatient laboratory tests, but did not prescribe a comprehensive payment system. The Secretary relies on HCFA Manuals and other informal statements to implement Congress's 1984 statutory mandate regarding the use of fee schedules for outpatient laboratory tests.

The requirements that govern Medicare payments for outpatient laboratory tests continue to evolve, with at least two major initiatives on the horizon. First, in its Unified Agenda published in the *Federal Register* on October 29, 1997, HCFA stated its intention to publish proposed regulations by September 1998 to implement Congress's 1984 mandate to create a fee schedule and establish a system for determining the appropriate amount of payment for laboratory tests. Second, in the Balanced Budget Act of 1997, Congress instructed the Secretary to adopt national coverage and administrative policies for outpatient laboratory tests through negotiated rulemaking. The culmination of these two initiatives could result in a comprehensive and uniform system for submission of bills and payment of claims for outpatient laboratory tests. If established through duly promulgated regulations, they would be the first ever adopted for Medicare reimbursement of hospital laboratory tests.

HCFA Guidelines

HCFA issues Intermediary, Carrier, and Hospital Manuals in order to provide guidance concerning administration of the Medicare program and participation in the program. The Manuals do not have the effect of regulations, but are intended to provide information on the processing of Medicare claims **(Tabs B-2; B-16; B-26)**.

The Manuals are designed to accommodate new pages as further interpretations of the law and changes in policy and procedures are made. Accordingly, supplements and revised sections, pages, or chapters are issued as needed. Program Memoranda specify the effective dates for the adoption of new policies or procedures. According to the Intermediary Manual, "[t]he [Program Memorandum's] effective date indicates at which point in the adjudicative process it applies" **(Tab B-2)**. Program Memoranda also specify whether they change policy or procedures, introduce new policy or procedures, or clarify existing policy or procedures **(Tabs B-1; B-15; B-25)**.

Although the dynamic nature of the Manuals makes them more useful in communicating current policies and procedures, it also makes it difficult to reconstruct the adjudicative standards at any given point in the past. The lack of a central archive for HCFA Manuals hindered our research in this area. Accordingly, the following discussion of Manual materials is not as straightforward as the presentation for the other sections of this report. To the extent possible, Manual materials were dated based on a combination of notations within the Manuals and reference to Program Memoranda.

Generally, the Intermediary, Carrier, and Hospital Manuals are intended to give consistent guidance to the various entities operating within the Medicare program. In some instances, policies or procedures appear verbatim in all three Manuals. Consistency, however, does not necessarily result in clarity or accuracy. The discussions below contain highlights from each of the Manuals. A more inclusive summary of the Manuals is included as an exhibit to this report **(Tab B-38)**.

The overall theme within the Manuals is the responsibility of Intermediaries and Carriers to safeguard Medicare Trust Funds by making only appropriate payments and recovering mistaken payments. Hospitals, of course, do not make Medicare payments, but instead make claims or submit bills to Intermediaries for such payments.

Similarly, the repetition of language in more than one Manual does not guarantee accuracy with respect to even one group of entities. In Hospital Manual § 442.6 and Intermediary Manual, Part 3, § 3627.8, for example, HCFA explains that "Section 9343(g) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 requires hospitals to report claims for outpatient services using HCPCS coding. HCPCS includes CPT-4 codes" **(Tabs B-28; B-3)**.[2] This statute,

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[2] HCPCS stands for the HCFA Common Procedure Coding System, a collection of codes used by providers to submit claims for medical services. CPT-4 stands for *Physicians* (continued...)

however, actually imposes the obligation upon Intermediaries, as it provides: "[N]ot later than July 1, 1987, each fiscal intermediary which processes claims under part B of Title XVIII of the Social Security Act shall require hospitals, as a condition of payment for outpatient hospital services under that part, to report claims for payment for such services under that part using a HCFA Common Procedure Coding System" **(Tab B-29)**. Thus, the characterization of the law contained in HCFA Manuals is not always correct.[3]

Intermediary and Carrier Newsletters

One of the primary ways that hospitals are informed of the government's position on Medicare issues is through newsletters from Intermediaries and Carriers. HCFA rarely communicates directly to hospitals, rather its pronouncements are filtered through Intermediaries and Carriers. Most Intermediaries and Carriers publish newsletters on a monthly basis. Each Intermediary and Carrier publishes its own newsletter, and so the content and quality of these newsletters varies from state to state. There is no common title or format for these newsletters, but many are entitled Medicare Report, Medicare Memo, Medicare Update, etc. These materials are referred to as "newsletters" throughout this report.[4]

The newsletters follow no general pattern when it comes to guidance on bundling outpatient laboratory tests together under one identifying code. Some newsletters phrase the bundling requirement in terms of how hospitals bill for outpatient laboratory tests; others phrase it in terms of how hospitals will be reimbursed for the tests. Prior to 1993, few newsletters discussed automated multichannel tests, sometimes referred to by the newsletters as chemistry tests or profiles. It is unclear if little was written by Intermediaries or Carriers on the subject or if the documents have been discarded. In 1993, there appears to be a significant increase in the

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2 (...continued)
Current Procedural Terminology, 4th edition, a publication of the American Medical Association listing codes for medical services.

3 In addition to the HCFA Manuals, HCFA, as part of its Correct Coding Initiative, compiles instructions on the billing of HCPCS and CPT codes for Medicare Part B Carriers in the National Correct Coding Policy Manual ("NCCPM"). Providers can request a copy of the NCCPM from the Department of Commerce's National Technical Information Service. The NCCPM is updated on a quarterly basis as a result of frequent changes in coding policy.

4 We have submitted Freedom of Information Act requests for all such materials to each Intermediary and Carrier, but many have not responded or are continuing to search their records for past pronouncements.

amount of materials available on bundling requirements, but the instructions are by no means consistent or uniform.

The guidance offered by Intermediaries and Carriers has varied greatly. Judging from their newsletters, it appears that these entities had conflicting goals. On the one hand, Intermediaries and Carriers were concerned that tests should be paid at the lower amount based upon bundled claims. On the other hand, Intermediaries and Carriers were concerned with medical necessity, and the only way that they could determine if tests were necessary was if hospitals submitted separate bills for the tests. These dual concerns resulted in constantly changing guidance. Furthermore, many Intermediaries and Carriers claimed to have installed edits to bundle claims, yet they also wanted to have claims submitted in bundled form. This may reflect a lack of confidence in their own computer edits.

Office of the Inspector General

The OIG issues Work Plans, Semiannual Reports, Red Books, and other publications setting forth its goals and reviewing its progress on various matters. As discussed below, it appears that the OIG first turned its attention to outpatient laboratory tests in 1984. In that year, the OIG focused on the billing practices of laboratories. After that, it appears that there was no public mention of outpatient laboratory tests until 1991. From 1991 until only recently, the OIG focused on HCFA, Intermediaries, Carriers, and state Medicaid programs. Moreover, the emphasis was on the *payment* practices of these entities, not the *billing* practices of hospitals or other providers. Indeed, the OIG's 1995, 1996, and 1997-98 Red Books all stated that "there is no requirement that the tests ordered as a panel by the physician be billed only as panel."

The emphasis on payment practices is significant because it shows that the OIG was primarily, if not exclusively, concerned with how providers were paid for outpatient laboratory tests, not how providers billed for those tests.

The billing practices of hospitals came under scrutiny in the OIG's April 1, 1997 - September 30, 1997 Semiannual Report and 1998 Work Plan. The Semiannual Report referred to the billing practices of hospitals as "abusive" and as "misconduct." It also described the enforcement efforts undertaken by the OIG in conjunction with the Department of Justice to recover double and treble damages for alleged overbillings by hospitals -- Project Bad Bundle. Similarly, a brief section in the 1998 Work Plan described unbundling as an "illegal" practice. In view of the OIG's previous pronouncements on the subject, none of which mentioned hospitals, these statement can only be viewed as a radical change in policy. This change in policy and its

reasons are neither disclosed nor discussed in any of the OIG's publications, including the Fraud Alerts periodically published by the OIG in the *Federal Register*.

1965: ORIGINS OF MEDICARE REIMBURSEMENT

Federal Laws and Regulations

In 1965, Congress included in the Medicare program a supplemental medical insurance program, known as Medicare Part B, to provide medical services to the elderly and disabled who elect to participate and pay premiums:

> There is hereby established a voluntary insurance program to provide medical insurance benefits . . . for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

42 U.S.C. § 1395j **(Tab A-1)**. Medicare Part B provides benefits to enrollees for "medical and other health services," 42 U.S.C. § 1395k, including "diagnostic laboratory tests." 42 U.S.C. § 1395x(s)(3) **(Tab A-2)**.

The reasonable charge limits of 42 U.S.C. § 1395u governed payment for outpatient laboratory tests prior to the adoption of fee schedules in 1984 **(Tab A-3)**. Intermediaries and Carriers determine the reasonable charge for outpatient laboratory tests using the rules set forth in subpart E of 42 C.F.R. § 405 **(Tab A-4)**. Under subpart E, the reasonable charge for an outpatient laboratory test is the lesser of: (1) the actual charge billed; (2) the customary charge; (3) the prevailing charge in the locality; or (4) the applicable Carrier charge.

1984: ESTABLISHMENT OF FEE SCHEDULES

Federal Laws and Regulations

In the Deficit Reduction Act of 1984, Congress ordered the Secretary to establish a payment system for outpatient laboratory tests based on a fee schedule:

> The Secretary shall establish fee schedules for clinical diagnostic laboratory tests for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

42 U.S.C. § 1395*l*(h) **(Tab A-5)**.

This statute required the Secretary to establish fee schedules for outpatient laboratory tests performed by physicians, independent laboratories, and hospital laboratories. Congress further instructed the Secretary to determine the amount of payment for bills submitted by any entity in one of two ways: (1) on the basis of the appropriate fee schedule by paying 80 percent of the lesser of "the amount determined under such fee schedule, the limitation amount for that test . . . or the amount of the charges billed for the test;" or (2) "on the basis of a negotiated rate" by paying 100% of the rate. 42 U.S.C.§ 1395*l*(a).

The payment methodology established by the Deficit Reduction Act of 1984 remains effective today and places clear limits on what Intermediaries and Carriers may pay to providers. Whether outpatient laboratory tests are bundled or unbundled, Intermediaries and Carriers are required by law to make the payment determination based on one of the two methods outlined in the statute. Absent a negotiated rate, Intermediaries and Carriers must determine and make payments equal to 80 percent of the lesser of the fee schedule, the limitation amount, or the charges billed *without regard to the billing practices of the provider*.

Office of the Inspector General

The OIG began to express concern about billing practices regarding outpatient laboratory tests in 1984. The OIG's initial focus was on the billing practices of independent laboratories, not hospital laboratories.

According to the OIG's Laboratory Investigative Guide, billing for manual as opposed to automated tests was one of the "more common types of criminal conduct associated with laboratory operation." The guide noted that "Most jurisdictions, realizing that manual tests cost more than their automated counterparts, allow for a higher fee if the test is manually done. This situation creates the opportunity for a number of abusive schemes." For example:

> [Smaller laboratories] will subcontract incoming work to a larger, automated laboratory, and then bill the health care carrier for the higher manual rate. [In addition] Automation permits the laboratory to run several (battery) tests with a single sample. Some lab owners will often disguise the series nature of the tests performed, and charge the program as if individual unit tests were done. This scheme is often accomplished by billing for half the

> tests on one date, and claiming a different service date for the remaining tests.

OIG Health Care Provider Fraud Technical Assistance Services, Laboratory Investigative Guide (May 1, 1984) **(Tab D-1)**.

1986: CONGRESS AND HCPCS

Federal Laws and Regulations

In the Omnibus Budget Reconciliation Act of 1986, Congress instructed Intermediaries to require that hospitals, *as a condition of payment*, report claims for outpatient hospital services using HCPCS codes:

> Not later than July 1, 1987, each fiscal intermediary which processes claims . . . shall require hospitals, as a condition of payment for outpatient hospital services under that part, to report claims for payment for such services under such part using a HCFA Common Procedure Coding System.

Pub. L. No. 99-509, § 9343(g), 100 Stat. 1874, 2041 (1986), *reprinted in* 42 U.S.C.S. § 1395u (History; Ancillary Laws and Directives (Reporting of Claims for Outpatient Hospital Services)) **(Tab A-6)**.

1987: BUNDLING BY PAYMENT AGENTS

Intermediary and Carrier Newsletters

The oldest newsletter found concerning laboratory unbundling is a Correction to a January 1987 Medicare Report Insert **(Tab C-1)**.[5] This newsletter defined multichannel tests (CPT codes 80002 through 80019) as "groups or panels of tests that can be performed on automated, multi-

[5] This document does not identify its author, but because it was obtained from the Assistant U.S. Attorney for the District of Columbia, it was probably published by Pennsylvania Blue Shield, the Carrier for Pennsylvania, Delaware, New Jersey, and the District of Columbia. Research on newsletters and other published guidelines, especially to show their historic development, is difficult due to the lack of consistent practices among agencies and payment agents, and the absence of a central repository of information.

channel equipment," and lists 26 tests that will be processed and reimbursed using profile codes (presumably 80002 through 80019).

This newsletter is noteworthy because: (1) it says that the Intermediary will bundle if the hospital does not -- "[w]hen three or more of the above tests are performed on the same day, and itemized charges are reported, they will be combined as processed with the appropriate code for the number of tests performed"; (2) it includes tests not listed in the CPT codebook's list of automated tests (the newsletter lists 26 tests that are considered multichannel tests, including CPK, GGT, and triglycerides); (3) it states that the bundling requirement applies to three or more tests in contrast to the CPT codebook, which applies multichannel codes to two or more tests; and (4) it refers to the bundling requirement as a reimbursement issue -- "[i]temized charges for three or more tests that are commonly part of automated batteries of tests will be *processed and reimbursed* as though they were performed on automated, multi-channel equipment." (Emphasis added.)

1988: BUNDLING INSTRUCTIONS AND LIABILITY FOR OVERPAYMENT

Federal Laws and Regulations

In 1988, the Secretary established basic billing requirements *as a condition* of Medicare payment by promulgating 42 C.F.R. § 424.32, which provides in relevant part:

> (a) A claim must meet the following requirements:
>
> > (1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by HCFA in accordance with HCFA instructions.
> >
> > (2) A claim for physician services must include appropriate diagnostic coding using ICD-9-CM.
> >
> > (3) A claim must be signed by the beneficiary or the beneficiary's representative . . . .
> >
> > (4) A claim must be filed within the time limits specified in § 424.44.

While this regulation governs general billing formats, it does not elevate informal bundling instructions to the level of a legal requirement.

HCFA Guidelines

Intermediary Manual, Part 3, § 3628 instructs Intermediaries to bundle claims received from hospitals in unbundled fashion. It also instructs Intermediaries to ensure that the correct fee schedules are used **(Tabs B-4; B-1)**.

Intermediary Manual, Part 3, § 3628 instructed:

> INT3 3628.B. Application of Fee Schedule. . . . Pay the lower of the applicable current fee schedule, the actual charge, or the national limitation amount. . . .
>
> * * *
>
> INT3 3628.D. Billing for Diagnostic Lab Tests. . . . Do not permit hospitals to submit separate bills for laboratory tests performed in different departments on the same day.
>
> * * *
>
> INT3 3628.H. Adjusted Fee Schedule. . . . The automated (profile) tests subject to the adjusted fee schedules tests are listed in codes 80002 - 80019 of the 1987 printing of the CPT-4.

A separate section of the Intermediary Manual deals with overpayment liability. Intermediary Manual, Part 3, § 3708, which was put into place by Program Memorandum No. 1298, dated October 1986, and Program Memorandum No. 1380, which issued sometime in 1988, explains when providers are liable for overpayments (*i.e.*, when they are at fault), provides a definition of fault, provides examples of situations where providers are liable, and establishes a four-year time limit after which payment decisions can be reopened "only in cases of fraud or similar fault" **(Tabs B-5; B-1)**. As with other HCFA Manuals, this section does not state that failing to use HCPCS or proper bundling techniques is a basis for finding that providers had submitted false claims, but merely states that providers are liable for any overpayments received, regardless of the reason, unless they are not at fault. Nothing in this section makes providers liable for paying double or triple the amount of the overpayment or other penalties.[6]

---

[6] Similar topics are covered in the Carrier Manual **(Tabs B-19 to B-24; B-15)**.

Two other sections of the Intermediary Manual are relevant: Intermediary Manual, Part 3, §§ 3709 and 3799, both of which concern the reopening of payment determinations (**Tabs B-6; B-8**). According to those sections:

> INT3 3709.2.B. You Have Not Taken Action to Reopen the Payment Decision Within Four Years (48 Months) After the Date of the Initial Payment Determination. -- Unless fraud or similar fault is present, a payment determination may not be reopened where you have not taken some action (which can be documented) questioning the correctness of the determination within 4 years (48 months) after the date the initial determination was approved. . . .
>
> INT3 3799.10 Unrestricted Reopening. A. Fraud or Similar Fault. -- A determination or decision may be reopened at any time if it was procured by fraud or similar fault, regardless of whether criminal prosecution has been or will be instituted. The fraud or similar fault may be that of the beneficiary, provider, physician, or any other person.
>
> 'Fraud or Similar Fault' means: Deception by a person who knows that the deception may result in unauthorized benefits to someone; An act which approximates fraud, i.e., the furnishing of information which the individual knows is incorrect or incomplete, or the deliberate concealment of information, without a judicial finding of fraud; A pattern of program abuse by physicians or suppliers resulting from practices that are inconsistent with accepted sound fiscal, business, or medical practice, such as:
>
> The furnishing of services that are in excess of the individual's needs, or of a quality that does not meet professionally recognized standards of health care; or the submittal of incorrect, incomplete or misleading information that results in payment for: Services that were not furnished; Services more expensive than those furnished; or Services that were not furnished under the conditions indicated on the bill.

Intermediary Manual, Part 3, § 3710 also sets forth procedures for recovery of overpayments (**Tab B-7**).

1989: UNCERTAINTY CONCERNING REIMBURSEMENT PRACTICES

HCFA Guidelines

From at least 1989 to the 1996 revision, Hospital Manual § 437.J stated that clinical laboratory tests would be reimbursed by Medicare as long as they were reasonable and necessary (**Tab B-27**). HCFA did not instruct hospitals to submit bills in bundles or any other particular manner.

According to the Hospital Manual:

> Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. In the case of multi-channel automated and/or batch automated (e.g., SMAC, CHEMICAL PROFILES, ASTRA) laboratory determinations, however, the physician may not be free to specify the tests the patient needs and there is normally only one charge for the battery of tests. The delivery of the service in this manner is much more economical than if the tests are performed individually. National guidelines for contractors on what tests are available in automated batteries are being developed. Until completed, use codes found in CPT-4 or sent to you by your intermediary."

In addition, Intermediary Manual, Part 3, § 3628.J, Carrier Manual, Part 3, § 5114.1L, and Hospital Manual § 437.J all direct that "[f]or Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests" (**Tabs B-4; B-27; B-17**).

Intermediary and Carrier Newsletters

In October 1989, Blue Cross of Pennsylvania, the Part B Carrier for Pennsylvania Delaware, New Jersey, and the District of Columbia, issued a Medicare Report addressing automated multichannel tests (**Tab C-2**). Rather than stating that these tests must be billed with CPT codes in the range 80002 through 80019, the newsletter merely requests that all multichannel tests be submitted on the same claim form. "When submitting claims for laboratory tests performed on automated equipment, please submit all your charges on one claim form." The newsletter then lists 25 tests considered to be automated tests, including GGT and triglycerides. It is noteworthy

that this newsletter does not state that laboratory tests must be bundled; rather, automated tests must merely be billed on the same claim form.

1990: PAYMENT REFORM AND BUNDLING BY PAYMENT AGENTS

Federal Laws and Regulations

In the Omnibus Budget Reconciliation Act of 1990, Congress instructed the Secretary to develop a proposal to replace the existing system of payment for hospital outpatient services, and to consider including payment for outpatient laboratory services in the system:

> The Secretary of Health and Human Services shall develop a proposal to replace the current system under which payment is made for hospital outpatient services . . . with a system under which such payments would be made on the basis of prospectively determined rates. In developing any proposal under this paragraph, the Secretary shall consider --
>
> * * *
>
> (iv) the feasibility and appropriateness of including payment for outpatient services not currently paid on a cost-related basis under the Medicare program (including clinical diagnostic laboratory tests and dialysis services) in the system.

Pub. L. No. 101-508, § 4151(b)(2), 104 Stat. 1388-72 (1990), *reprinted in* 42 U.S.C.S. § 1320b-3 (History; Ancillary Laws and Directives (Prospective Payment System for Hospital Outpatient Services)) **(Tab A-7)**.

Intermediary and Carrier Newsletters

In a 1990 Attention Memo, the Illinois Carrier placed responsibility on itself to bundle multichannel tests **(Tab C-3)**. This newsletter listed 30 tests that it considered to be automated multichannel tests. The newsletter did not state, however, that these tests must be billed in bundles. Rather, it said that the Carrier would bundle the claims. "Effective for all claims received February 1, 1990, and later, the above tests will be combined and coded with the appropriate multi-channel test code when two or more are billed."

1991: CONFUSION CONCERNING HCPCS AND CPT CODES

HCFA Guidelines

In Hospital Manual § 442.6 and Intermediary Manual, Part 3, § 3627.8, HCFA states that "Section 9343(g) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 requires hospitals to report claims for outpatient services using HCPCS coding. HCPCS includes CPT-4 codes" **(Tabs B-28; B-3)**. This statute, however, actually imposes the obligation upon Intermediaries: "[N]ot later than July 1, 1987, each fiscal intermediary which processes claims under part B of Title XVIII of the Social Security Act shall require hospitals, *as a condition of payment for outpatient hospital services* under that part, to report claims for payment for such services under that part using a HCFA Common Procedure Coding System" **(Tab B-29)** (emphasis added). Thus, HCFA Manuals are not quite accurate. Congress did not impose a substantive legal obligation on hospitals. Rather, Congress instructed Intermediaries to condition payment to hospitals on the use of HCPCS codes.

HCFA's assignment of bundling responsibility to Intermediaries and Carriers is repeatedly made apparent in various sections of the Manuals. HCFA advised that Carriers would accept claims for laboratory services where the laboratories have separately billed for the tests performed. HCFA also told the Carriers to bundle the claims and pay them. Under some limited circumstances, HCFA even provided the Carriers with discretion in choosing whether to bundle at all.

Until 1996 the Intermediary Manual, **(Tab B-4a)**, required Intermediaries to have edits that bundled claims :

> INT3 3628.J Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. In the case of multi-channel automated and/or batch automated (e.g., SMAC, CHEMICAL PROFILES, ASTRA) laboratory determinations, however, the physician may not be free to specify the tests the patient needs and there is normally only one charge for the battery of tests. The delivery of the service in this manner is much more economical than if the tests are performed individually. Install edit procedures to identify situations where the provider bills individual tests where billing for the automated battery would be appropriate based upon carrier practices in your area.

The relevant provisions of the Carrier Manual stated that:

> CAR3 5114.1L(2) Separately Billed Tests That Are Commonly Part of Automated Battery Test. -- If you receive claims for laboratory services in which the physician or laboratory has separately billed for tests that are available as part of an automated battery test, and, in your judgment, such battery tests (including mail order battery tests) are frequently performed and available for physicians . . . and the test results can be received within medically acceptable time limits, make the following determinations:
>
> - If the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the battery that includes these tests, make payment at the lesser amount for the battery. The payment allowance for a battery cannot exceed the payment allowances fee schedules for the individual tests.
>
> - Where only some of the tests in a battery of tests are covered, payment cannot exceed the amount that would have been paid if the covered tests had been ordered individually from the laboratory.
>
> * * *
>
> - When three or more tests are performed for a patient on the same day, determine whether to base payment on an automated battery (panel) test that includes such tests rather than to base payment on the individual or separately billed tests. Use code 80002 of the [CPT-4 (1989 printing)] for the above determination when two tests from the commonly performed automated tests are included on a claim containing three or more tests in total.
>
> * * *
>
> CAR3 5114.1.G. National Limitation Amount. . . . Currently, no specific national limitation amounts apply to allergy, organ, or disease oriented panels/profiles. However, the individual tests that comprise such panels are subject to the national limitation and where applicable, to the adjusted fee schedule. Ensure that the payment allowance for the panel/profile, therefore, does not exceed the lower of (1) the sum of the applicable fee schedule amounts (or national limitation amounts, if lower) for the

individual tests included in the panel/profile, or (2) the sum of the fee schedule amount you have established for the panel/profile.

You are responsible for applying the national limitations in calculating your payment allowances.

CAR3 5114.1.H. -- Summary of Payment Rules for Clinical Diagnostic Laboratory Tests. The following rules apply in determining the amount of Part B payment for clinical laboratory tests:

* * *

- If payment is made to a hospital for tests furnished for an outpatient of that hospital, the payment is the lesser of the actual charge, the fee schedule amount, or the national limitation amount and Part B deductible and coinsurance do not apply.

- For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount or the national limitation amount. Existing carrier jurisdiction rules apply. Part B deductible coinsurance do not apply.

Until 1995, Carrier Manual, Part 3, § 5114.1L(2) provided that, if two tests were performed on a patient on the same day, Carriers were not required to review whether panels or individual charges would result in lower payment. In addition, Carriers were authorized to pay for an entire battery of tests if at least one test was reasonably related to a specific complaint or symptom **(Tabs B-18; B-15)**.[7]

- Although you are not required to make the same determination when fewer than three tests are performed on one day for a patient, you are not precluded from making this review or from establishing an automated panel payment for fewer than three tests.

---

7 The comparable section of the Intermediary Manual similarly directs Intermediaries to bundle separately billed claims. Intermediary Manual, Part 3, § 3628 grants the same discretion to Intermediaries not to bundle as the Carrier Manual. HCFA also provides Intermediaries with the discretion to add to the list of tests that the Intermediary may bundle. See Program Memorandum No. 1686 **(Tab A-1)**.

- Where a battery of tests is performed, determine whether at least one test in the automated battery performed initially or as a follow up measure can be reasonably related to a specific complaint or symptom. Accordingly, where at least one test of an initial automated battery of tests can be reasonably related to a specific complaint or symptom, the payment allowance for the complete initial battery of tests is allowable. The payment allowance for an initial battery of tests cannot exceed the total of the payment allowance for all the tests if purchased individually. Where a battery of tests is repeated, however, only those individual tests in the battery which are required to follow the patient's progress are covered. Follow-up tests performed at a frequency greater than is necessary for the reasonable medical management of the patient's condition are not covered. Where no test in an automated battery of tests performed initially or as a follow-up measure can be reasonably related to a specific complaint or symptom, no payment is allowed for the battery.

Intermediary and Carrier Newsletters

A Medicare Advisory believed to be from the South Carolina Intermediary or Carrier dated April/May 1991 gave instructions regarding automated multichannel tests **(Tab C-4)**. This newsletter listed 27 tests considered to be multichannel tests, including CPK, GGT, and triglycerides. The newsletter instructed providers to bill separately when one or two multichannel tests were completed, but said that, if three or more tests are performed, then CPT codes 80003 through 80019 should be used. The newsletter also gave providers the option of using CPT Code 80002 if two tests were completed, but did not require this practice.

In September 1991, Blue Cross Blue Shield of Pennsylvania, the Carrier for Pennsylvania, Delaware, Maryland, New Jersey, and the District of Columbia, distributed an Educational Package for Providers of Independent Clinical Laboratory Services **(Tab C-57)**. This publication did not inform hospitals that they must bundle, but said that the Carrier would combine automated multichannel tests:

- Procedure Codes 80003 through 80019 represent groups or panels of tests which can be performed on automated, multi-channel equipment.

- Your claim should include the number of tests performed in the panel or battery.

* * *

- The following tests are commonly performed as groups and combinations on automated, multi-channel equipment. When three or more of these tests are reported separately, the

> charges will be combined and payment based upon the appropriate number of tests reported. [22 tests listed]

Office of the Inspector General

The OIG expressed renewed interest in billing practices for outpatient laboratory tests in 1991. The 1991-92 OIG Work Plan announced that there would be an audit of such practices. According to the Work Plan:

> This audit will determine if Medicare fees for clinical laboratory tests adequately reflect price reductions due to automation. There are indications that the Medicare payment rates are too high for certain high volume, low cost laboratory tests.

1991-92 OIG Work Plan (Dec. 1, 1990) **(Tab D-2)**. As the Work Plan indicates, in 1991, the OIG was concerned with HCFA's payment rates for outpatient laboratory tests, not with the billing practices of providers.

1992: BUNDLING BY PAYMENT AGENTS

Intermediary and Carrier Newsletters

In a Medicare Part A Bulletin from Florida dated June 1, 1992, the Intermediary notified hospitals that, if they did not bundle multichannel tests, then the Intermediary would automatically bundle them **(Tab C-5)**. According to the Bulletin:

> When two or more of the following tests are performed, they should be coded with the appropriate automated multi-channel test procedure codes (80002-80019) when performed on the same day. If providers do not code these tests in the multi-channel format, the system will automatically roll them up and reimburse the tests at the multi-channel rate.

This newsletter listed 48 CPT codes that the Intermediary would bundle into multichannel profiles. The newsletter also stated that, if more than one profile was billed to the same patient on the same day, then the tests would be rolled together into a single profile. "The system will also roll up more than one multi-channel profile performed on the same day for individual tests performed in addition to a multi-channel profile." This Bulletin is representative of other Intermediary pronouncements.

In September 1992, Blue Cross Blue Shield of Oklahoma, the Oklahoma Intermediary, told hospitals in Medicare Information Bulletin that it would deny all claims for an automated panel and a component of that panel **(Tab C-58)**. "Claims billed with incorrect CPT codes or claims with duplicated CPT codes (e.g., billing for an automated panel plus the individual components of that panel) will be denied."

1993: CONFUSION CONCERNING BUNDLING

Federal Laws and Regulations

In 1993, nine years after Congress's directive in the Deficit Reduction Act of 1984, the Secretary published proposed regulations in the *Federal Register* for the payment of outpatient laboratory services. Payment for Clinical Diagnostic Laboratory Tests, 58 Fed. Reg. 43832 (1993) **(Tab A-8)**. As stated in the preamble, the proposed regulations "would implement . . . the requirements of a number of laws [dating back to 1984], the most recent being the Omnibus Budget Reconciliation Act of *1990*. . . . Since 1984, statutorily-imposed fee schedules have been implemented by instructions to HCFA regional offices, fiscal intermediaries, and carriers. This proposed rule would codify these existing policies in regulations." (Emphasis added.) As acknowledged by HCFA, no regulations had yet been promulgated.

Intermediary and Carrier Newsletters

In 1993, Intermediaries and Carriers began issuing more newsletters related to automated multichannel tests without clarifying the issues. The confusion about bundling was evident in the treatment of the issue by Blue Cross/Blue Shield of Illinois, the Intermediary and Carrier for Illinois. In 1993, Blue Cross/Blue Shield of Illinois issued four newsletters evidencing continued change in its bundling policy.

In a Medicare Flyer dated April 30, 1993, Blue Cross/Blue Shield of Illinois, in its capacity as the Intermediary, defined automated multichannel tests as tests performed "in groups or combinations that can be performed on automated multi-channel equipment" **(Tab C-6)**. This newsletter listed 33 tests considered to be multichannel tests. It listed the tests by name and CPT code number, and gave the following bundling instruction: "The [listed] tests should be combined and coded as the appropriate multi-channel tests, whether or not the tests are performed on automated equipment. Itemizing charges for tests that can be part of an automated multi-channel test is considered fragmenting." Nevertheless, the newsletter went on to say that, if hospitals did not bundle claims, then the Intermediary would do so. "Medicare combines separately billed tests with the appropriate code and makes *payment based upon the fee schedule allowance for the multi-channel code*." (Emphasis added.)

The next pronouncement we obtained from the Intermediary was a Medicare Memo dated August 16, 1993 **(Tab C-7)**. This newsletter defined multichannel tests as if the Intermediary had never addressed the issue. "Effective August 1, 1993, the following lab HCPCS codes are considered to be part of an automated multichannel test and are to be billed using one of the lab codes between 80002 and 80019 rather than billed as separate tests." After giving that billing instruction, the newsletter listed 23 tests considered to be automated multichannel tests. The Intermediary's confusion is evident in its unexplained reduction of the number of tests subject to bundling from 33 to 23.

That August, Blue Cross/Blue Shield of Illinois, in its capacity as the Carrier, issued a Medicare Part B Bulletin that defined multichannel tests in the same manner that the Intermediary had

defined them in the same month **(Tab C-8)**. "When performed on the same day, tests should be combined and coded as the appropriate multi-channel test." The August 1993 Bulletin also noted that Medicare would bundle the tests if laboratories did not. "Medicare combines separately billed tests to the appropriate code and makes payment based on the allowed charge for the multi-channel code." The Bulletin listed 31 tests that were subject to the bundling requirement.

Finally, in a follow-up Medicare Part B Bulletin dated December 1993, the Carrier noted that the list of tests in the August 1993 Bulletin was incomplete and that one additional test (CPK) was subject to bundling **(Tab C-9)**. The December Bulletin noted that "one CPT code has been added to the list of clinical laboratory procedures which are subject to automated multichannel test guidelines." Such language indicates that the code was recently added to the list, even though the list of codes in the August Bulletin included that test.

Blue Cross/Blue Shield of Illinois apparently had different definitions of bundling for hospital laboratories and independent laboratories (the Intermediary pronouncements listed 23 and 33 multichannel tests, and the Carrier pronouncements listed 32 multichannel tests), even though these tests are all reimbursed under Medicare Part B.

Other Carriers also addressed the bundling issue in 1993. In a Medicare Part B Bulletin dated May 19, 1993, the Michigan Carrier listed 22 multichannel tests, including GGT, CPK, and triglycerides, and then gave the following instructions for how these tests should be billed: "For any combination of the tests listed below, use the appropriate code 80002-80019, according to the number of tests performed" **(Tab C-10)**. No further guidance was provided.

In September 1993, Blue Cross Blue Shield of Kansas, the Intermediary and Carrier for Kansas, stated that automated laboratory tests cannot be billed unless they are ordered by the physician and are medically necessary **(Tab C-59)**. According to Medicare Bulletin #93-8:

> Where automated lab tests are done as a panel but billed separately, you may not bill for tests that were not ordered, or not medically necessary, even though they were performed.
>
> Please provide this information to all in your facility who have need of it. Continued incorrect billing could be considered as a possible fraud issue.

1994: INTRODUCTION OF BUNDLING EDITS

Intermediary and Carrier Newsletters

In 1994, many Intermediaries and Carriers still assumed the responsibility of bundling claims themselves. Others, however, indicated that hospitals bore the responsibility to bundle.

The dual nature of the Intermediaries' position is evident in the Medicare Electronic Services Clinical/Reference Laboratory Billing Guide dated June 1994[8] **(Tab C-11)**. The Billing Guide informed hospitals that "[w]hen two or more of these tests are reported separately, the charges will be combined and payment based on the appropriate number of tests reported." The Billing Guide went on to list 31 laboratory tests subject to the billing requirement but noted that the 31 tests did not constitute a comprehensive list of multichannel tests; rather, it stated that all tests that can be performed on multichannel equipment are subject to the bundling requirement. "Any test. . . which can be performed on automated multi-channel equipment should be billed as part of the automated battery and should not be billed separately." Thus, the Billing Guide expected hospitals to bundle, but informed hospitals that the Intermediary would bundle if they did not.

In contrast, a Blue Cross/Blue Shield of Maryland Medicare Part A Provider Bulletin dated January 27, 1994 treated bundling solely as a billing issue **(Tab C-12)**. The Bulletin listed 23 laboratory tests subject to the bundling requirement but noted that "[i]f your automated equipment performs additional tests, those tests should also be included in codes 80002-80019." The Bulletin then stated that tests must be bundled: "The above codes [80002-80019] *must* be used when two or more of the [listed] tests are performed." (Emphasis in original.) The Intermediary took no explicit responsibility for bundling and cited no legal requirement that required hospitals to bundle, although it did go on to say that "[i]mproper billing of the components of panels or multichannel tests may be viewed as fraud or abuse."

In a Medicare Memo dated April 29, 1994, the Virginia Intermediary listed 22 tests subject to the bundling requirement **(Tab C-13)**. The Intermediary then gave an instruction that appeared to prohibit billing for more than one multichannel test per day. "More than one multi-channel test code should be billed only when the tests are distinctly separate." The Memo did not explain what was meant by "distinctly separate" or describe exactly what was being prohibited.

A June 1994 Program Bulletin published by Blue Cross Blue Shield of Washington, the Intermediary for Alaska and Washington, informed hospitals that the Intermediary would bundle automated laboratory claims **(Tab C-60)**. This 1994 Bulletin also gave a series of examples of how the Intermediary would bundle:

> Multichannel tests are usually billed using HCPCS codes 80002-80019, depending on the number of component tests included in the multichannel battery. At a minimum, any two or more of the following [22] tests will be considered to be performed on multichannel equipment and will be paid for at the multichannel price:
>
> * * *

---

8 This document does not identify its author, but because it was obtained from the Assistant U.S. Attorney for the District of Columbia, it was probably published by the Intermediary for Washington, D.C.

> The following roll-up procedures for components billed separately will be utilized, per a directive from HCFA.
>
> * * *
>
> Example 1: Codes 80006 and 64170 are billed, and there is a single date in the "Statement Covers Period", assume the 84170 is an addition to 80006, pay the claim as 80007.
>
> * * *
>
> Example 2: Codes 80004 and 80005 are billed, and there is a single date of service, roll the 2 multichannels into a higher multichannel, i.e., 80009.
>
> * * *
>
> Example 3: Codes 80002 and 80011 are billed, assume 80002 represents 1 test and 80011 represents 11 tests. The correct combined multichannel code is 80012.

Similarly, in a June 21, 1994 memorandum, the Ohio Intermediary informed hospitals that it would install edits to bundle laboratory tests **(Tab C-61)**. In describing the edits, the Intermediary did not instruct hospitals to bundle:

> [T]he following procedures/assumptions will be utilized in processing the claim:
>
> - All individual HCPCS codes billed will be compared to those subject to roll-up. Any that match will be rolled (changed) into the appropriate multi-channel HCPCS[.]
>
> EXAMPLE: Claim is billed with individual tests of 82040, 82250, 82251, and 82310. These tests will be rolled up (changed) to 80004 and be reimbursed accordingly.
>
> * * *
>
> - If a claim is submitted with a HCPCS subject to roll-up, AND a multi-channel HCPCS, we will increase the number of tests in the multi-channel by 1, the unit will remain the same.

EXAMPLE: Codes 80006 and 84170 are billed, the "From" and "Through" dates are the same, and there is 1 unit of service for 84170. we will assume 84170 is in addition to 80006, and change the HCPCS to 80007 and reimburse accordingly.

- If 2 different multi-channel tests are billed on the same claim, we will roll them to the proper higher number multi-channel code.

  EXAMPLE: Codes 80004 and 80005 are billed for a single date of service. we will roll the codes to 80009 and reimburse accordingly.

The South Carolina Intermediary and other Intermediaries took the position that bundling was a pricing issue and informed hospitals that as of July 1, 1994, it had installed edits to bundle laboratory claims. In a June 19, 1994 Medicare Advisory, the Intermediary told hospitals that multichannel tests were subject to bundling **(Tab C-14)**. But rather than instructing hospitals to bundle claims themselves, the Intermediary explained that its computerized edits would "roll up" multichannel tests. "In the case of multi-channel and/or batched automated laboratory determinations, there is normally only one charge for a battery of tests." The Advisory informed hospitals that as of July 28, 1994, edits would be installed to bundle tests that hospitals submitted separately. "At a minimum, any two or more of the following tests would be considered to be performed on multi-channel equipment and would be reimbursed at the multi-channel price."

The South Carolina Advisory listed 22 tests subject to the bundling edits. The Advisory also gave four examples of how the edits would "roll together" multichannel tests. The edits bundled separate claims and added together two or more profiles billed on the same day. According to the Advisory, the Intermediary would bundle 80005 and 80006 as an 80011 and would bundle 80002 and 80011 as an 80012.

The South Carolina Intermediary reminded hospitals of these edits via an Administrative Message dated June 30, 1994 **(Tab C-15)**. This e-mail noted that HCFA mandated these edits: "HCFA has mandated that the pricing edits for laboratory tests utilizing automated equipment . . . be installed effective July 1, 1994." It is worth noting that the e-mail referred to this as a *pricing edit* rather than a *billing edit*, underscoring the point that these edits refer to how payments will be made rather than how bills should be submitted.

Other states did not always provide as much detail about laboratory bundling as the South Carolina Intermediary. For example, a Medicare News Bulletin from the Carrier for Oregon and Alaska dated July 19, 1994 informed hospitals about multichannel code 80002 in an abbreviated fashion **(Tab C-16)**. The Carrier told hospitals that, if two automated multichannel tests are performed, then code 80002 should be used. "More than two tests would [sic] be billed using the appropriate code in the series 80003 through 80019. If a single multi-channel test is

performed on automated multi-channel equipment, we ask that you bill using the CPT code for the specific test performed." The Carrier gave no additional explanation about bundling.

The confusion concerning automated tests is evident from a Medicare Part B Bulletin for Michigan dated October 19, 1994 **(Tab C-17)**. When billing for laboratory tests, both the number of tests and the number of services are listed in the bill. The Carrier noted that Michigan providers "were previously instructed to bill the number of tests in each code as the number of services." The Carrier went on to say, however, that there is only one service for multichannel tests even though multichannel equipment is capable of running a number of tests. "When submitting charges for CPT Codes 80002-80019 . . . providers should bill 'one' number of service for each code." Prior to October 1994, the Carrier evidently believed that each test done on a multichannel instrument was a separate service. Such a belief is consistent with the idea that the tests could be billed separately.

The confusion concerning bundling was evident in the treatment of the issue by Blue Cross Blue Shield of North Dakota, the Intermediary and Carrier for 10 states. Blue Cross Blue Shield of North Dakota, in its capacity as the Intermediary, published a Medicare A Bulletin in December 1994 that explained automated multichannel tests in billing terms **(Tab C-63)**. "For outpatient services rendered on/after July 1, 1994, the following list identifies those laboratory tests that are frequently done in groups and must be billed as automated multichannel tests." The Bulletin went on to list 21 tests subject to bundling. The Bulletin did not, however, describe the authority for the billing requirement.

In contrast, Blue Cross Blue Shield of North Dakota, in its capacity as the Carrier, gave different billing guidelines **(Tab C-64)**. In a Medicare B News Bulletin dated November 1994, the Carrier said that it would bundle separately billed laboratory claims:

> If Medicare receives a claim for laboratory service in which the physician or laboratory has separately billed for tests that are available as part of an automated battery (panel) test, and are frequently performed and available for physician's use and the test results can be received within medically acceptable time limits, then:
>
> 1. If the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the battery (panel) that includes these tests, payment will be made at the lesser amount for the battery (panel).
>
> 2. Payment for the battery (panel) is applied whether or not a particular laboratory has the automated equipment.
>
> If the physician or laboratory routinely performs a test as part of the battery (panel) it should be reported as part of the automated battery test (i.e., triglycerides).

* * *

> When a postpayment review is conducted an clinical documentation indicates that tests are performed as part of a battery (panel) but billed for separately the following will apply: Medicare will adjust the claim to the appropriate multichannel test and request that the reimbursement for the difference between payment for the appropriate multichannel test and payment for the separately billed test be refunded.

Office of the Inspector General

The OIG's April 1, 1994 - September 30, 1994 Semi-Annual Report stated that the OIG had initiated a series of four nationwide reviews on Medicare Part B payments for chemistry and hematology tests performed on an outpatient basis. The report described the OIG's investigations as follows:

> The intermediary [which was not identified in the report] concurred that overpayments resulted from unbundling and duplicate charges [and] agreed to develop edits and to initiate recovery of overpayments. The intermediary also informed OIG that claims are processed through a system shared with 20 other contractors. The OIG is working with HCFA to identify overpayments due to systematic problems with claims processing systems at all Medicare contracts.

The report also made the following recommendations:

> The fiscal intermediary should install edits to detect and prevent overpayments for unbundled or duplicate charges for chemistry and hematology tests performed by hospitals on an outpatient basis, and initiate recovery from hospitals for identified overpayments.

The report concluded that "Early, positive HCFA action on OIG's findings has eliminated the need for extended review." April 1, 1994 - September 30, 1994 OIG Semi-Annual Report (Apr. 1994) **(Tab D-3)**. As in previous years, the OIG's focus was on payment practices for outpatient laboratory tests, not the billing practices of hospitals.

The above Semi-Annual Report referred to an August 1993 OIG report from an audit of the Massachusetts Carrier **(Tab D-3a)**. In the review of the Massachusetts Carrier, the OIG considered the quality of the edits that the Carrier had in place to bundle lab tests. The report notes that the edits in place by both hospitals and the Intermediary were inadequate:

> The [Intermediary]'s . . . existing systems edit for chemistry panel tests contains logic to recode three or more individual tests into the

> applicable single panel code. If three or more of the individual tests are contained on the same claim, the system will group them into the appropriate single panel code according to the total number of panel tests (from 3 to 19 or more tests) contained on the claim. Our review disclosed, however, that the system cannot detect or roll up multichannel tests inappropriately coded under more than one panel code, duplicate units of the same panel code, or a panel code(s) and individual test code(s) to the higher appropriate panel code.
>
> * * *
>
> Hospital systems are designed to bundle individual tests into panels when they submit them for payment. We found that some hospital billing systems are programmed to identify and roll up selected panel tests into one panel and treat the remaining tests as a second panel. These claims were paid as two separate panels by the [Intermediary]. In other cases, when the hospital system does not identify the test as belonging to a specific panel, it groups those it can identify into one panel and submits the remaining tests individually. When the [Intermediary] receives the claim, it recognizes the first panel and groups the individual tests (if more than two) into a second panel and pays the claim as two separate panels. If a panel and less than three tests are submitted in a claim, the [Intermediary] pays the panel and the two tests separately.
>
> For example, a number of hospitals are separately charging a four test panel under the umbrella term called electrolytes. Any remaining panel tests are rolled up into a second panel. Since the [Intermediary]'s system does not have edits to detect two panels submitted on the same claim together, reimbursement is made for two panels. The reimbursement for the two panels is higher than if the tests were reimbursed as one panel. Officials at the [Intermediary] stated that this billing practice is not in accordance with hospital billing guidelines.

Later in 1994, the Inspector General sent a memorandum to the Administrator of HCFA outlining the results of the OIG's review of Medicare Part B payments for outpatient laboratory tests. Once again, the emphasis was on payment practices, not billing practices.

The report stated that "Carrier payment systems should contain edits to detect and prevent the payment of unbundled and duplicate chemistry tests and hematology profiles." Using Massachusetts as an example, the OIG said that "These overpayments occurred because edits were not in place to detect all instances of unbundling or to detect duplicate payments."

With regard to corrective action, the report stated that:

> The HCFA staff agreed that carrier overpayments for clinical laboratory services are a nationwide issue and should be included with HCFA's [review] to ensure accurate FI payments for outpatient clinical laboratory claims. [W]e agree with HCFA's proposed corrective action [*i.e.*, implementing additional bundling and duplicate payment edits at carriers]. As a result of the agreements reached with HCFA staff to initiate corrective action, we plan no further audit work in this area. Therefore, the overpayment errors identified are considered potential since they have not been verified as would be the case under normal audit procedures.

OIG, Medicare Part B Payments By Carriers for Chemistry Tests and Hematology Profiles Performed by Independent and Physician Laboratories (May 3, 1994) **(Tab D-4)**.

1995: CONFUSION CONCERNING BUNDLING EDITS

HCFA Guidelines

In November 1995, HCFA issued Program Memorandum No. AB-95-13, which told Intermediaries and Carriers, in sometimes confusing language, that three additional chemistry tests would be considered automated multichannel tests as of January 1, 1996, and that there was a revision in CPT terminology **(Tab B-30)**. According to the Memorandum:

> Effective January 1, 1996, three tests are added to the list of tests which are considered automated tests. The additional tests are creatine kinase (CK, CPK), GammaGlutamyltransferase (GGT), and triglyceride. Also, on January 1, 1996, a revision occurs in the terminology for CPT-4 code 80019. Currently, CPT-4 code 80019 references automated multichannel test [sic]; 19 or more clinical chemistry tests, but on the effective date, CPT-4 code 80019 will only reference 19 automated tests.
>
> To provide for the billing of the three additional automated tests, use the following temporary codes when more than 19 automated tests are performed:
>
> G0058 automated multichannel test; 20 clinical chemistry tests
>
> G0059 automated multichannel test; 21 clinical chemistry tests
>
> G0060 automated multichannel test; 22 clinical chemistry tests

There were also significant revisions to the Intermediary Manual in 1995 related to fraud and abuse. HCFA told Intermediaries in Program Memorandum No. 1663 that it revised Intermediary Manual, Part 3, § 3950 in its entirety. The revisions allocate responsibilities to "make only appropriate payments" and "recover any mistaken payments" to Intermediaries, and describe the actions (which are primarily administrative) to be taken to protect the Medicare Trust Funds **(Tabs B-9 to B-14)**.

In contrast to the Intermediary Manual, Carrier Manual, Part 3, § 5114, as revised in 1995, contains a lengthy section on outpatient laboratory claims. Notably, the Manual instructs Carriers to bundle claims for blood chemistry tests that are capable of being performed on automated equipment but are submitted in unbundled fashion **(Tab B-17)**.

According to the Carrier Manual:

> CAR3 5114.1.B. Clinical Diagnostic Laboratory Services Subject to Fee Schedule. -- For purposes of the fee schedule, clinical diagnostic laboratory services include laboratory tests listed in codes 80002-89399 of the [CPT-4], 1991 printing. . . .
>
> * * *
>
> The following codes that delineate allergy, organ or disease oriented panels/profiles are not currently subject to the national limitation amounts because laboratories do not always utilize the same array or number or tests in a particular panel. However, the national limitation amount applies to each test included in the panel/profile. (See 5114.1.G). 80050-80099; 86421-86422.
>
> Know which individual tests have been performed when claims are received using panel/profit [sic] codes. This does not need to be reported on each bill as long as you are confident that every laboratory reporting a panel or profile uses a consistent set of tests. If there is variation in content of the panel or profile, establish a uniform definition and require laboratories that do not comply with this definition to identify the individual tests when billing the panel or profile.
>
> * * *
>
> CAR3 5114.1.F. Adjusted Fee Schedule. . . . The automated tests subject to the adjusted fee schedules tests are listed in codes 80002-80019 of the 1990 printing of the CPT-4. . . .
>
> * * *

Where these adjusted fee schedule tests are part of allergy, disease or organ panels/profiles, you must assure that your fee for the panel/profile does not exceed the sum of the fees for the individual components after accounting for the reductions due to the adjustment.

CAR3 5114.1.L. Laboratory Tests Utilizing Automated Equipment. . . .

(1) Determining Payment for Automated Tests. -- The common automated tests comprise specific groupings of blood chemistries which enable physicians to more accurately diagnose their patients' medical problems.

* * *

While the component tests in automated profiles may vary somewhat from one laboratory to another, or from one physician's office or clinic to another, group together those profile tests which can be performed at the same time on the same equipment for purposes of developing appropriate payment allowances. For Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests. While laboratory entities may bill additional tests using automated profile codes and be paid according to 5114.1, the above listed 22 tests are the only tests that you may group into automated profiles if they are billed separately. Future revisions to this list will be made through manual revisions.

Payment is made only for those tests in an automated profile that meet Medicare coverage rules. Where only some of the tests in a profile of tests are covered, payment cannot exceed the amount that would have been paid if only the covered tests had been ordered. . . .

* * *

(2) Separately Billed Tests That Are Commonly Part of Automated Test Profiles. -- If you receive claims for laboratory services in which the physician or laboratory has separately billed for tests that are available as part of an automated profile test, make the following determinations:

- If the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the profile that includes these tests, make payment at the lesser amount for the profile. Conversely, the payment allowance for a profile cannot exceed the payment allowance for the individual tests.

- The limitation that payment for individual tests not exceed the payment allowance for an automated profile is applied whether or not a particular laboratory has the automated equipment. . . .

- When one or more automated profile tests are performed for a patient on the same day, determine whether to base payment on an automated profile that includes such tests rather than to base payment on the individual or separately billed tests. For example, compare the allowance for code 80002 of the [CPT-4] for the above determination when one or two tests from the commonly performed automated tests are included on a claim.

Intermediary and Carrier Newsletters

Confusion about multichannel tests continued during 1995. Although HCFA had instructed Intermediaries and Carriers to install bundling edits in 1994, it was apparent by June 1995 that some Intermediaries were struggling to put the edits into place. Further, Intermediaries had differing views about whether bundling requirements were billing instructions or reimbursement instructions.

In 1995, the South Carolina Intermediary sent out three newsletters concerning multichannel tests and the installation of bundling edits. In these newsletters, the Intermediary took the position that bundling was a payment issue rather than a billing issue. The Intermediary informed hospitals that laboratory claims for automated profiles would be bundled together into profiles in an Administrative Message to providers dated May 19, 1995 **(Tab C-22)**. This e-mail told hospitals that "Some laboratory tests performed on the same date are required to be combined for purposes of payment as automated profile tests or other panel tests." It is important to note that bundling is referred to for *purposes of payment* rather than *purposes of billing*. Later, in the same message, the Intermediary noted that tests would be combined for pricing purposes. "We will use [the date of service] to determine when to roll up automated profile tests, and combine individual tests for *pricing purposes* when tests are subject to automated profile organ/disease panel pricing." (Emphasis added.)

In a Medicare Advisory dated June 1995, the South Carolina Intermediary again stated that HCFA had issued instructions requiring Intermediaries to create edits to bundle claims in the 80000 series of CPT codes **(Tab C-21)**. In order to facilitate these edits, the Intermediary said that "if a claim's date of service spanned two or more days, there must be a line item date of

service for each HCPCS code equal to 80002 through 89399." This instruction apparently was necessary for the edits to work properly because the edits probably bundled claims with the same date of service. Notably, the newsletter did not inform hospitals exactly what the edits would do. Rather, it merely said that "This edit affects all HCPCS codes in the range 80002 through 89399." It is unclear what the Intermediary meant when it said "affects all codes."

The June 1995 Advisory noted that there has been confusion concerning the bundling requirement. "Since there has been confusion regarding this edit, HCFA has changed the effective date of the requirement." Apparently, Intermediaries were unclear about how to install the edits and may have resisted their use to the point that their effective date had to be postponed.

In a September 1995 Medicare Advisory from the South Carolina Intermediary, hospitals were reminded that the bundling edits were scheduled to become effective at the end of September 1995 **(Tab C-23)**. This Advisory repeated the language of the June 1995 Advisory, which summarily told hospitals that the edits would apply to codes in the "80000 series of CPT codes." But the September Advisory referred to bundling as a billing requirement enforced by HCFA. "Since there has been confusion regarding this edit, HCFA has delayed the enforcement of its billing requirement until October 1, 1995." It is unclear why the Advisory referred to billing requirements when bundling edits concern the reimbursement of claims. Moreover, the Advisory did not inform hospitals of what they must do in order to comply with the bundling requirement.

The idea that bundling is a payment issue rather than a billing issue is also reflected in a March 1995 Medicare Update published by the Virginia Intermediary **(Tab C-24)**. This Update began by reminding hospitals that the Intermediary was implementing system edits that would bundle multichannel tests by referencing its memo dated April 29, 1994. The Update then stated that the edits would be in place as of April 1, 1995. "Beginning with services on and after April 1, 1995, our system will require line item service dates on laboratory services whenever the from and through dates on your claim span more than one day. In addition, specific edits will be implemented to bundle individual tests into an *organ/disease panel code* [as opposed to a blood chemistry code] when appropriate." (Emphasis added.) The Update went on to note that these edits were put in place in order to make sure that repayment was proper. "These changes will further ensure the *proper payment* and coding of laboratory tests." (Emphasis added.) Thus, while the Virginia Intermediary often presented the bundling requirement as a billing requirement, it did note that edits were in place to insure proper payment.

In December 1995, AdminaStar of Kentucky, the Intermediary and Carrier for Kentucky, informed hospitals of new codes for automated multichannel tests by repeating much of HCFA Program Memorandum AB-95-13 in a Hospital Provider Letter **(Tab C-52)**. AdminaStar told hospitals that three additional tests were considered automated multichannel tests and that HCFA created three new profile codes:

> Effective January 1, 1996, three tests are added to the list of tests which are considered automated tests. The additional tests are

> creatine kinase (CK, CPK), GammaGlutamyltransferase (GGT), and triglyceride. Also, on January 1, 1996, a revision occurs in the terminology for CPT-4 code 80019. Currently, CPT-4 code 80019 references automated multichannel test; 19 or more clinical chemistry tests, but on the effective date, CPT-4 code 80019 will only reference 19 automated tests.
>
> To provide for the billing of the three additional automated tests, use the following temporary codes when more than 19 automated tests are performed:
>
> G0058 automated multichannel test; 20 clinical chemistry tests
> G0059 automated multichannel test; 21 clinical chemistry tests
> G0060 automated multichannel test; 22 clinical chemistry tests

Many other Intermediaries informed hospitals of these new guidelines using similar or identical language in late 1995 or early 1996. These Intermediaries include: Blue Cross Blue Shield of Washington, the Alaska and Washington Intermediary **(Tab C-53)**; Blue Cross Blue Shield of Oklahoma, the Oklahoma Intermediary **(Tab C-54)**; and Blue Cross Blue Shield of North Dakota, the Intermediary for North Dakota, South Dakota, Arizona, Nevada, Washington, Wyoming, Colorado, Hawaii, Oregon, and Hawaii **(Tab C-55)**. The Carrier for Minnesota also published a newsletter that addressed this change using similar language **(Tab C-56)**.

The billing/payment dichotomy was evident in Medicare Part B Bulletins for Michigan. In a Michigan Medicare Part B Bulletin dated May 1995, independent laboratories were reminded of the billing instructions for multichannel tests **(Tab C-18)**. The newsletter described the bundling requirement as both a billing requirement and a reimbursement requirement. First, the newsletter pronounced that "[i]temizing charges for tests that can be part of an automated multi-channel test is considered fragmenting." In the next sentence, however, the newsletter informed independent laboratories that the Carrier would bundle the tests if the laboratories did not. "Medicare combines separately billed tests to the appropriate code and makes payment based on the allowed charge for the multi-channel code." The newsletter listed 23 tests subject to the bundling requirement, including CPK, GGT, and triglycerides.

Seven months later, the Michigan Carrier published another Medicare Part B Bulletin describing the unbundling requirements **(Tab C-19)**. The December 1995 Bulletin informed providers that CPT Code 80019, which previously referred to 19 or more clinical chemistry tests, had been supplemented with codes G0058, G0059, and G0060 for 20, 21, and 22 tests, respectively. The Bulletin stated that three additional tests were to be added to the list of tests considered to be automated for bundling purposes: cholesterol (83721), GGT, and triglycerides. While the newsletter said that these tests were *added* to the list, both GGT and triglycerides were already on the list published in the May 1995 Medicare Part B Bulletin, evidencing the Carrier's uncertainty about its previous bundling instructions to independent laboratories.

Similarly, in a May 1995 Medicare Part B Bulletin for Illinois, the Carrier stated that it would bundle tests, while at the same time asserting that it might be considered fragmenting if independent laboratories billed tests in an unbundled format **(Tab C-20)**. In language identical to the May 1995 Michigan Bulletin, the Carrier said that "itemizing charges for tests that can be part of an automated multi-channel test is considered fragmenting. Medicare combines separately billed tests to the appropriate code and makes payment based upon the allowed charge for the multi-channeled code." The second sentence indicates that codes are used to determine payment rather than billing. Finally, these newsletters listed 23 tests that were considered to be part of the bundling requirement, including CPK, GGT, and triglycerides.

In a Medicare Part B Bulletin for Illinois dated December 1995, the Carrier informed independent laboratories of the additional multichannel codes (G0058-G0060) **(Tab C-26)**. The laboratories were told that three additional tests were added to the multichannel test list -- cholesterol, GGT, and triglycerides -- and that there were three additional multichannel automated test codes (G0058-80060). The Bulletin gave no instructions, however, concerning the use of the new codes or additional bundling instructions.

In a November 1995 cover letter attached to a fee schedule, the Florida Carrier listed three additional tests that would be considered multichannel tests **(Tab C-25)**.[9] "Three tests are added to the list of tests which are considered automated tests. The additional tests are cholesterol, GGT and triglyceride." The letter noted that three additional profile codes had been created to accommodate the extra automated codes: G0058, G0059, and G0060 for 20, 21, and 22 automated laboratory tests, respectively. While this letter informed independent laboratories of the new codes and the new automated profiles, it did not state what should have been done with these codes.

Hematology issues are rarely addressed in Intermediary or Carrier newsletters, but they are discussed in some detail in a Medicare Part B Special Newsletter from the Oregon/Alaska Carrier dated September 1995 **(Tab C-27)**. It appears that the Carrier was trying to inform independent laboratories that hemogram indices would not be reimbursed. "Additional automated hemogram indices, one to three indices, or 85030, four or more indices will not be reimbursed. Such indices are a by-product of automation and will not be separately compensated." It is important to note that the newsletter did not say that indices should not be billed; it merely stated that they would not be reimbursed.

The newsletter also discussed how reimbursement would be made for platelet counts. First, the Carrier informed independent laboratories that they have some choices when billing platelet counts. "CPT codes 85023, 85024, or 85025, should be billed when a complete blood count with platelets is medically indicated." Second, the Carrier stated that, if there is no clear medical necessity for a test, then it would be automatically reduced to CPT code 85022 or denied. "If there is no clear medical indication for the platelet count, the CPT code will be reduced to 85022. If the complete blood count is not medically indicated, it will be denied." The bundling

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[9] The Wisconsin Carrier sent out an identical cover letter and fee schedule.

issue is also addressed, but it is referred to as a billing error. "If 85595 is billed together with 85023, 85024, 85025, 85027, it will be denied as a billing error." The newsletter did not indicate why this was a billing error, but given that codes 85023, 85024, 85025, 85027 refer to complete blood counts with platelets and code 85595 refers only to platelets, it could be redundant to bill for both.

Office of the Inspector General

The 1994-95 OIG Work Plan reiterated the OIG's intention to proceed with its investigation of outpatient laboratory tests. Contrary to previous pronouncements, the Work Plan did not indicate that the OIG's audit work in this area was completed. According to the Work Plan:

> Our review will be limited to clinical laboratory tests that measure the chemical and hematological composition of blood, two areas where an earlier OIG review disclosed significant overpayments. These overpayments occurred because the claims processing system of the contractor reviewed did not detect claims for chemistry tests that should have been grouped together for payment purposes. Further, the system did not detect duplicate claims for chemistry and hematology tests. These duplicate claims were for tests that were either claimed under more than one panel or claimed as part of a panel of tests and also as an individual test. Our review will determine if the same deficiencies exist at other fiscal intermediaries.

1994-95 OIG Work Plan (June 1994) **(Tab D-5)**. Once again, the focus was on the behavior of the payment agents -- *i.e.*, Intermediaries and Carriers -- not providers such as hospitals.

An Inspector General report from January 1995 provides further evidence of the OIG's continued interest in payment policies concerning outpatient laboratory tests. According to the report, HCFA guidelines require compliance with the CPT Manual, but "allow carriers to determine which additional tests should be added to carrier specific panel test lists." As a result, the OIG said that the purpose of its report was to "identify chemistry tests that should be paid as a panel but are not currently required to be paneled by HCFA." Specifically, the OIG recommended that HCFA:

- Update its guidelines by expanding the national list of chemistry panel tests to include the 10 automated chemistry tests identified by our audit. . . .
- Establish a process whereby advances in technology and laboratory practices are periodically reviewed to update the national panel test list.

In summarizing HCFA's response to the OIG's previous recommendations, the report stated that:

> This report is the fourth in a recent series concerning unbundled chemistry and hematology tests. Two of the prior reports involve compliance issues while the other relates to HCFA policy. In response to our prior reports, HCFA officials agreed to institute our recommendations and to work with [16]the OIG in correcting the findings regarding unbundled chemistry and hematology tests. In addition, HCFA has issued a nationwide critical task order to develop uniform system edits for laboratory services.

OIG, Review of Chemistry Tests Performed on Automated Laboratory Equipment (Jan. 1995) **(Tab D-6)**. Plainly, the OIG's primary concern was with the manner in which payments were made to providers, not the manner in which providers billed for outpatient laboratory tests.

Moreover, the OIG admitted in its 1995 Red Book, a compendium of OIG recommendations that have not yet been fully implemented, that there was no requirement to bundle outpatient laboratory tests for billing purposes. According to the 1995 Red Book:

> [T]he OIG [has] found that although prices on individual tests are being reduced by legislation, panels are still generally being billed as individual tests to Medicare. Medicare polices are not sufficient to control the billing of profile tests because *there is no requirement that the tests ordered as a panel by the physician be billed only as a panel.* The HCFA's guidelines do not address the problem of panels as a marketing mechanism of the laboratory industry nor the problem of the industry billing the contents of the panels individually. (Emphasis added.)

1995 OIG Red Book **(Tab D-7)**. Although the Red Book flatly states that there is no bundling requirement, the OIG mistakenly refers to profiles and panels interchangeably, evidencing its confusion concerning the bundling issue.

1996: CONTINUED CONFUSION CONCERNING BUNDLING

HCFA Guidelines

The Manuals uniformly presume that hospitals will bill claims separately (*i.e.*, not bundle claims). Intermediaries and Carriers are instructed how to evaluate such claims to determine whether they are properly paid as well as whether bundling is appropriate. The Manuals do not equate the submission of unbundled claims with fraud or false claims. Rather, hospitals are advised to anticipate adjustments by the Intermediary to ensure that the lesser of individual components or panels are paid for claims.

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[10] That OIG report refers to three other OIG reports, one is attached **(Tab D-4)**, but we have not yet been able to obtain the others.

Intermediary Manual, Part 3, §§ 3628.J and K discuss payment practices for automated laboratory tests and organ/disease panels **(Tabs B-4; B-1)**. According to these sections, which were implemented by Program Memorandum No. 1686:

> INT3 3628.J. Laboratory Tests Utilizing Automated Equipment. . . . While the component tests in automated profiles may vary somewhat from one laboratory to another, or from one physician's office or clinic to another, group together those profile tests which can be performed at the same time on the same equipment for purposes of developing appropriate payment allowances. *For Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests.* . . . [T]he above listed 22 tests are the only tests that you may group into automated profiles if they are billed separately.
>
> * * *
>
> Separately Billed Tests That Are Commonly Part of Automated Test Profiles. -- *If you receive claims for laboratory services in which the provider has separately billed for tests that are available as part of an automated profile test*, make the following determinations: If the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the profile that includes these tests, *make payment at the lesser amount for the profile*. Conversely, the payment allowance for a profile cannot exceed the payment allowances for the individual tests.
>
> * * *
>
> When one or more automated profile tests are performed for a patient on the same day, *determine whether to base payment on an automated profile that includes such tests rather than to base payment on the individual or separately billed tests*. (Emphasis added.)
>
> INT3 3628.K. Organ or Disease Oriented Panels. -- The following codes represent organ or disease panels that must be paid at the lower of the billed charge, the allowance for the panel or the allowance for the sum of the components. When panels contain 1 or more automated tests, determine the correct price for the panel by using the price for the automated profile plus the price for individual tests. Payment for the total panel may not exceed the allowance for individual tests. All Medicare coverage rules apply.

In April 1996, HCFA issued Program Memorandum No. AB-96-3, which informed Intermediaries and Carriers of a new "QP" modifier used to indicate whether automated multichannel tests are ordered individually or as part of a CPT-defined panel **(Tab B-31)**. HCFA also stated that use of the modifier was not mandatory:

> We have established a national HCPCS modifier that can be entered on a claim and will allow laboratories to attest that documentation exists to show that the ordering physician . . . ordered the test(s) individually or as a CPT -recognized panel. The modifier can be used for automated tests, i.e. 80002 through 80019, G0058, G0059, G0060.
>
> * * *
>
> HCFA has no requirement that laboratories use the modifier.

HCFA subsequently clarified the use of this new modifier in Program Memorandum No. AB-96-8, which described permissible uses of the modifier **(Tab B-32)**. According to the Memorandum:

> The modifier cannot be used with automated profile codes 80002 through 80019, G0058, G0059, G0060, *unless* the laboratory has documentation showing that the component tests included under those codes were ordered individually by the physician. In this case, the *laboratory* bundles the tests into the correct CPT code (i.e., CPT 80002-80019, G0058-G0060) for billing purposes and may report the QP modifier with the automated profile code. (Emphasis in original.)

Carrier Manual, Part 3, § 14001 was also updated in 1996 to state that Carriers are responsible for detecting, deterring, and preventing a provider's "Unbundling or 'exploding' charges, e.g., the billing of a multichannel set of lab tests to appear as if the individual tests had been performed" **(Tabs B-37; B-36)**. This statement is an oversimplification because, in using automated multichannel equipment, hospitals are performing individual tests, albeit as part of a group (profile) of individual tests. HCFA's difficulty with this concept may relate to the rapid pace of technological changes occurring in laboratories.[11]

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[11] Hospital Manual § 437.J was also revised, effective October 4, 1996, to state that "no distinction is generally made in determining payment [presumably between tests performed manually and those performed on automated testing equipment] because of the numerous technological advances and innovations in the clinical laboratory field and the increased availability of automated testing equipment to all entities that perform clinical diagnostic testing" **(Tabs B-27; B-25)**.

In 1996, there was a significant change in Hospital Manual § 437.J. From at least 1989 to the 1996 revision, Hospital Manual § 437.J stated that clinical laboratory tests would be reimbursed if they were reasonable and necessary, and instructed hospitals to use CPT-4 codes until national guidelines are developed regarding what tests are available in automated batteries **(Tab B-27)**.

According to the old version of Hospital Manual § 437.J:

> Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. In the case of multi-channel automated and/or batch automated (e.g., SMAC, CHEMICAL PROFILES, ASTRA) laboratory determinations, however, the physician may not be free to specify the tests the patient needs and there is normally only one charge for the battery of tests. The delivery of the service in this manner is much more economical than if the tests are performed individually. National guidelines for contractors on what tests are available in automated batteries are being developed. Until completed, use codes found in CPT-4 or sent to you by your intermediary.

In 1996, however, this section was revised to state that profile tests should be grouped together *for payment purposes* and that claims for laboratory services would be paid "at the lesser amount of the profile" **(Tabs B-27; B-25)**.

According to the new version of Hospital Manual § 437.J:

> HOSPT 437.J. Laboratory Tests Utilizing Automated Equipment. . . . While the component tests in automated profiles may vary somewhat from one laboratory to another or from one physician's office or clinic to another, group together those profile tests which can be performed at the same time on the same equipment *for the purpose of developing appropriate payment allowances*. For Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests. . . .
>
> * * *
>
> Separately Billed Tests That Are Commonly Part of Automated Test Profiles. -- *If you receive claims for laboratory services* in which the provider has separately billed for tests that are available as part of an automated profile test, make the following determinations: If the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the profile that includes these tests, *make payment at the lesser amount*

> *for the profile*. Conversely, the payment allowance for a profile cannot exceed the payment allowances for the individual tests.[12] (Emphasis added.)
>
> * * *
>
> When one or more automated profile tests are performed for a patient on the same day, determine whether to base payment on an automated profile that includes such tests rather than to base payment on the individual or separately billed tests. . . .

The Hospital Manual presupposes that hospitals will bill for individual tests, but states that, for payment purposes, Medicare considers many of the tests to be automated profiles. In some instances, however, the Hospital Manual quotes language directly from the Intermediary Manual, causing confusion. The above-quoted language from Hospital Manual § 437.J illustrates this confusion because hospitals do not "receive claims for hospital services" and, therefore, cannot "base payments" on claims received **(Tabs B-27; B-25)**.

Other parts of Hospital Manual § 437 discuss billing requirements for outpatient laboratory tests, but also place responsibility on Intermediaries to determine the proper payment rate **(Tabs B-27; B-25)**. According to this section:

> HOSPT 437. Billing For Clinical Diagnostic Laboratory Services Other than To Inpatients. Clinical diagnostic laboratory tests are paid on the basis of fee schedules.
>
> * * *
>
> Individual laboratory tests are identified using the HCFA Common Procedure Coding System (HCPCS) codes and terminology.
>
> * * *
>
> HOSPT 437.D. Billing for Diagnostic Lab Tests. Follow requirements for submission of the HCFA-1450 in 460 [sic]. Use revenue code 30X or 31X when billing lab services subject to the fee schedule.
>
> * * *

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12 This language also appears in Intermediary Manual, Part 3, § 3628, which addresses payment of claims by Intermediaries.

> Do not submit separate bills for laboratory tests performed in different departments on the same day. . . .
>
> * * *
>
> HOSPT 437.H. Adjusted Fee Schedule. Where these adjusted fee schedule tests are part of disease or organ panels, *your Intermediary must assure that the fee for the panel does not exceed the sum of the fees for the individual components* after accounting for the reductions due to the adjustment.
>
> * * *
>
> HOSPT 437.K. Organ or Disease Oriented Panels. -- The following codes represent organ or disease panels that *must be paid* at the lower of the billed charge, the allowance for the panel or the allowance for the sum of the components. When panels contain 1 or more automated tests, determine the correct price for the panel by using the price for the automated profile plus the price for individual tests. Payment for the total panel may not exceed the allowance for individual tests. All Medicare coverage rules apply. . . . (Emphasis added.)

Intermediary and Carrier Newsletters

In 1996, the confusion and misapplication of the guidelines concerning multichannel tests by HCFA and the OIG was matched by Intermediaries and Carriers. While bundling edits were supposed to have been installed in 1994 and 1995, the focus in 1996 shifted from bundling to medical necessity. Intermediaries informed hospitals that every test in a multichannel profile (80002-80019) must be medically necessary.[13] This changed the prior rule that only one test in a profile had to be medically necessary. Further, some Intermediaries continued to give vague instructions concerning which tests must be bundled and whether bundling is a billing or a reimbursement requirement. The list of tests subject to the bundling requirement continued to change throughout 1996 as well.

In an Information Bulletin dated December 4, 1996, the Oklahoma Intermediary described which tests were considered automated multichannel tests and informed hospitals that the Intermediary would bundle the laboratory tests **(Tab C-62)**. The Oklahoma Intermediary explicitly stated that automated multi-channel tests could be billed separately:

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[13] This new guideline was probably based on HCFA's realization that, whereas earlier types of equipment were only capable of preforming a predetermined number of tests, automated multichannel equipment is capable of performing any combination of individual tests. As a result of this advancement in technology, HCFA could determine the medical necessity of each test. See fn. 10.

> For Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests. While laboratory entities may bill additional tests using automated profile codes, the above listed 22 tests are the only tests that will be grouped into automated profiles if they are billed separately. Future revisions to this list will be made through manual revisions.
>
> Separate payment will not be allowed to be made for multiple automated profile codes.
>
> * * *
>
> EXAMPLE: Codes 80007 and 80009 are billed on the same claim form for the same date of service. Payment will only be allowed for code 80009. Code 80007 will not be paid since it contains a lower number of tests. If a laboratory performs 16 automated tests on the same date, code 80016 *or each of the individual test codes should be billed in order for proper payment to be made*. If an error, for example, codes 80007 and 80009 are billed with the same date of service, only code 80009 will be paid. In order to make proper payment, in this case, the provider will submit an adjustment canceling code 80009 and resubmit as code 80016. (Emphasis added.)

In a Medicare Part A Bulletin dated August 30, 1996, the Florida Intermediary noted that HCFA had changed its instructions regarding the billing of automated multichannel profiles to require all tests in the profile to be medically necessary **(Tab C-32)**. "The revised HCFA instructions *require that all tests in an automated profile be medically necessary* and is a change from the former policy which allowed all tests to be paid as long as at least one was medically necessary." (Emphasis in original.)

This Bulletin listed 22 tests subject to the bundling requirement and characterized the requirement as a payment guideline. "Separate payment will not be allowed to be made for multiple automated profile codes performed on the same day." Three paragraphs later, however, the Bulletin stated that "for Medicare payment purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests." This appears to make bundling a billing and not a payment issue. The Bulletin also stated that tests that are not bundled "will be grouped into automated profiles." By referring to bundling as both a payment issue and a billing issue, it remains unclear who is responsible for bundling.

The issue of medical necessity also arose frequently in Intermediary pronouncements from South Carolina during 1996. In a South Carolina Medicare Advisory dated September 1996, the Intermediary informed hospitals that HCFA had amended the Carrier Manual and would make similar changes to the Intermediary Manual as of October 1, 1996 **(Tab C-33)**. The

Intermediary noted that one important change was that all tests in an automated profile must be medically necessary, whereas the previous rule was that only a single test in a profile must have been necessary. "The requirement that all tests in the automated profile be medically necessary is a change from the former policy that allowed all [profile] tests to be paid as long as at least one was medically necessary." The Advisory also noted that local policy had not been developed regarding bundling of the 22 multichannel tests and that the Intermediary did not expect to scrutinize the billing of these automated profile tests:

> Most of the local policies developed to date do not address those tests included in the list of 22 that can be billed using automated profile codes. Therefore, we do not expect that automated profile billing will be systematically scrutinized unless unusual patterns of billing are detected. We expect most contractors will monitor the use of consistent patterns of billing for 19 through 22 automated tests.

This newsletter shows that the Intermediary was more concerned about medical necessity than about bundling requirements.

In a South Carolina Medicare Advisory dated August 1996, the Intermediary reminded hospitals of Medicare's concern about the medical necessity of multichannel tests **(Tab C-34)**. The Intermediary told hospitals of a new "QP" modifier used to indicate whether multichannel tests are ordered individually or as part of a CPT-defined panel. (See the discussion concerning the introduction of this modifier in the section of this report on HCFA Guidelines for 1996.) The use of this modifier apparently was an attempt to have multichannel tests ordered individually, thus insuring that they were medically necessary. It also reflects the Intermediary's competing concerns regarding the bundling of multichannel tests. While it appears that the Intermediary wanted the tests to be bundled, it also appears that the Intermediary wanted the tests to be ordered individually. These kinds of conflicting views added to the confusion over bundling requirements.

Also in 1996, the Virginia Intermediary issued instructions relating to billing for hematology tests. In a Medicare Update dated January 1996, the Intermediary informed hospitals that, effective February 26, 1996, all claims for hematology indices (85029 and 85030) would be denied. "Effective *February 26, 1996*, all *85029* and/or *85030* laboratory services would be denied" **(Tab C-37)** (emphasis in original). This instruction apparently reflects a refinement in the Intermediary's understanding of hematology indices. It also reflects the Intermediary's understanding that it is the Intermediary's responsibility to deny claims rather than to instruct hospitals not to bill for claims.

Carriers also addressed the medical necessity issue in 1996. In an Illinois Medicare Part B Bulletin dated March 1996, the Carrier noted that there were 22 tests subject to the bundling requirement and stated that the tests would be grouped together automatically by the Carrier **(Tab C-28)**. "The 22 tests listed below are the only tests that will be grouped into automated panels if they are billed separately." In a Medicare Part B Bulletin dated December 1996,

however, the same Carrier listed 23 multichannel tests subject to the bundling requirement and informed independent laboratories that claims for unbundled tests may be denied **(Tab C-29)**. "Medicare reimbursement may be denied for blood chemistries that can be billed as part of an automated multi-channel panel, but are billed separately." The Carrier also noted that "Itemizing charges for blood chemistries included in such panels is considered fragmenting and possibly fraudulent." It is unclear why the Carrier said it would bundle in March 1996, and then said that it would deny claims that were not bundled in December 1996. This may be because the Carrier did not actually have the required edits in place.

In a January/February 1996 Communique, the Wisconsin Carrier reviewed automated multichannel bundling requirements **(Tab C-30)**. This review was done in the context of informing independent laboratories that the bundling requirements had changed. With respect to blood chemistries, the Communique listed 22 tests that would be bundled together under the multichannel panels. The Communique indicated that the Carrier would bundle claims, but also stated that "For Medicare purposes, the tests on this list must be grouped together when billed separately and considered automated profile tests." This language makes it unclear whether the Carrier wanted the tests to be listed together so that the Carrier would bundle them or whether the Carrier wanted the bundled code to be used. The Communique indicated that bundling was a payment issue, not a billing issue. "In no event, however, may payment for the covered tests exceed the payment allowed for the profile." The Communique devoted an entire section to "Separately Billed Tests That are Commonly Part of an Automated Battery Tests." It explained what would happen if tests were billed separately:

1. Payment will be based on the battery which includes these tests. Reimbursement for a battery of tests will not be higher than the reimbursement which would have been made if the tests were paid separately.

2. When one or more tests are performed on a patient on the same day, payment will be based on the lesser of the reimbursement for the automated battery (panel) which includes these tests or the reimbursement for the individual or separate billed tests.

The Florida Part B Carrier also comprehensively reviewed the requirements for multichannel tests in a Special Issue published sometime after May 1996 **(Tab C-31)**. The Special Issue was based upon a HCFA determination that, in Florida, multichannel profiles had been billed in substantially greater quantities than in the rest of the country. It listed 22 tests subject to the automated multichannel bundling rules, and it examined each component test in detail, explaining when each component was medically necessary. The Special Issue focused on the medical necessity of each of the component tests. Remarkably, the 13-page Special Issue does not contain any directions regarding bundling requirements.

While some Intermediaries and Carriers provided detailed instructions relating to multichannel tests, others gave only abbreviated instructions. In a Medicare Memo dated February 1996, the

Wisconsin Carrier informed independent laboratories about bundling requirements in very general terms **(Tab C-35)**. In this Memo, the Carrier stated that, as of January 1, 1996, three new tests would be added to the list of tests considered to be automated: CPK, GGT, and triglycerides. The Memo also informed laboratories that there were three new automated multichannel test codes: G0058, G0059, and G0060. Other than stating that these new codes existed, the Carrier gave no instructions on how the codes should be used.

In a July 1996 Communique, the Wisconsin Carrier further informed independent laboratories that they needed to submit a single claim for all multichannel tests and that the tests could not be reported on different forms **(Tab C-36)**. Presumably, this was because the unbundling edits would not work if the tests were reported on different forms. "Because [multichannel] tests are being billed on separate claims, they are not being combined and reimbursed at the multi-channel test allowance. If this is being done to circumvent payment for the multi-channel test, we consider this fraudulent billing." It appears that the Carrier believed that it had adequate edits in place to process multichannel tests listed together on the same bill. Rather than requiring them to use bundled CPT codes, the Carrier instructed the laboratories to bill for multichannel tests on the same form. The laboratories could interpret this instruction as permission to bill for multichannel tests with separate codes.

In a Medicare Part B Update dated November/December 1996, the Florida Carrier noted that it had failed to include three codes in a list of tests that it considered to be automated multichannel tests, saying that the list should have included albumin, carbon dioxide content, and chloride **(Tab C-38)**.

Office of the Inspector General

During 1996, OIG pronouncements concerning outpatient laboratory tests were similar in content and tone to its earlier pronouncements, but especially focused on the reimbursement policies of state Medicaid programs.

According to the 1996 Red Book, the OIG's reviews of outpatient laboratory tests disclosed that:

> State agencies are reimbursing providers for laboratory services which exceed the Medicare limits or were duplicated for payments [sic] purposes. In addition, it was determined that these overpayments are occurring because the State agencies do not have adequate computer edits in place to prevent the payment of unbundled or duplicated claims for chemistry, hematology, or urinalysis tests. [As a result] The respective State agencies should install edits to detect and prevent payments that exceed the Medicare limits and billings which contained duplicative tests, recover overpayments for clinical laboratory services identified in each of the reviews, and make adjustments for the Federal share of the amounts recovered by the State agencies.

1996 OIG Red Book (Jan. 1996) **(Tab D-8)**.

Similarly, the 1996 Work Plan stated that "We will review the adequacy of procedures and controls over the payment of Medicaid claims which contain clinical laboratory tests to determine whether chemistry, hematology, and urinalysis tests were either appropriately grouped together (bundled into a panel) or not otherwise duplicated for payment purposes." 1996 OIG Work Plan (Jan. 1996) **(Tab D-9)**.

A more specific example of the OIG's concern for the practices of payors, as opposed to providers, was the OIG's effort to work with state Medicaid agencies to remedy perceived deficiencies in their payment programs. For example, the OIG developed a partnership plan to help the Massachusetts Division of Medical Assistance ("DMA") determine the "adequacy of procedures and controls over the processing of Medicaid payments for clinical laboratory services." The OIG added that it was satisfied that HCFA could rely on the audit in meeting its program oversight responsibilities.

According to the report:

> The Massachusetts State auditors found that the DMA did not have adequate controls to ensure proper payment of chemistry, hematology, and urinalysis claims when more than one test was performed on the same day on behalf of a Medicaid recipient. In this regard, the DMA's payment process did not detect claims for chemistry and urinalysis tests that should have been grouped together (bundled into a panel) for payment purposes. . . . Specifically, we found that DMA's payment process did not detect claims for chemistry and urinalysis tests that should have been grouped together . . . .

As a result, the auditors recommended that the DMA:

- Undertake a review of its claims processing system to determine the type of edits that are necessary to prevent the inappropriate payment of Medicaid claims.
- Oversee the development and implementation of the identified edits.
- Undertake a review of claims paid for chemistry, hematology, and urinalysis testing for the period between the end of the audit period and the present.
- Identify and recover all overpayments that have been made to providers for clinical laboratory services. . . .

The report stated that the DMA was in general agreement with the OIG's recommendations, but also noted that the DMA had concerns about the OIG's methodology, which could affect its

monetary findings. Office of Inspector General's Partnership Plan -- Massachusetts State Auditor's Report on Medicaid Payments for Certain Clinical Laboratory Tests (Feb. 12, 1996) **(Tab D-10)**.

The OIG's reports for California, Illinois, Missouri, North Carolina, Ohio, and Virginia came to similar conclusions and made similar recommendations. In summarizing its initiatives at the state level, the OIG stated that:

> Our audit of Medicaid claims for outpatient clinical laboratory services in 14 States disclosed that the Medicaid State agencies did not have adequate controls to detect and prevent inappropriate payments for laboratory tests. . . . This included potential overpayments for hematology profiles and indices that were duplicated or may have been medically unnecessary.

The OIG's response was to recommend that state agencies:

> (1) install system edits and controls to detect and prevent the types of errors disclosed in our audit (2) recover the Medicaid overpayments for clinical laboratory services identified in our audit, and (3) reimburse the Federal Government for its share of any recoveries made by the State agency. . . . We are also recommending that the Health Care Financing Administration (HCFA): (1) reemphasize the Medicaid requirement that State agency payments for outpatient clinical laboratory services not exceed the amounts recognized by Medicare for the same services, (2) consider having State agencies update their provider billing instructions to reflect Medicare bundling procedures, and (3) follow-up on the estimated $27.4 million ($15.7 million Federal share) in potential overpayments identified in our audits to ensure that the State agencies have implemented needed edits, initiated recovery actions, and credited the Federal Government for its share of any recoveries.

The report went on to note that:

> Regarding our second recommendation, HCFA plans to advise Medicaid State agencies that they should consider using the Medicare bundling procedures for the chemistry, hematology, and urinalysis tests examined in the OIG audit. However, *HCFA will not tell the State agencies that they must use Medicare bundling procedures for other types of laboratory tests or medical services as long as they stay within the Medicare upper limit for payments* and are consistent with the principles of efficiency, economy, and quality of care. (Emphasis added.)

OIG, Medicaid Payments for Clinical Laboratory Tests in 14 States (Dec. 1996) **(Tab D-11)**. Although this report concerns state Medicaid agencies, it is noteworthy in illuminating the disagreements between HCFA and the OIG concerning bundling requirements.

At the end of 1996, the OIG reiterated the finding made in the 1995 Red Book concerning the absence of any requirement to bundle outpatient laboratory tests for billing purposes. According to the 1996 Red Book:

> [T]he OIG [has] found that although prices on individual tests are being reduced by legislation, panels are still generally being billed as individual tests to Medicare. Medicare polices are not sufficient to control the billing of profile tests because *there is no requirement that the tests ordered as a panel by the physician be billed only as a panel.* The HCFA's guidelines do not address the problem of panels as a marketing mechanism of the laboratory industry nor the problem of the industry billing the contents of the panels individually. (Emphasis added.)

1996 OIG Red Book (Jan. 1997) **(Tab D-12)**.

1997: CONFLICTING INSTRUCTIONS AND PROJECT BAD BUNDLE

Federal Laws and Regulations

In response to the perceived Medicare financing crisis in 1997, Congress instructed the Secretary to, among other things, make significant changes in the overall system of payment for laboratory tests in the Balanced Budget Act ("BBA") of 1997, Pub. L. No. 105-33 §§ 4553-54, 111 Stat. 460-61 (1997) (to be codified in scattered sections of 42 U.S.C.). The BBA mandates that the Secretary implement improvements in the administration of laboratory test benefits, including a requirement that the Secretary adopt "national coverage and administrative polices" for the payment of outpatient laboratory tests.[14] Each of these directives highlights the lack of uniformity in the current system for the payment of laboratory services.

Congress recognized that "[s]ignificant variations exist among carriers in rules governing requirements labs must meet in filing claims for payments." H. Rep. No. 105-149, at 734 (1997). In response to the noted disarray of the current system, Congress directed the Secretary to conduct a "review of the adequacy of the current methodology and make recommendations regarding alternative payment systems ." Pub. L. No. 105-33, § 4553, 111 Stat. 460, *reprinted in* 42 U.S.C.S. § 1395*l* (Supp. 1997) (History; Ancillary Laws and Directives (Study and Report

[14] In addition, Congress required that the Secretary develop a prospective payment system for all outpatient hospital services. The system is to be implemented by January 1, 1999. Payment for hospital laboratory services will be included in the prospective rate. 42 U.S.C.S. § 1395*l*(t) (Supp. 1997).

on Clinical Laboratory Tests)) **(Tab A-9)**. The Secretary's study also "must analyze and discuss the relationship between such payment systems and access to high quality laboratory tests for Medicare beneficiaries, including availability and access to new testing methodologies."

In addition to the study, Congress ordered the Secretary to adopt and implement a uniform payment system. Under this directive, the Secretary must divide the country into no more than five regions and designate a single Carrier for each region. Moreover, the Secretary must adopt "national coverage and administrative policies for clinical diagnostic laboratory tests . . . using a negotiated rulemaking process." Pub. L. No. 105-33, § 4554 (1997), 111 Stat. 460, 461, *reprinted in* 42 U.S.C.S. § 1395u (Supp. 1997) (History; Ancillary Laws and Directives (Improvements in Administration of Laboratory Tests Benefit)) **(Tab A-10)**. The policies must:

> promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory tests payable under [Part B] in connection with:
>
> * * *
>
> (C) The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.
>
> * * *
>
> (F) Procedures for filing claims and for providing remittances by electronic media.

If the Secretary proposes a payment system incorporating specific federal laws and regulations governing the billing practices of hospitals for outpatient laboratory tests, such a system would mark a significant departure from the variety of informal instructions that comprise the current payment system.

On October 29, 1997, HCFA's Unified Agenda, published in the *Federal Register*, set a September 1998 deadline to publish in final form a regulation regarding the payment of laboratory tests and the creation of a fee schedule for such tests. Payment for Clinical Diagnostic Laboratory Tests, 62 Fed. Reg. 57514 (1997) **(Tab A-11)**. The notice of the proposed rulemaking was published in the *Federal Register* in 1993. The final regulation would replace informal processes currently employed to implement Congress's mandate in the Deficit Reduction Act of 1984 that the Secretary adopt fee schedules for the payment of laboratory tests.

HCFA Guidelines

In March 1997, HCFA announced that it would again change the billing and reimbursement guidelines for automated multichannel tests in Program Memorandum AB-97-5 **(Tab B-33)**. HCFA decided to discontinue the use of automated profiles (CPT codes 80002-80019, G0058-G0060) and to require hospitals to bill all laboratory tests individually, unless they are part of a

CPT-defined panel. In short, unbundling would be required. To facilitate this change, HCFA announced the creation of four new panels:

> New laboratory panels were approved by the American Medical Association (AMA) Current Procedural Terminology (CPT) Board at their November 1996 meeting. CPT codes for these new laboratory panels will not be available for use until January 1, 1998.
>
> The Health Care Financing Administration (HCFA) has decided to permit billing now on the basis of the new laboratory panels and has established temporary codes to be used effective April 1, 1997 until December 31, 1997. On January 1, 1998, the new CPT codes become effective. The new laboratory panels are as follows:
>
> * * *
>
> G0095 Hepatic Function Panel A (with Bilirubin, total and direct)
>
> * * *
>
> G0096 Basic Metabolic Panel
>
> * * *
>
> G0097 Electrolytes Panel
>
> * * *
>
> G0098 Comprehensive Metabolic Panel

In Program Memorandum AB-97-5, HCFA also established an interim billing policy, effective April 1, 1997 through March 31, 1998 **(Tab B-33)**. Under this policy, hospitals may continue to bill using the old profile codes (80002-80019, G0058-G0060), or they may bill using the new panel codes. If a hospital decides to use the new codes, then it has to individually bill for all tests that are not part of a CPT-defined panel. A hospital cannot, however, mix the new codes with the old codes:

> [I]f additional automated tests are performed along with any one (or more) of the new automated profile codes, the laboratory may use only one of the following billing options:
>
> Option No. 1 Use the new, automated profile-type, panel codes (G0095-G0098) and, as needed, other CPT disease and organ

> panel codes and individually listed codes of any additional automated tests performed (i.e., each additional test would be a separate line item using its appropriate CPT code). Do *not* use CPT codes 80002-80019 or G0058-G0060.
>
> Option No. 2 Use the current codes (i.e., the automated multichannel procedure codes (80002-80019 and G0058-G0060) and any other current CPT codes. Do *not* use the new automated profile codes G0095-G0098.
>
> HCFA would strongly encourage laboratories to bill using Option No.1 as soon as possible since effective January 1, 1998, this will be the only method by which laboratories will be allowed to bill these tests. Beginning January 1, 1998, the CPT codes 80002-80019 and G0058-G0060 will not be usable as billing codes but the payment amounts associated with pricing of these automated profiles will continue. For example, *if two automated profile tests are performed, the individual codes for the two automated tests must be billed instead of code 80002.* (Emphasis added.)

Under the new system, HCFA has instructed hospitals to bill in an "unbundled" fashion even though Intermediaries and Carriers use the profile codes for payment purposes. In addition, HCFA has continued to clearly place responsibility for bundling on Intermediaries and Carriers:

> For pricing, you [*i.e.*, Intermediaries or Carriers] will sum (count) the number of automated profile tests billed and payment will be at the same rate as the former code 80002. HCFA will continue to provide updated pricing for the deleted profiles of automated tests (i.e., 80002-80019 and G0058-G0060). Permanent codes will be provided by CPT for the new laboratory panels. The effective date of the permanent codes will be January 1, 1998.

Program Memorandum AB-97-17, published in September 1997, clarifies the new guidelines **(Tab B-34)**. This Memorandum also explains how Intermediaries and Carriers should process claims. In Attachment 3 the Program Memorandum, HCFA stated that under the new guidelines, *hospitals were not required to bundle at all*:

> Q4. Must laboratories use the new codes whenever possible?
>
> A4. No. The new automated profile codes are provided as a convenience for billing. *If a laboratory chooses, it can bill each of the component tests of these profiles individually.* (Emphasis added.)

Thus, the Memorandum clearly permits hospitals to bill the components of an organ/disease panel separately.

The use of these new billing guidelines originally was intended to become mandatory on January 1, 1998, but in December 1997, HCFA postponed the effective date of the guidelines in Program Memorandum AB-97-23 **(Tab B-35)**. According to the Program Memorandum:

> HCFA will allow a three month grace period beginning January 1, 1998 in which laboratories may continue to use the former codes. Claims for laboratory services performed after March 31, 1998 using codes 80002-80019 or G0058-G0060 should be rejected.

These recent HCFA publications tell hospitals that, effective April 1, 1998, they are required to bill all chemistry tests separately, unless the tests make up a CPT-defined panel. If the codes comprise a panel, then hospitals can choose to use the individual codes or the panel code. Under these guidelines, hospitals are required to "unbundle" all tests that are not part of an organ/disease panel.

Intermediary and Carrier Newsletters

Considering that Hospital Manual § 437.J was amended in late 1996, one would expect that this amendment would be reflected in newsletters sent to hospitals in 1997. That was not always the case. Many Intermediaries informed hospitals that existing guidelines would remain in effect, while others focused on recasting unbundling as a billing issue rather than a reimbursement issue. Additionally, the amount of correspondence related to hematology tests increased. Finally, Intermediaries informed hospitals, apparently for the first time, that the failure to bundle laboratory claims may be a violation of the False Claims Act.

Some payment organizations, however, began characterizing bundling requirements as billing issues rather than payment issues. An example of this shift in position is contained in the notes from a 1997 Hospital Workshop sponsored by the South Carolina Part A Intermediary concerning the new version of Hospital Manual 437.J **(Tab C-43)**. According to the notes:

1. All tests in an automated profile must be medically necessary to be billed to Medicare.

2. Allowance for panel versus allowance for sum of tests ordered.

3. The fiscal intermediary may no longer bundle tests billed separately.

4. The laboratory is held accountable since they are the entity which receives reimbursement from Medicare.

These statements indicate that the South Carolina Intermediary was shifting the responsibility for bundling claims from itself to hospitals. Prior to 1997, the South Carolina Intermediary consistently said that it would bundle claims on behalf of hospitals and, therefore, its departure from that position in 1997 is significant.

Possibly the first time an Intermediary or Carrier expressly suggested that unbundling may be considered a violation of the False Claims Act appears to be a South Carolina Medicare Advisory dated May 1997 **(Tab C-44)**. In that publication, the Intermediary informed hospitals of Medicare Fraud Alert OIG 97-01, which referred to an investigation into laboratory billing irregularities in Ohio under the False Claims Act. (See the section of this report on the Office of the Inspector General for 1997.) The Advisory did not give a specific explanation of what was considered fraudulent, but merely informed hospitals of the OIG's investigation.

In 1997, many Carriers simply repeated their prior instructions concerning multichannel tests, thereby indicating that there had been no change in how those claims would be processed. In an update to the Montana Medicare Part B Policy Billing Manual dated September 12, 1997, the Carrier informed independent laboratories that they should group tests together and, if they did not, the Carrier would bundle the tests automatically **(Tab C-39)**. "*For Medicare payment purposes*, the tests on the list below must be grouped together and submitted as an automated panel, rather than separately submitted. If tests are not grouped together, this Carrier will group the tests and reimburse for an automated service." (Emphasis added.) The Billing Manual then listed the same 22 tests that the Carrier had previously listed. The Billing Manual did note, however, that all tests in an automated profile must be medically necessary.

In a similar manner, the Wisconsin Part B Carrier repeated its prior instructions relating to multichannel tests in a Communique dated July 1997 **(Tab C-40)**. This Comminque listed the same 22 tests that had previously been listed and then repeated the same directions relating to the bundling of laboratory charges that appeared in its January/February 1996 Communique.

Likewise, a Medicare Part B Provider Handbook for Michigan dated December 1997 repeated the Carrier's previous instructions concerning bundling **(Tab C-41)**. The Handbook listed 23 tests considered to be automated tests and then stated that Medicare would combine the tests if independent laboratories did not. "Medicare combines separately billed tests to the appropriate code and makes payment based upon the allowed charge for the multi-channel code." The Manual also stated that "[i]temizing charges for tests that can be part of an automated channel test is considered fragmenting." As in the past, however, the Carrier did not clarify who was primarily responsible for bundling.

Not all Intermediaries and Carriers had effective edits in place in 1997 to properly bundle claims. In a Medicare Memo dated February 14, 1997, the Wisconsin Part B Carrier informed independent laboratories of its "Artificial Intelligence" system, which apparently was used to insert edits and bundle claims **(Tab C-42)**. The Memo listed the edits that were in place. For example, it listed an edit for complete blood counts (CBC), and noted that it would automatically reject any blood indices such as CPT Codes 85029 and 85030. It did not, however, list a specific

edit for multichannel tests. Based on this Memo, it appears that there were no bundling edits in place at the time.

Instructions related to hematology billing also increased in 1997. A Medicare Part B Bulletin for Michigan dated February 1997 included instructions about the processing of complete blood count (CBC) tests **(Tab C-45)**. The Bulletin noted that CBC tests are often performed on automated equipment and expressed concern that "CBCs are often ordered when only one element of the CBC is necessary. Moreover, the CBC is commonly ordered when only one count in a CBC is indicated."

The Bulletin listed the different types of blood counts and the related CPT codes without giving a detailed description of how each one was different. It also noted that "CPT codes 85029 and 85030 for additional automated hemogram indices *are not reimbursable* as they are computerized calculations. Medicare *does not pay* for manual or automated calculations of percentage, ratio or distribution." (Emphasis in original.)

The Bulletin also noted that when a combination of blood tests are performed, the combination codes should be used rather than a multiple set of individual codes. "When there is a combination code that describes the test performed, then that code must be used rather than multiple separate codes. For example, when a hemogram, manual leucocyte differential and automated platelet count are performed, use code 85023, instead of codes 85007, 85021 and 85595." This appears to be the first published instruction that hematology tests must also be bundled.

Other Carriers, however, did not specify a similar hematology bundling requirement. In a Florida Medicare Part B Update dated July/August 1997, the Carrier informed independent laboratories that hematology indices were not reimbursable **(Tab C-46)**. "Both procedure codes 85029 and 95030 are not reimbursable as they are computerized calculations. This policy change is effective for series rendered August 18, 1997." From this language, it appears that, prior to August 1997, independent laboratories could bill for additional computerized indices. The Update went on to describe situations in which CBC tests are medically necessary. It does not describe any bundling requirements related to hematology.

CBC tests were also discussed in the Montana Medicare Part B Alpha Policy Billing Manual, which was published on July 14, 1997 **(Tab C-47)**. After a lengthy discussion of CBC tests and when they are medically necessary, the Manual stated that automated indices are not reimbursable. "Additional automated hemogram indices [85029 and 85030] will not be reimbursed." The Manual does not give any indication that hematology tests must be bundled.

In late 1997, Carriers and Intermediaries began telling hospitals about HCFA's new guidelines regarding the use of automated profiles codes. Medicare Northwest, the Oregon Intermediary, informed hospitals that multichannel codes were being eliminated in a Medicare Bulletin dated December 1997 **(Tab C-48)**. According to the Bulletin:

> Multi-channel codes -- codes 80002-80019 and G0058-G0060 are deleted from the 1998 HCPC/CPT coding. However, HCFA will allow a 3-month grace period beginning January 1, 1998 for the use of these codes. Claims for services performed after March 31, 1998 using these codes will be rejected.

In a supplemental mailing also dated December 1997, Oregon hospitals were told what to do in lieu of using the multichannel codes **(Tab C-49)**. The Oregon Intermediary informed hospitals of the new panels and told them that, under the new guidelines, they had to bill some tests individually:

> If you are performing some, but not all, of the tests in the panel, the tests should be listed individually.
>
> * * *
>
> The automated profile codes are provided as a billing convenience only. If a laboratory chooses, it can bill each of the component tests of the profile individually.

The Utah Intermediary informed hospitals of the new billing guidelines in a December 2, 1997 Memorandum **(Tab C-50)**. This Memorandum was virtually a word-for-word reiteration of HCFA's Program Memorandum AB-97-5, but hospitals were informed of the new panels and told that they were not required to bundle laboratory claims:

> If a laboratory has a custom panel that includes other tests, in addition to those in the defined CPT or HCPCS panels, the additional tests, whether on the list of automated tests or not, are billed separately in addition to the CPT or HCPCS panel code if any of the CPT or HCPCS panel code(s) is/are billed.
>
> * * *
>
> The new automated profile codes are provided as a convenience for billing. If a laboratory chooses, it can bill each of the component tests of these profiles individually.

Office of the Inspector General

The OIG began 1997 where it left off in 1996 -- apparently frustrated in its efforts to reform the payment system to its satisfaction. Moreover, the OIG reiterated the finding contained in the 1995 and 1996 Red Books concerning the absence of any requirement to bundle outpatient laboratory tests for billing purposes. According to the 1997-98 Red Book:

> [A]lthough prices on individual tests are being reduced by legislation, panels are still generally being billed as individual tests

> to Medicare. Medicare polices are not sufficient to control the billing of profile tests because *there is no requirement that the tests ordered as a panel by the physician be billed only as a panel.* The HCFA's guidelines do not address the problem of panels as a marketing mechanism of the laboratory industry nor the problem of the industry billing the contents of the panels individually. (Emphasis added.)

The same document said that state Medicaid agencies are reimbursing providers for laboratory services in excess of Medicare limits and stated that "These overpayments are occurring because the State agencies do not have adequate computer edits in place to prevent the payment of unbundled or duplicated claims for chemistry, hematology, or urinalysis tests." 1997-98 OIG Red Book **(Tab D-13)**.

Similarly, the 1997 Work Plan indicated that a follow-up review of the payment policies of Intermediaries would be undertaken, but also stated that the review would focus on the billing practices of providers:

> This follow-up review will determine the adequacy of procedures and controls used by Medicare fiscal intermediaries to process Medicare payments for clinical laboratory services performed by hospital laboratories on an outpatient basis. Clinical laboratory services include chemistry, hematology and urinalysis tests. The review will focus on whether providers properly bill for tests provided to the same beneficiary on the same day.

1997 OIG Work Plan (Jan. 1997) **(Tab D-14)**.

Sometime in 1997, the OIG began to assert that unbundling was a violation of the False Claims Act. For example, Medicare Fraud Alert OIG 97-01 stated that "[a]n investigation into laboratory billing irregularities in several Ohio hospitals" has shown that "false claims" for outpatient laboratory tests had been submitted **(Tab D-15)**. This Fraud Alert, however, placed much of the blame on unnamed consulting firms in saying that: "[T]he practice of fragmenting lab billings [*i.e.*, unbundling] was promoted by consulting firms that promised to increase hospital revenue in return for a commission consisting of a percentage of the first year's increase." In response, the OIG recommended that "OI Special Agents become aware of the implications of this consulting practice" and "should take steps to determine whether there are such contracts in effect and make note of them."

In March 1997, the OIG published a model compliance plan for clinical laboratories developed in cooperation with several provider groups and industry representatives. The model compliance plan was designed to "assist laboratory providers in crafting and refining their own compliance programs." According to the plan:

> All laboratories should provide all of their clients with annual written notices that set forth: (1) The Medicare medical necessity policy; (2) the individual components of every laboratory profile that includes a multichannel chemistry test or other automated multiple test result (e.g., 80002-80019, G0058-G0060); (3) the CPT or HCPCS codes that the laboratory uses to bill the Medicare program for each such profile; (4) the Medicare National Limitation Amount for each CPT or HCPCS code used to bill Medicare for each profile and its components; and (5) a description of how the laboratory will bill Medicare for each profile.

With regard to CPT and HCPCS codes, the model compliance plan stated that:

> Laboratory compliance policies should ensure that the CPT or HCPCS code that is used to bill Medicare or Medicaid accurately describes the service that was ordered and performed. Laboratories should choose only the code that most accurately described the ordered and performed test. To ensure code accuracy, laboratories may wish to include a requirement that the codes be reviewed by individuals with technical expertise in laboratory testing before such codes are approved for claims submissions. The OIG views intentional up coding (i.e., the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service) as rasing false claims issues. If a laboratory continues to have questions about code selection, even after review by technical experts, the facility should direct its questions to its Medicare carrier or intermediary.

The OIG also asserted that "the submission of a claim for tests that were either not ordered or were not performed" and that "billing for both the calculations and the underlying tests [on which the calculations are based]" raised potential false claims issues for laboratories.

Finally, the OIG stated that laboratories should develop policies to ensure proper billing practices for automated multichannel tests.

> Laboratory compliance policies should ensure that the laboratory bills Medicare appropriately for automated multichannel chemistry tests. All tests appearing on HCFA's most recent list of automated multichannel chemistry tests should be billed using the appropriate CPT (80002-80019) or HCPCS (G0058-G0060) codes. Tests appearing on this list should not be billed individually unless only one such analyte test is ordered and performed.

Publication of the OIG Model Compliance Plan for Clinical Laboratories (Mar. 3, 1997) **(Tab D-16)**. *Remarkably, the OIG apparently was unaware of HCFA's March 1997 revisions concerning bundling requirements, which are exactly the opposite of the OIG's pronouncements on the subject.*

The OIG also continued its emphasis on working with states to improve their payment practices regarding outpatient laboratory tests. October 1, 1996 - March 31, 1997 OIG Semi-Annual Report (Mar. 1997) **(Tab D-17)**; OIG, Medicaid Payments for Clinical Laboratory Tests in Eight States (Aug. 1997) **(Tab D-18)**.

An OIG report on laboratory tests performed by independent laboratories and physician-owned laboratories published in November 1997 contained a series of contradictory statements concerning outpatient laboratory tests. The report stated that:

> [M]ost Carrier policies and procedures did not always ensure proper payment of chemistry, hematology, and urinalysis claims submitted by independent and physician laboratories. Most Carriers attempted to prevent some types of unbundling of chemistry claims [but] policies and related procedures and controls were not consistently applied to preclude payment for all forms of chemistry unbundling on a nationwide basis."

The report went on to state that:

> HCFA has attempted to assure that uniform payment policies and procedures are followed by all Carriers and to promote accurate coding and reporting of services by physicians. . . . In this regard, the "National Correct Coding Initiative" sets out to develop correct coding methodologies and to control improper coding that caused inappropriate increases of payments in Part B claims.

The same report stated that the Carrier Manual requires Medicare providers to "group outpatient laboratory tests into the applicable panel and profile test codes when the tests are performed for the same patient on the same date of service" and provides that "if an overpayment to a supplier is caused by multiple processing of the same charge (e.g., through overlapping or duplicate bills), the supplier does not have a reasonable basis for assuming that the total payment it received was correct and thus should have questioned it. The supplier is, therefore, at fault and liable for the overpayment."

Notwithstanding the acknowledged lack of any legal authority requiring hospitals to bundle, the OIG proceeded to blame hospitals for the failure of HCFA and its payment agents to institute proper payment practices. According to the report:

> While Carrier's policies and procedures did not always ensure that proper payments were made in accordance with applicable laws,

> regulations and guidelines, overpaid laboratory providers were ultimately responsible for billing the Medicare program for such claims.

Hence, the OIG, in conjunction with U.S. Attorneys' Offices, focused its investigative efforts on the billing practices of laboratories:

> The [OIG] in cooperation with the U.S. Attorney's Office of the Department of Justice are currently involved in a number of investigations involving overbilling which has occurred at a number of laboratories.

OIG, Review of Clinical Laboratory Tests Performed by Independent Laboratories and Physicians (Nov. 1997) **(Tab D-19)**.

These contradictory statements and enforcement actions are clear evidence of the OIG's confusion concerning departmental policy on outpatient laboratory tests. These inconsistent and legally unsupported pronouncements sent contradictory signals to HCFA, Intermediaries, Carriers, laboratories, and especially hospitals concerning their responsibilities with regard to proper payment and billing practices for outpatient laboratory tests.

The OIG's April 1, 1997 -September 30, 1997 Semiannual Report was unambiguous in focusing on the impropriety of unbundling. The Semiannual Report used words such as "fraud," "excessive," "abusive," and "misconduct" to characterize the billing practices of hospitals and described the OIG's enforcement efforts in detail. The section of the report on Project Bad Bundle is worth quoting at length:

> The OIG, DOJ and multiple States have joined forces to combat Medicare and Medicaid fraud in hospital outpatient laboratory billing practices. A project begun in Ohio by OIG, DOJ and the Medicare carrier showed such promise, it was extended nationwide as Project Bad Bundle. This project seeks to recover improper claims plus penalties related to erroneous or excessive claims submitted for hematology and automated blood chemistry tests by hospital outpatient laboratories. These abusive practices stem from the unbundling and double billing of laboratory tests and the billing for certain medically unnecessary tests, which have been found to be widely practiced abuses.
>
> Laboratory services are particularly vulnerable to this practice because of the multiple number of tests ordered at one time and the capability of automated equipment to run several tests from one sample. *The reimbursement for tests bundled into a panel is less than that for each test run separately, and hospitals are required to bill certain groupings of blood tests using a "bundled" code.*

> The OIG and DOJ are working together on the national project to provide data to the United States Attorney's offices interested in pursuing this recovery initiative in their districts. The OIG also collaborated with DOJ to produce a model settlement agreement, including compliance measures, which was disseminated to all participating districts throughout the United States.
>
> Project Bad Bundle targets hospital outpatient laboratories using an ongoing computer-based audit of claims submitted for outpatient laboratory services. A letter from the United States Attorney's Office is then sent to each hospital identifying the scope of the abusive practice at that facility and its potential exposure under the Federal Civil False Claims Act. In many jurisdictions, the hospitals are invited to participate in a self-audit program, the results of which are separately verified. In recognition of their participation in this self-audit process, the hospitals generally receive the benefit of double rather than triple damages for settlement purposes. In other jurisdictions, the hospitals may not be asked to do a self-audit, in which case treble damage are generally sought. In these cases, however, the hospital may request the opportunity to do a self-audit in exchange for the benefit of double damages. The terms of all of the settlements require implementation of compliance measures to correct the identified misconduct and to prevent future similar misconduct. The date, the OIG has recorded settlements with over 40 hospitals as a result of Project Bad Bundle and its predecessor pilot, and recovered more than $10.7 million. (Emphasis added.)

April 1, 1997 - September 30, 1997 OIG Semiannual Report **(Tab D-20)**. This report is clear in indicating that the OIG considers unbundling to be a violation of the False Claims Act, but it fails to identify any statute or regulation to support its conclusions. It also erroneously states that reimbursement for panels is less than for individual tests. In fact, Intermediaries are supposed to reimburse hospitals as the lower of the two rates.

1998: CHARACTERIZATION OF UNBUNDLING AS "ILLEGAL"

HCFA Guidelines

As stated above, HCFA's new guidelines, which require unbundling of tests that are not part of an organ/disease panel, were originally scheduled to become effective on January 1, 1998, but were postponed by Program Memorandum AB-97-23 to April 1, 1998 **(Tab B-35)**.

Intermediary and Carrier Newsletters

Intermediary and Carrier newsletters published in 1998 focused on HCFA's requirement that chemistry tests must be unbundled unless they are part of an organ/disease panel. Similarly, the

newsletters also informed hospitals of the changes made in the 1998 edition of the CPT code book. One important change was the elimination of the automated profile codes (80002-80019). Blue Cross/Blue Shield of North Dakota, the Carrier for ten states, noted in Medicare Bulletin #163 that profile codes may no longer be used and that panel codes are to be used at the hospital's convenience **(Tab C-51)**. According to the Bulletin, which was published in February 1998:

> The codes 80002 through 80019 used to group automated, multichannel tests will no longer be valid codes for the automated, multichannel tests.
>
> * * *
>
> Multichannel tests 80002-80019 and G0058 - G0060 have been deleted and will not be valid beginning April 1, 1998 . . . .
>
> The new automated profile codes are provided as a convenience for billing. If a laboratory chooses, it can bill each of the component tests of these profiles individually.

Office of the Inspector General

In the 1998 Work Plan, the OIG continued its emphasis on the billing practices of hospitals and, for the first time, used the word "illegal" in a public document to describe unbundling, although in practice it clearly regarded unbundling as illegal at least as early as 1996, as shown by the enforcement efforts described in the April 1, 1997 - September 30, 1997 Semiannual Report. The Work Plan further summarized the OIG's enforcement efforts:

> The Office of Investigations launched Project Bad Bundle to identify hospitals that unbundle blood chemistry tests when using automated equipment and then bill for each analysis separately, or bill for an automated test in addition to several of the analyses separately. "Unbundling" refers to the illegal practice of submitting individual bills for separate tests that should be bundled together into a single bill for a group of related tests. The amount allowed under Medicare for this "bundled" amount is considerable [sic] lower than the sum of the amount for tests billed separately. Under this initiative, the total civil settlement to date is $8.8 million and involved 24 hospitals.

1998 OIG Work Plan **(Tab D-21)**.

Shortly after the issuance of the 1998 Work Plan, on February 11, 1998, the OIG published a model compliance plan for hospitals that did not refer to unbundling as an illegal practice, but merely as "the practice of submitting bills piecemeal or in fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together and

therefore at a reduced cost." Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (1998) **(Tab D-22)**.

The OIG has yet to reconcile its model compliance plan to conform to HCFA's revised reimbursement system.

PNEUMONIA CODING: INVESTIGATIONS, DEFENSES AND AFFIRMATIVE COMPLIANCE MEASURES

A SPECIAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION

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INTRODUCTION

This white paper analyzes one of the federal government's most active current enforcement initiatives against hospitals — the Pneumonia Coding Project. Through this project, the United States Department of Health and Human Services Office of Inspector General ("OIG") and United States Attorneys Offices ("USAOs") are investigating hospitals in all regions of the country for alleged False Claims Act ("FCA") violations arising from the alleged "upcoding" of inpatient pneumonia cases.

While every hospital has unique facts and circumstances requiring specific consideration, there are common issues that American Hospital Association ("AHA") members and their counsel should consider. This white paper provides a primer for AHA members regarding the Pneumonia Coding Project and offers possible actions and responses.

Section I, below, discusses the government's concerns and inquiries. It summarizes the government's allegations and provides background on the government's enforcement initiative. Section II offers an analysis of the legal issues relating to the government's FCA theories, relevant to those hospitals defending active pneumonia investigations. Section III analyzes affirmative compliance measures for hospitals to consider.

This white paper is not intended as legal advice. Hospitals should consult qualified counsel to obtain legal advice relevant to their particular facts and circumstances.

I. THE GOVERNMENT'S ALLEGATIONS AND ENFORCEMENT INITIATIVE

A. Summary of Government Contentions

The Pneumonia Coding Project is a joint effort by the OIG and the Department of Justice ("DOJ") focused on claims submitted to Medicare for inpatient treatment of patients with pneumonia. Medicare pays for inpatient hospital treatment based upon the beneficiary's

principal diagnosis at the time of admission. Hospitals assign ICD-9-CM[1] diagnostic codes corresponding to the patient's principal and secondary diagnoses. A diagnostic related group ("DRG") code is then assigned, based on the ICD-9-CM codes. Medicare payment for inpatient hospital services is a fixed amount per hospital, based on the DRG. Typically, and of particular importance in the context of pneumonia, a number of different ICD-9-CM codes feed into a designated DRG code. A principal diagnosis of pneumonia typically results in assignment of either DRG 79 or DRG 89, depending on the specific ICD-9-CM code selected.[2] Generally, DRG 89 relates to simple pneumonia and DRG 79 relates to more complex pneumonia. There is a $2,000-$2,500 per case difference in Medicare reimbursement between the lower-paying DRG 89 and higher-paying DRG 79.

The government's allegation underlying the pneumonia investigations is that hospitals unjustifiably used ICD-9-CM codes 482.83 (Pneumonia, Other Gram-Negative Pneumonia), 482.89 (Pneumonia, Other Specified Bacteria) and other ICD-9-CM codes that led to higher reimbursement at the DRG 79 level. According to the government's theory, in many such cases, hospitals should have used ICD-9-CM codes that resulted in lower reimbursement at the DRG 89 level.

B. Origins of Pneumonia Coding Project

The government's interest in pneumonia coding appears to have originated from a 1996 *qui tam* suit filed in the Eastern District of Pennsylvania by Health Outcomes Technology, a

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1 AICD-9-CM≅ stands for International Classification of Diseases, Ninth Revision, Clinical Modification.

2 If there are no complicating or comorbid conditions, DRG 80 or 90 may apply, instead of DRG 79 or 89.

Pennsylvania consulting firm.[3] That suit, which remains partially sealed, accused over 100 hospital defendants of pneumonia "upcoding." The *qui tam* allegations focused on the alleged excessive use by the defendant hospitals of a single ICD-9-CM code: 482.89 (Pneumonia, Other Specified Bacteria), which leads to DRG 79. The Complaint alleged that "ICD-9 code 482.89 is to be used by a Medicare provider only in circumstances where the patient suffers from a strain of bacterial pneumonia that has been specifically identified by a health care professional, but such strain does not have an individual corresponding ICD-9 diagnostic code." (Exh. 1 at ¶ 126). The Complaint further asserted that "[b]ecause the most common types of bacterial pneumonia are enumerated in ICD-9 codes 480 through 487, it should be uncommon for a hospital to use ICD-9 code 482.89." (Exh. 1 at ¶ 130).

The allegations in the *qui tam* Complaint were based on publicly available Medicare data from 1993 and 1994. Hospitals were named as defendants if, based on an analysis of claims data, their usage of ICD-9-CM code 482.89 exceeded the national average for frequency of ICD-9-CM codes by a certain threshold. According to the Complaint, ICD-9-CM code 482.89 is assigned to fewer than 4% of all Medicare pneumonia cases nationally. (Exh. 1 at ¶ 132). The Complaint contained no hospital-specific information beyond analysis of publicly available data, and it contained no information regarding the 100 defendant hospitals' alleged intents to defraud.

C. Government Statements About The Pneumonia Coding Project

The OIG first publicly described the Pneumonia Coding Project in its Work Plan for fiscal year 1998, published in October, 1997, stating:

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[3] *See United States ex. rel. Health Outcomes Technologies v. [under seal]*, Civ. No. 96-1552 (E.D. Pa.) (redacted complaint attached, Exh. 1.)

> The Pneumonia DRG Upcoding Project was initiated to identify hospitals that falsify the diagnosis and diagnosis related group on claims from viral to bacterial pneumonia. The Office of Investigations is currently working with the Department of Justice to initiate a nationwide project in this area.[4]

In its 1999 Work Plan, the OIG revised its description to note that the government is investigating pneumonia cases as both civil and criminal matters:

> This cooperative effort with the Department of Justice focuses on information that hospitals have upcoded the diagnosis-related group for pneumonia claims from viral to bacterial pneumonia. By doing this, the hospitals obtained almost $2,500 extra per claim in reimbursement. The OIG is looking at both civil and criminal implications.

This same description appears in the 2000 and 2001 Work Plans.

The OIG has also described this Project in its Semi-Annual Reports to Congress. The reports for October 1, 1997 through March 31, 1998 and April 1, 1998 through September 30, 1998 describe the Project in some detail:

> The OIG and DOJ are investigating whether hospitals across the country have routinely assigned the incorrect diagnosis code to hospital admissions for bacterial pneumonia. Medicare pays for inpatient hospital services based on DRGs, which are assigned based on the diagnosis codes identifying the condition(s) treated during the hospital admission. One diagnosis code [482.89] is to be used for 'bacterial pneumonia - other specified bacteria,' *i.e.*, where a physician diagnoses the patient with a pneumonia caused by a specific bacteria and there is no other diagnosis code for that particular bacteria. This code should rarely be used since there are specific diagnosis codes for pneumonia caused by almost all known pneumonia-causing types of bacteria. Because cases that should properly be coded as 'other specified bacteria' are expected to be complex, such cases are generally assigned a higher-paying DRG than most pneumonia cases. The OIG believes that many hospitals have been using the 'other specified bacteria' diagnosis

[4] The OIG Work Plans and Semi-Annual Reports to Congress, cited and quoted herein, are available on the OIG=s web page, <www.dhhs.gov/progorg/oig>.

> code for hospital admissions where the physician has not diagnosed a specific bacteria as the cause of the pneumonia. In such cases, the hospital should use a different diagnosis code for 'bacterial pneumonia - unspecified,' which generally results in the case being assigned to a DRG which pays several thousand dollars less than the code for 'other specified bacteria.'

In its Semi-Annual Report for October 1, 1998 through March 31, 1999, the OIG made some minor revisions to its description to the Pneumonia Coding Project, indicating that it was looking beyond ICD-9-CM code 482.89:

> Medicare inpatient hospital stays are reimbursed based on the diagnosis-related group (DRG) that is assigned to the patient's stay. The determination of the appropriate DRG for a particular case depends upon the hospital's assignment of diagnosis code(s) from the International Classification of Diseases, 9th Revision, Clinical Modification to the inpatient stay. Most pneumonia cases are grouped into one of four DRGs, one of which results in significantly higher payment to the hospital than do the others. Most pneumonia cases are grouped into the lower-paying DRGs. The OIG has found that a small percentage of hospitals across the country have assigned a disproportionate number of pneumonia cases diagnosis codes that result in an admission being assigned the higher paying DRG. Review of the medical records has demonstrated that most of the cases assigned these specific diagnosis codes at these hospitals should have been assigned a diagnosis code that would result in assignment of a lower-paying DRG.

This description has appeared in all subsequent Semi-Annual Reports. *See* OIG, Semi-annual Report for April 1, 1999 - September 30, 1999 at 10; OIG, Semi-Annual Report for October 1, 1999 - March 31, 2000 at 13; OIG, Semi-Annual Report for April 1, 2000 - September 30, 2000 at 11.

Aside from announcing specific settlements, the DOJ has not said a great deal about the Pneumonia Coding Project. In his February 1, 1999 address to the American Hospital Association, Deputy Attorney General Eric H. Holder, Jr. identified the Pneumonia Coding

Project as a basis for "the continuing need for aggressive enforcement efforts." (Exh. 2.) Mr. Holder also said that the Pneumonia Coding Project involved "illegal billing practices [that] violate clear and unambiguous Medicare rules." Id. (Unfortunately, Mr. Holder did not identify these "clear and unambiguous" rules).

D. Nature Of Government's Investigations

In some instances, the government's pneumonia coding investigations have been triggered by the filing of other *qui tam* suits. In many other instances, OIG data analyses appear to have spurred the investigations. The OIG has conducted studies that compare a hospital's frequency of ICD-9-CM codes 482.89 and 482.83, or overall DRG 79 frequency, to the hospital's total number of pneumonia cases. Based upon such studies, the OIG has targeted certain hospitals for investigation. The OIG, however, has neither published the standards used to determine which hospitals should be contacted, nor advised the industry whether any standards exist. Because the OIG has never published the basis and parameters of its data analysis, it is difficult to determine the accuracy and reliability of these studies. Before accepting or relying on the OIG's calculations for local and national utilization averages, hospitals should inquire about the basis of those averages and seek to independently verify them.

After a hospital is targeted for investigation, the OIG and DOJ contact the target hospital to seek additional information. The method of contacting the hospital varies from state to state. In some cases, the hospital is contacted by letter from the local U.S. Attorney's Office requesting a voluntary production of medical records. The government has created a model "contact letter" to make the initial contact. (*See* Exh. 3). In other cases, the government has issued administrative subpoenas for medical records and other documents prior to any direct

communication with the target hospital. The OIG has created a model subpoena, which can be modified by each U.S. Attorney's Office. (*See* Exh. 4). The subpoenas and letters may request both medical records and other types of documents, such as personnel records for medical records personnel, coding guidelines or policies, contracts, reports and other documents relating to coding consultants.

The government is particularly interested in hospitals that used coding consultants. Although, as discussed below, reasonable reliance upon a qualified consultant should provide a good defense to an FCA allegation, the government generally seems to view the use of coding consultants with suspicion. Indeed, some coding consultants are currently the subjects of criminal and civil investigations.

After a hospital produces its medical records and other documents, the government typically turns the records over to a consultant retained by the government to review the coding. The medical records are usually reviewed by the consultant's nurse reviewer. Often, the government's consultant applies a very stringent coding standard, requiring a physician's express identification of the bacterial pathogen in the diagnostic statement in order to support ICD-9-CM codes 482.83 or 482.89. (Defenses based on technical coding issues are set forth below in Section II. C-G). Based on the consultant's report, the government develops an error rate and extrapolates that error rate to an alleged overpayment. Typically, the government will seek to settle the matter for two times the overpayment amount, and will demand that the settling hospital enter into a Corporate Integrity Agreement with the OIG.

If contacted by the DOJ or OIG, hospitals should prepare to respond to the government charges of FCA violations. Depending on the relevant facts and circumstances, hospitals should

prepare to proffer facts demonstrating the absence of any fraudulent intent on the part of the hospital. The hospital should also prepare to analyze critically the government's coding review. Examples of such defenses are provided in Section II, below.

According to the OIG's April 1 through September 30, 2000 Semi-Annual Report, 22 hospitals have settled pneumonia investigations for a total of over $23.6 million. In addition, the $840 million settlement reached by HCA-The Hospital Company included over $403 million for inpatient DRG coding allegations, including pneumonia coding. An HCA subsidiary, Columbia Management Company, also pled guilty to Medicare fraud allegations based upon inpatient pneumonia coding.[5] Moreover, following a self-disclosure to the OIG, Community Health Systems, Inc. paid $31 million and entered into a Corporate Integrity Agreement to settle government claims concerning improper DRG coding, including pneumonia coding.[6]

II. LEGAL ISSUES AND DEFENSES RELEVANT TO PNEUMONIA CODING INVESTIGATIONS

A. Application of the False Claims Act and the Deputy Attorney General Guidelines

The fundamental premise in defending FCA investigations is that every inpatient coding error is not a violation of the FCA. Indeed, for a hospital to be liable under the FCA for pneumonia claims, the government must prove at trial that the hospital:

(1) "knowingly;"

(2) presented or caused to be submitted to a federal health program;

(3) a false or fraudulent claim for payment.

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5 Judith Thorn, AHCA Agrees to pay U.S. $840 Million to Settle Criminal, Civil Allegations,≅ 9 *BNA=s Health Law Reporter* 1879 (Dec. 21, 2000).

6 ACHS Settles >Upcoding= Charges,≅ 9 *BNA=s Health Law Reporter* 737 (May 18, 2000).

31 U.S.C. § 3729(a)(1). Under the FCA, one has acted "knowingly" if one acted with "deliberate ignorance" or in "reckless disregard" of the truth or falsity of the claim submitted. 31 U.S.C. § 3729(b). Therefore, if a hospital has made a coding error due to an innocent mistake, as opposed to acting with deliberate ignorance or reckless disregard as to whether claims were accurate, the hospital should not be found liable under the FCA.[7]

The FCA is a powerful enforcement tool. It provides for treble damages and penalties of $5,000-10,000 for each false claim. *See* 31 U.S.C. § 3729(a).[8] Such penalties for each false claim are potentially ruinous for most hospitals. As a result, many hospitals have settled with the government on terms that are perhaps less favorable than the expected result at trial, because they are unwilling to risk possibly fatal liability.

Following criticism by AHA and others of "Project Bad Bundle," the DOJ's national lab unbundling enforcement initiative, Deputy Attorney General Eric Holder issued a memorandum on June 3, 1998 entitled "Guidance on the Use of the False Claims Act in Civil Health Care Matters" ("DOJ Guidelines") (Exh. 5). The DOJ Guidelines acknowledge the potential for abuse of the FCA, and set forth standards for DOJ and USAO attorneys to follow before making

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7 The elements of a criminal case will vary according to the charge, but will require a higher degree of intent than is required under the civil FCA. Conviction under the criminal FCA requires the government to prove that one presented a claim to the United States Aknowing such claim to be false, fictitious or fraudulent.≅ 18 U.S.C. › 287. The government must prove the defendant actually knew that the claim submitted was false, fictitious or fraudulent. *See United States v. Barker*, 967 F.2d 1275, 1278 (9th Cir. 1992) (Ato be false, a claim must not only be inaccurate but consciously so≅). In addition, the government must prove its facts in a criminal case beyond a reasonable doubt, a higher standard than a civil FCA case. *See id.*

8 On August 30, 1999, the DOJ promulgated regulations increasing penalties to $5,500-11,000 for each false claim, for claims submitted on or after September 29, 1999. 64 Fed. Reg. 47099, 47104 (Aug. 30, 1999).

allegations of FCA violations. Broadly speaking, the DOJ Guidelines require DOJ attorneys to be certain that there is a proper legal and factual foundation before they may allege violations by healthcare providers of the FCA. Specifically, DOJ attorneys are called upon to:

- Determine whether false claims were submitted. According to the DOJ Guidelines, this requires:
  - (i) an examination of relevant statutory and regulatory provisions and interpretive guidance;
  - (ii) the verification of the data and other evidence; and
  - (iii) conducting necessary investigative steps.
- Determine whether the provider knowingly submitted the false claims. According to the DOJ Guidelines, this requires DOJ attorneys to:
  - (iv) review notice given to the provider of the rule or policy upon which a potential case would be based;
  - (v) evaluate the clarity of the rule or policy allegedly breached;
  - (vi) consider the pervasiveness and magnitude of the false claims;
  - (vii) consider whether the hospital has a compliance plan or other steps to comply with billing rules;
  - (viii) consider past remedial efforts to identify and remedy the wrongful conduct under consideration;
  - (ix) assess whether the Health Care Financing Administration ("HCFA"), the fiscal intermediary ("FI") or other government agents supplied guidance to the provider;
  - (x) consider whether the provider has previously been audited for the same matter; and
  - (xi) consider any other information that bears on the provider's state of mind.

Although the DOJ maintains that the DOJ Guidelines are not privately enforceable, they at least set forth the standards to which the DOJ holds itself. The government must apply the

facts and circumstances of a hospital's pneumonia coding case to these guidelines before DOJ attorneys, under the DOJ's own standards, may properly accuse a hospital of FCA violations. Accordingly, a hospital's specific pneumonia coding circumstances must be evaluated under the rubric of the DOJ Guidelines. Hospitals and their counsel should be aware of the DOJ Guidelines and should remind government attorneys of their application.

In Sections II. C-G below, a number of technical coding and other considerations possibly relevant to a hospital's defense are set forth. Each of these considerations should be reviewed and applied against the standards of the FCA and the DOJ Guidelines. As noted above, coding errors do not necessarily equate to a violation of the FCA. Under the FCA, the government must establish more.

B. Regulatory Underpinnings For ICD-9-CM Coding And DRG-Based Reimbursement

Under the prospective payment system for hospital inpatient services, Medicare reimburses hospitals an amount based on the DRG for the particular discharge. *See* 42 U.S.C. § 1395ww(d). Congress directed the Secretary of Health and Human Services to "establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups." 42 U.S.C. § 1395ww(d)(4)(A).

Accordingly, HCFA regulations provide that each discharge is to be assigned a DRG related to the patient's principal diagnosis:

> HCFA establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstracted from the inpatient bill for that discharge.
>
> (1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to

the hospital), secondary diagnoses, procedures performed, and discharge status.

(2) Each discharge is assigned to only one DRG (related . . . to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay....

42 C.F.R. § 412.60(c)(1)-(2).

As a condition of payment, HCFA regulations effectively require hospitals to include ICD-9-CM codes on inpatient bills, which are then used for DRG assignment. Since 1985, HCFA has required hospitals to use Form HCFA-1450 (also referred to as a "UB-92" or, formerly, as a "UB-82") as "the prescribed form[] for claims" submitted to Medicare for hospital inpatient services. *See* 42 C.F.R. § 424.32(b) (formerly designated at 42 C.F.R. § 1662). Form HCFA-1450 contains fields in which hospitals are to fill in the principal and secondary diagnoses using ICD-9-CM codes. Thus, HCFA's regulations indirectly require the use of ICD-9-CM codes through the requirement that hospitals submit claims using Form HCFA-1450.[9]

Currently, the federal government is responsible for maintaining and updating the ICD-9-CM codes.[10]

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[9] By contrast, HCFA regulations expressly require the inclusion of ICD-9-CM codes for claims for physician services. *See* 42 C.F.R. ɜ 424.32(a)(2).

[10] ICD-9-CM codes are derived from the World Health Organization=s (WHO) International Classification of Diseases system (AICD≅). After World War II, the WHO created the ICD system for classifying morbidity and mortality information for statistical purposes, indexing medical records by disease and operations, and facilitating data storage and retrieval. In its original conception, the ICD system was expected to promote international comparability in the collection, processing and analysis of mortality statistics.

To streamline storage and retrieval of diagnostic data, the U.S. Public Health Service (APHS≅) and the Veterans Administration began testing the utility of ICD in the context of hospital coding in 1950. In 1956, the American Medical Association and the American Medical Record Association conducted a study of the relative merits of coding systems for diagnostic indexing. Following the study, the major users of ICD for hospital indices

C. Absent Legal or Regulatory Guidance, Hospitals Follow The Conventions Of Professional Coders When Preparing Medicare Claims.

Notwithstanding Deputy Attorney General Holder's assertions of "clear and unambiguous Medicare rules," coding standards have been imprecisely defined, recorded, and implemented. There are no federal statutes or regulations describing proper coding procedures or standards for pneumonia. Furthermore, as the OIG has long understood, selecting an ICD-9-CM code depends on industry conventions and the professional judgment and experience of trained coding personnel:

> Processing a Medicare claim for payment commences with the patient's discharge from the hospital . . . . At the time of discharge, the attending physician (1) lists the principal diagnosis, secondary diagnoses and any inpatient procedures on the front of the chart; and (2) signs an attestation certifying the correctness of these statements.[11] The hospital then assigns ICD-9-CM codes to

(continued...)

consolidated their experiences and published their own adaptation of the ICD system in December 1959. In 1968, PHS published the Eighth Revision International Classification of Diseases, Adapted for Use in the United States. This publication eventually became commonly known as ICDA and was used to code diagnostic data for official morbidity and mortality statistics in the United States for a number of years.

In February 1977, the National Center for Health Statistics (ANCHS≅), a component of the Centers for Disease Control and part of HHS, convened a committee to provide guidance and counsel in the development of the ICDA. The committee included representatives of numerous organizations, including HCFA, WHO, AHA, the American Medical Record Association, the American Association of Health Data Systems and the American College of Physicians. The result of these efforts was ICD-9-CM, a clinical modification of WHO=s Ninth Revision to the ICD. Essentially, the ICD-9-CM modifies the WHO's three-digit ICD diagnosis codes by adding a fourth and fifth digit where possible, to allow for greater specificity in classifying diagnoses.

ICD-9-CM has been in use since January 1979, with modifications. At present, a federal interdepartmental committee chaired by NCHS and HCFA, known as the Coordination and Maintenance Committee, updates and maintains the ICD-9-CM. Changes to ICD-9-CM are published annually in the Federal Register.

11 [The attestation requirement was removed from the Code of Federal Regulations in 1994. *See* 59 Fed. Reg. 11003 (March 9, 1994).]

> all diagnoses and procedures for each discharge, using the rules of the Uniform Hospital Discharge Data Set (UHDDS) and the *coding conventions known to Accredited Record Technicians (ARTs) and Registered Record Administrators (RRAs), the professional personnel trained in management of medical records and use of coding systems*. These codes are shown on the 'face sheet' of the medical record and on the claim for payment from Medicare.

United States Department of Health and Human Services Office of Inspector General, "National DRG Validation Study — Special Report on Coding Accuracy," No. OIA-12-88-01010 (Feb. 1, 1988) (emphasis added) (Exh. 7).

Given the absence of a regulatory framework, several resources have helped shape industry coding convention. First among these sources is the previously discussed *International Classification of Diseases, Ninth Revision, Clinical Modification, Sixth Edition* ("ICD-9-CM Manual"), issued by the Department of Health and Human Services ("HHS"). This publication sets forth the actual codes and sequencing instructions for use in coding under ICD-9-CM.

A second important source for coding conventions is the *Official ICD-9-CM Guidelines*. (Exh. 12). The *Official Guidelines* are published by PHS and HCFA, and are developed and approved by HCFA, NCHS, AHA and the American Health Information Management Association ("AHIMA"). The *Official Guidelines* set forth general coding principles to assist coders where the *ICD-9-CM* Manual does not provide direction.

Another influential source of coding conventions is the *Coding Clinic for ICD-9-CM*. The *Coding Clinic* is published quarterly by the Central Office of the AHA, in cooperation with HCFA, NCHS and AHIMA. The *Coding Clinic* is intended to provide reference for official coding advice pertaining to questions regarding specific problems encountered during the coding process.

Additional resources include guidebooks, authoritative texts and journals, and various digest and periodical articles. *See, e.g.*, F. Brown, *ICD-9-CM Coding Handbook, With Answers*, published by the AHA.

Finally, local Peer Review Organizations ("PRO") and Fiscal Intermediaries sometimes offer guidance on coding matters through local medical review policies, or through the results and comments made in reviews and audits.

D. Historical Coding Conventions and Practice Are Not Free of Ambiguity

Medical record coding is not governed by federal regulations; rather, it is dependent upon informal industry convention. This informality creates some ambiguity about appropriate coding practice. These ambiguities are evident in the cases where a specific code cannot be assigned and the coder must use an "unspecified" or "other specified" code. Ambiguities also exist about which information should be used when coding. Changes in published coding instructions, such as in the case of mixed bacterial pneumonia, are another source of ambiguity.

1. The Distinction Between "Not Elsewhere Classified" and "Not Otherwise Specified" Is Confusing

The government's theory asserts that code 482.89 (Pneumonia, Other Specified Bacteria) should rarely be used because "there are specific diagnosis codes for pneumonia-causing types of bacteria." OIG Semi-Annual Reports to Congress (1997-98).[12] Yet, the difference between codes for "other specified" conditions and codes for "unspecified" conditions has confused many coders, especially in the context of pneumonia coding. An "other specific" code is also referred to as a "not elsewhere classified" or "NEC" code, and an "unspecified" code is also referred to as a "not otherwise specified" or "NOS" code.

[12] A list of ICD-9-CM codes for bacterial pneumonia is attached as Exhibit 8.

When a more specific code is not available, coders are directed to use codes with either "Not Elsewhere Classified" (NEC) or "Not Otherwise Specified" (NOS) labels. According to the *Official Guidelines for Coding and Reporting*, NEC codes are used "when the information at hand specifies a condition but no separate code for that condition is provided." *Official Guidelines* at 1.3. NOS codes are to be used "when the information at hand does not permit either a more specific or 'other' [NEC] code assignment." *Id.*

In the context of pneumonia, ICD-9-CM code 482.89 (Pneumonia, Other Specified Bacteria) is an NEC code, and 482.9 (Bacterial Pneumonia Unspecified) is an NOS code. "Other specified bacteria" (NEC) means that the type of bacteria causing the pneumonia can be ascertained and "specified," but no ICD-9-CM code corresponds to the particular specified bacterial pneumonia. An "unspecified bacteria" (NOS) means that the type of bacteria causing the pneumonia cannot be ascertained; all that is known is that the pneumonia is bacterial (as opposed to viral).

Exacerbating the confusion between NOS and NEC as applied to pneumonia, ICD-9-CM code 482.83 (pneumonia, other gram-negative bacteria) is considered *both* an NEC and an NOS code. Since 482.83 is a subdivision of code 482.8 (Pneumonia due to other specified bacteria), code 482.83 is considered an "other specified" or NEC code. But, code 482.83 is also defined to include "gram-negative pneumonia NOS" or unspecified gram-negative pneumonia.[13] Under this latter definition, code 482.83 applies to patients with gram-negative pneumonia where the exact type of gram-negative bacteria is unknown or unspecified. As such, code 482.83 can be assigned, even when the exact pathogen is not "specified," as long as the pathogen is known to

[13] St. Anthony=s Publishing, *Premier ICD-9-CM Codebook*, 6th ed. (2001) at 210 (Exh. 8).

be gram-negative bacteria. The identification of the bacteria as gram-negative makes the diagnosis an "other specified" (NEC), while the lack of identification of a specific type of gram-negative bacteria makes the diagnosis "unspecified" (NOS). This subtle distinction significantly complicates superficially simple concepts.

At least one leading coding treatise has recognized the confusion created by NEC and NOS codes. In her coding handbook, published by the AHA, Faye Brown noted "Although their meanings appear simple, [NEC for not elsewhere classified and NOS for not otherwise specified] are often misunderstood and misapplied by coders." F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1991) at 17 (Exh. 9). Because articulating the distinction between "other specified" and "unspecified" is difficult for even experienced coders, there is little doubt why some coders have been confused. While some coders are reluctant to admit that they do not understand the distinction, such reluctance can impair a hospital's ability to present a defense to an FCA allegation.

The likelihood of confusing "unspecified" and "not otherwise specified" is illustrated by an April 8, 1992 letter from the Morbidity Classification Branch Chief of the PHS to a health care industry consultant. Discussing proposed modifications to the ICD-9-CM codes for pneumonia, the PHS official wrote in part:

> As you can see, under the proposed modifications, gram negative pneumonia NOS [not otherwise specified] will be assigned to 482.83, while gram positive pneumonia NOS will be assigned to 482.89. Both types of bacterial pneumonia are currently assigned to 482.8, since the ICD-9-CM currently makes no distinction between the two.

Exh. 6, Letter to F. Keifer from S. Meads, dated April 8, 1992. This letter shows that even the Branch Chief of PHS has confused pneumonia NOS and pneumonia NEC, because, contrary to the letter, 482.89 is an "other specified" or NEC diagnosis.

2. Medicare Policy and Coding Authorities Direct Coders To "Thoroughly Review" The Entire Medical Record To Select Most Specific ICD-9-CM Code Possible

In some instances, an admitting physician describes a patient's illness as "pneumonia" in the medical record, but does not state whether the patient has a viral or a bacterial pneumonia. In other instances, the physician describes the patient's illness as "bacterial pneumonia," but does not further describe the organism or type of organism. The government now contends that in the first scenario, ICD-9-CM code 486 (Pneumonia, Organism Unspecified) must be selected because the physician failed to state whether the pneumonia was viral or bacterial. In the second scenario, the government now contends that ICD-9-CM code 482.9 (Bacterial Pneumonia Unspecified) must be selected because the physician failed to state the specific bacterial organism that caused the pneumonia. In these contexts, the government has accused hospitals of FCA violations for failure to use 486 and 482.9 (each of which leads to DRG 89).

The government's position is correct that if nothing is known other than that the patient had "pneumonia" or "bacterial pneumonia," then ICD-9-CM 486 and 482.9, respectively, are appropriate. Overlooked by the government's theory, however, is the fact that a review of the entire medical record often turns up significant information beyond what is contained in the limits of a physician's written diagnostic statement. In fact, reviewing the entire medical record (including information related to treatment, response to treatment, symptoms, laboratory results, and patient demographic information) can assist in coding a diagnosis of pneumonia with greater

specificity than the imprecise and generic statements of "pneumonia" or "bacterial pneumonia." *See* F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) at 33-34 (Exh. 11).

The government's position on coding is based on the premise that medical records personnel may not select an ICD-9-CM code based on information in the entire medical record. Rather, the coders are limited to the physician's statements of the patient's diagnosis in the medical record. As discussed below, the government's position can be criticized on two separate bases: (1) hospitals have not defrauded Medicare when, after thoroughly reviewing the medical records, they selected the most specific ICD-9-CM code corresponding to the physician's pneumonia diagnosis; and (2) many coding authorities — including government publications — instructed hospital coders to review the entire medical record (not just the physician's statements) to select the most specific pneumonia ICD-9-CM code possible.

First, the Medicare prospective payment system was designed to reimburse hospitals based on the hospital resources typically consumed in treating patients with a particular diagnosis. *See* 42 U.S.C. § 1395ww(d)(4)(B) (directing Secretary to assign "an appropriate weighting factor" to each diagnosis-related group "which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups"). Therefore, determining a patient's true condition by reviewing the entire medical record is consistent with the intent of the prospective payment system. Indeed, if one can determine that a patient probably had a type of pneumonia for which Medicare reimburses under DRG 79 based on a review of the entire medical record, then Medicare would have paid what it was supposed to pay. It appears incongruous to accuse a hospital of having violated the FCA by attempting to code a patient's actual medical condition based on the entire medical

record, through review of the patient's symptoms, the treatment provided, the response to treatment, laboratory results, and patient demographic characteristics while insisting on accuracy.

Moreover, the precise bacterial organism is not always clinically relevant to a physician, even though it is relevant to the hospital. For the physician's purposes, it may often suffice to document the condition as "pneumonia" or "bacterial pneumonia." Because greater specificity in diagnosis coding is required for reimbursement purposes than may be required for treatment purposes, however, the documentation needed for proper treatment and the documentation the government now contends is necessary for Medicare reimbursement may not always coincide. Accordingly, relying solely on what the physician has documented may lead to reimbursement levels different from what Medicare was designed to pay if the record is not thoroughly reviewed.

Second, the government position that coding may only be based on the physician's own statements, without considering the entire medical record, conflicts with coding industry practices and authorities instructing otherwise. In fact, although some coding authorities support the government's position, there are many leading coding authorities that direct coders to review the entire medical record to determine the most specific ICD-9-CM code consistent with the physician's diagnosis. *See, e.g., Official ICD-9-CM Guidelines for Coding and Reporting* at 1.3; AHA, *Coding Clinic* (First Quarter, 1994) at 17-18; AHA, *Coding Clinic* (Third Quarter, 1994) at 10; F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1994) at 34 (Exh. 10). These authorities are discussed below.

As a reimbursement proposition, the government's position is supported by the Second Quarter, 1998 edition of the *Coding Clinic* which restricts coding to the treating physician's diagnostic statements. According to this edition of the *Coding Clinic*, if a physician's diagnostic statement merely states "pneumonia," then the coder must use 486 (Pneumonia, Organism Unspecified). The Second Quarter, 1998 *Coding Clinic* also suggests that coders ask treating physicians to supplement their diagnostic statement in the medical record if a more specific diagnostic code would be supported by the medical records.[14] Of course, even though HCFA is one of the Cooperating Parties for the *Coding Clinic,* that publication is not a statement of law or binding regulation.

On the other hand, the regulatory definition of "principal diagnosis" indicates that coders should "study" the medical record to determine the most specific code applicable to the diagnosis. "Principal diagnosis" is defined as "the diagnosis established *after study* to be chiefly responsible for causing the patient's admission to the hospital." 42 C.F.R. § 412.60(c)(1) (emphasis added). The regulation does not, however, specify what is meant by "after study," but that language appears to indicate, at least, that the medical record should be reviewed to determine the proper diagnosis.

Other coding authorities more explicitly directed coders to go beyond the physician's diagnostic statements to ascertain the most specific ICD-9-CM code supported by the entire medical record. While coders were only to code pneumonia if the physician made a diagnosis of pneumonia, coding authorities told coders to scrutinize the medical records to determine the most specific pneumonia ICD-9-CM code. For instance, the government's *Official ICD-9-CM*

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14 AHA, *Coding Clinic*, (Second Quarter, 1998) at 3-6.

Guidelines For Coding And Reporting advised coders to review the entire medical record to select the most specific code possible, and directed coders not to use "unspecified" codes (such as 486 and 482.9) unless a thorough review of the medical record fails to disclose a more specific code for the diagnosis in question. Guidelines 1.2 and 1.3 of *Official ICD-9-CM Guidelines For Coding And Reporting* provide in part:

- *Guideline 1.2*: "Diagnostic and procedure codes are to be used at their highest level of specificity."
- *Guideline 1.3*: "Codes labeled 'otherwise specified' (NEC — not elsewhere classified) or 'unspecified' (NOS — not otherwise specified) are used only when *neither* the diagnostic statement *nor a thorough review of the medical record provides adequate information to permit assignment of a more specific code*."

Health Care Financing Administration, *Official ICD-9-CM Guidelines For Coding And Reporting* (1997) (emphasis added). Guideline 1.2 creates a presumption against the use of codes 486 and 482.9, and Guideline 1.3 directs coders not to use 486 and 482.9 unless a "thorough review of the medical record" fails to provide adequate information to permit assignment of a more specific code. In plain words, coders are directed to review thoroughly a medical record to determine the most specific ICD-9-CM code to use. In short, a cryptic diagnostic statement by a physician does not end the coder's obligation to review the medical record and identify, where possible, a code at the "highest level of specificity." *See id.*

The *Coding Clinic* has repeated the instruction in Guideline 1.3 that an "unspecified" code (such as ICD-9-CM codes 486 and 482.9) should not be used unless a "thorough review of the medical record" fails to provide adequate information to support a more specific code. *See, e.g.*, January-February, 1986 (quoting Guideline 1.3); First Quarter, 1997 (same). The Third Quarter, 1994 *Coding Clinic* addressed the issue of ICD-9-CM code selection in cases in which

"[a] patient is discharged with the diagnosis of pneumonia; however, the physician's diagnostic statement does not specify the organism." In response, the *Coding Clinic* stated:

> Code assignment is always based on the physician's diagnostic statement. If the physician has not specified the organism, then code 486, Pneumonia unspecified, should be assigned. All code assignments should be based upon the medical record documentation; therefore, it is inappropriate to assume the presence of an organism when the documentation cannot support the code assignment.
>
> * * *
>
> As stated in the January-February, 1986 *Coding Clinic* and the official coding guidelines (Guideline 1.3) unspecified codes '. . . are used only when neither the diagnostic statement nor a *thorough review of the medical records* provides adequate information to permit assignment of a more specific code.' An unspecified code should be assigned when the information at hand does not permit either a more specific or 'other' code assignment.

Third Quarter, 1994 *Coding Clinic* (emphasis added). Though not free of ambiguity, this guidance appears to advise coders that: (1) a physician's diagnostic statement of pneumonia is required to code pneumonia; and (2) the coder must review medical record documentation to determine which specific pneumonia code is appropriate.

As early as 1994, the *Coding Clinic* called upon coders to conduct a thorough review of the medical records to identify the most specific pneumonia code. The First Quarter, 1994 edition of the *Coding Clinic* considered the question: "Is code 482.89, Other bacterial pneumonia, the correct code assignment for a patient with pneumonia and a gram stain identifying gram positive cocci?" The *Coding Clinic* responded:

> No, code 482.89, Other bacterial pneumonia, Other specified pneumonia, should not be assigned *solely* on the basis of a gram stain. A sputum gram stain finding of gram-positive cocci is not necessarily indicative of a bacterial pathogen and, therefore, should not be coded as a specified cause of bacterial pneumonia *without*

> *further chart documentation or definitive sputum cultures.* If the physician states that the patient had a bacterial pneumonia without further specification, assign code 482.9, Bacterial pneumonia unspecified. If the physician does not specify an etiology, code 486, Pneumonia, organism unspecified, should be assigned.

First Quarter, 1994 *Coding Clinic* (emphasis added). Thus, the *Coding Clinic* instructs coders that the selection of a specific code corresponding to a particular bacterial pneumonia can be based on further "chart documentation or definitive sputum cultures," sources which are expressly not limited to "physician statements." The direction in the final two sentences of the response, that coders should use "unspecified" codes of 482.9 and 486 where the physician fails to specify the type of bacteria or etiology, apparently only applies to the situation where a more particular code is not ascertainable from the medical record or a definitive sputum culture.

Authoritative texts also instructed coders to determine the ICD-9-CM code based on a thorough review of the medical record to achieve greater specificity than provided in the physician's diagnostic statement. As one leading text states in pertinent part:

> The source document for coding and reporting diagnoses and procedures is the medical record. Although discharge diagnoses are usually recorded on the face sheet or the discharge summary of the record, further review of the medical record is needed to ensure complete and accurate coding. Operations and procedures often are not listed on the face sheet or are not described in sufficient detail, making a review of operative reports, pathology reports, and other special reports imperative.
>
> * * *
>
> If there is enough information to make it likely that an additional diagnosis should be reported, the physician should be consulted; no diagnosis should be added without the approval of the physician.
>
> * * *
>
> [D]iagnoses are not always recorded with sufficient information for required specificity in coding. A diagnosis of pneumonia may not indicate the organism responsible for the infection; a review of diagnostic studies of the sputum may provide this information. A diagnosis of fracture may indicate the bone but not the particular part of the bone,

> information necessary for accurate code assignment; the X-ray report will provide this information. A diagnosis of myocardial infarction may not specify the wall affected; the electrocardiogram report includes this information. It is appropriate to use medical record information to provide more specificity in coding without obtaining concurrence from the physician.
>
> [The text then offers four examples] "that are often recorded with less-than-complete information but can be coded more specifically by reference to diagnostic reports within the medical record," [including:]

Diagnosis:	Pneumonia	486
Laboratory Report:	*Klebsiella present in sputum*	*482.0*

F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) at 33-34 (Exh. 11). According to this text, while a coder may not determine a *diagnosis* without physician approval, a code may be assigned for that diagnosis using "medical record information to provide more specificity in coding without obtaining concurrence from the physician."[15]

Therefore, according to this text, if a physician's diagnostic statement merely provides "pneumonia" or "bacterial pneumonia," a coder should review the entire medical record to identify a more specific ICD-9-CM code for pneumonia. In the textbook's example, where the physician's diagnostic statement simply stated "pneumonia" and a lab result indicated specific bacteria, the coder was instructed to use the code corresponding to that specific bacteria. Both the textbook's general guidance — and its specific example on pneumonia coding — directly contradict the coding premise of the government's investigative theory.

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15 Until September 1, 1995, a HCFA regulation required the admitting physician to attest that the "narrative descriptions of the principal and secondary diagnoses and the major procedures performed are accurate and complete." 42 C.F.R. ∋ 412.46 (1994). While the regulation was in effect, if a coder believed that a more specific pneumonia code applied than the code appearing on the attestation, it may have been appropriate to obtain a revised attestation before finalizing the coding change. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1994) at 34 (Exh. 10).

The significant industry guidance that directed coders to supplement the physician's diagnostic statement with a review of the entire medical record is not contradicted by any Medicare rule or regulation. Indeed, there is no regulation that restricts diagnosis coding to the physician statement. Absent such a legal restriction, accurate coding requires the coder to review and consider all available information in order to choose the most accurate code possible.

3. Coding Instructions Changed For Mixed Bacterial Pneumonia

Changes in the instructions regarding coding for mixed bacterial pneumonia also caused confusion among many hospital coders. The Third Quarter, 1988 *Coding Clinic* provided instructions regarding the coding of mixed bacterial pneumonia that were "superseded" by the Second Quarter, 1997 *Coding Clinic*. The Third Quarter, 1988 *Coding Clinic* stated that the "diagnoses of gram-negative pneumonia, probable gram-negative pneumonia and mixed bacterial pneumonia should be assigned to ICD-9-CM Code 482.8 [now 482.89], Pneumonia due to other specified bacteria," resulting in DRG 79. Nine years later, the Second Quarter, 1997 *Coding Clinic* reversed this 1988 instruction as to mixed bacterial pneumonia, and advised that code 482.9 (Bacterial Pneumonia Unspecified), which results in DRG 89, should be used when the diagnosis cannot be determined with any greater specificity than mixed bacterial pneumonia. The *Coding Clinic* noted that "[t]his advice supersedes advice published in *Coding Clinic*, Third Quarter 1988, page 11." Second Quarter, 1997 *Coding Clinic*.

A government challenge to the coding of mixed bacterial pneumonia cases prior to the second quarter of 1997 reasonably can be defended on the grounds that coders were following express instructions then in effect. Even after the second quarter of 1997, it is unreasonable to

expect that all hospital coders immediately learned of the change in coding convention as expressed in the *Coding Clinic,* and that publication is neither a law nor a Medicare requirement.

E. Many Coding Errors Do Not Have Reimbursement Consequences

Depending on the facts, a hospital may also have defenses available that coding errors identified by the government did not result in billing errors. A number of different pneumonia ICD-9-CM codes lead to DRG 79. Accordingly, even if the government has identified an error in ICD-9-CM coding, the provider should still review the medical record to determine whether the coding error actually resulted in an incorrect payment.

For example, the government has challenged many hospitals' usage of ICD-9-CM 482.89 (Pneumonia, Other Specified Bacteria) in cases when the hospital could legitimately have assigned code 482.83 (Pneumonia, Other Gram-Negative Bacteria). Both 482.89 and 482.83 result in DRG 79 reimbursement. Therefore, the alleged coding error did not lead inevitably to an increase in reimbursement to the hospital.

The Third Quarter, 1988 *Coding Clinic* set out a number of clinical factors that support a diagnosis of gram-negative pneumonia:

> The findings in a debilitated, chronically ill, or aged patient that suggest a complicating gram-negative pneumonia include: (1) worsening cough, dyspnea, reduction of oxygen level, (2) fever, (3) purulent sputum, (4) patchy infiltration on chest x-ray (in addition to those previously noted densities caused by a primary underlying disease), and (5) elevated leukocyte count or a normal count in aged and debilitated patients. . . . Gram negative pneumonia usually appears as a complication of anesthesia, surgery . . . , trauma, or various chronic illnesses, such as cardiac failure, advanced carcinoma, uremia, or alcoholism. Gram-negative pneumonia is a common complication of COPD and immunosuppressive states.

Third Quarter, 1988 *Coding Clinic*; *see also* L. Tierney, M.D., S. McPhee, M.D. & M. Papadakis, M.D., *Current Medical Diagnosis & Treatment* (1997) at Table 9-8. Where these clinical factors are present and suggest a gram-negative pneumonia, hospitals can take the position that using ICD-9-CM code 482.89, even if inaccurate, did not result in increased payment because the ICD-9-CM code for gram-negative pneumonia [482.83] is also assigned to DRG 79.

One reason that some coders used 482.89 instead of 482.83 to code gram-negative pneumonia cases may have been confusion engendered by the Third Quarter, 1988 *Coding Clinic* and a 1992 redesignation of pneumonia ICD-9-CM codes. As noted above, the Third Quarter, 1988 *Coding Clinic* instructed coders to assign the ICD-9-CM code for pneumonia due to other specified bacteria, which is now 482.89, to gram-negative pneumonia cases. In 1988, code 482.8 was the code for pneumonia due to other specified bacteria. On October 1, 1992, the ICD-9-CM codes were restructured, and former code 482.8 was divided into four new codes including: 482.83 (Pneumonia, Other Gram-Negative Bacteria) and 482.89 (Pneumonia, Other Specified Bacteria). Thus, after October 1, 1992, pneumonia due to unspecified gram-negative pneumonia should have been coded to 482.83. Because the Third Quarter, 1988 *Coding Clinic* stated that gram-negative pneumonia should be assigned to the then-existing code for pneumonia due to other specified bacteria, some coders after 1992 used 482.89, persisting in using the code for other specified bacterial pneumonia. Such coders were apparently unaware that newly created 482.83 had been created for unspecified gram-negative pneumonia, and could have employed that code. Hospitals under investigation for alleged excessive usage of 482.89 should determine

whether coders believed this code was the code to use for cases of probable gram-negative pneumonia.

F. Significance of Physician Attestation

Until September 1, 1995, hospitals were required to obtain a signed attestation from the attending physician certifying the principal diagnosis, secondary diagnoses and the names of any major procedures performed. The attestation provided:

> I certify that the narrative descriptions of the principal and secondary diagnoses and the major procedures performed are accurate and complete to the best of my knowledge.

42 C.F.R. § 412.46 (1994). HCFA explained this requirement as a protective mechanism to ensure the validity of the data on each claim. During the time the regulation was in effect, HCFA "believed that the physician was in the best position to attest to th[at] information." *See* 60 Fed. Reg. 45778, 45807 (1995). Thus, HCFA believed, if the physician attested to the data included in the hospital claim, the accuracy of that claim could be accepted.

In an effort to reduce the administrative burden on physicians, HCFA eliminated the requirement that a physician attest to the validity of each individual hospital claim submitted. *See* 60 Fed. Reg. at 45779. Many hospitals, however, continued to obtain signed physician attestations similar to those formerly required by regulation with each Medicare claim submitted.

Depending on the facts and circumstances, the signed physician attestations may provide some hospitals with a defense, at least as to certain challenged claims. If the attending physician attested to the validity of a diagnosis or ICD-9-CM code set forth on a face sheet before the claim is submitted for payment, the attestation provides ample support for the hospital's coding and would undermine any notion that the hospital violated the FCA.

G. Reasonable Reliance Upon Advice of Consultants

It is eminently reasonable for healthcare providers to seek guidance from qualified consultants to help prepare, review and submit claims to Medicare on behalf of the provider. The complex and ever-changing web of rules relating to Medicare claims submission all but demands that even the most sophisticated hospitals seek specialized expertise. The use of such consultants in many cases arises from a hospital's desire both to comply with the Medicare billing rules and to ensure that the hospital receives all the reimbursement to which it is entitled for patient care. Indeed, those charged with managing a hospital have fiduciary duties to ensure the hospital receives the full payment to which it is entitled, in addition to their obligations to follow the law.

A hospital's good faith reliance on the advice of an expert coding consultant may afford a defense to a FCA violation.[16] The FCA imposes liability on one who "knowingly" presented or caused to be presented a false or fraudulent claim for payment. *See* 31 U.S.C. § 3729(a). A hospital that engaged a qualified expert billing consultant to assist in coding, to ensure that inpatient claims were accurately presented and properly submitted, can argue that it did not "knowingly" submit a false claim, even if the government now attacks the claim as mis-coded. Hospitals can press that good faith reliance on a qualified consultant demonstrates a lack of fraudulent intent. On the other hand, the reliance on a consultant defense would not be available where a hospital knowingly relied upon dubious advice. *See United States v. Lorenzo*, 768 F.

[16] Cases outside the healthcare context hold that reasonable reliance on consultants is a defense to fraud or other culpable conduct. *See, e.g.*, *Sammons v. Commissioner*, 838 F.2d 330, 337 (9th Cir. 1988); *Wehri v. Security Bank of Hebron*, 212 B.R. 963 (D.N.D. 1997); *Vaughan v. Murray*, 116 B.R. 473 (E.D. Va. 1990); *Ewing v. Commissioner*, 91 T.C. 396, 423-24 (1988).

Supp. 1127, 1132 (E.D. Pa. 1991) (provider liable under FCA, where provider knew that consultant's advice was based on incomplete portrayal of the facts).

Although there are thus many factual issues to consider in preparing a defense based on "good faith reliance," the defense should be available where a provider relied in good faith on a qualified consultant.

III. AFFIRMATIVE COMPLIANCE MEASURES

By now, most hospitals have implemented a compliance program. Whether pursuant to a hospital's formal compliance program or otherwise, there are a number of affirmative compliance measures that hospitals should consider in connection with pneumonia coding. These measures include: (1) reviewing current pneumonia coding practices; (2) conducting a self-review of past pneumonia cases; and (3) making refunds to Medicare in the event the hospital concludes it was overpaid for pneumonia cases. While these compliance measures are discussed here in the context of pneumonia, they also provide a basis for hospitals to review other areas of government inquiry that pose a risk of coding error, such as septicemia (DRG 416).

Each of the topics discussed below warrants a more complete discussion and analysis that is beyond the scope of this document. Only the key considerations and basic points are addressed here. Hospitals should confer with qualified counsel for legal advice, and should read the discussion below to help them identify issues to discuss with their counsel.

A. Review Current Coding Practices and Operations

In light of the attention the government's Pneumonia Coding Project has received and the clarifications to pneumonia coding conventions set forth in the Second Quarter, 1997 and Second Quarter, 1998 editions of the *Coding Clinic*, the government now expects hospitals to be coding

pneumonia cases based solely on the physician's written diagnostic statement (which the physician may supplement based on coder inquiry). Similarly, the government now expects hospital coders to distinguish correctly 482.89 (Pneumonia, Other Specified Bacteria) from 482.9 (Bacterial Pneumonia Unspecified), and to make the other fine distinctions among the ICD-9-CM pneumonia codes.

Accordingly, hospitals should consider undertaking compliance measures to ensure and document that their coders have a good understanding of current pneumonia coding standards. This can be accomplished through inservice training, evaluation by qualified outside consultants, or having compliance department personnel discuss pneumonia coding with the medical records staff to ensure that the coders feel confident. Education of the medical staff is also beneficial so that their diagnostic statements can be as accurate as possible.

As an additional measure, hospitals should consider monitoring and auditing for a period of time all claims coded with 482.83 or 482.89, or with DRG 79. Such monitoring will validate and document that the coders have a competent grasp of current pneumonia coding standards.

As noted, this review of current coding measures need not be limited to pneumonia. Although the educational message can be diluted if hospitals attempt to squeeze too many different topics into the inservice training, hospitals may wish to select other difficult to code conditions that can create a potential for allegations of "upcoding," such as diagnostic codes relating to DRGs 416 (septicemia), 296 (nutritional and miscellaneous metabolic disorders) and 127 (heart failure and shock).

B. Evaluate Whether Self-Review Of Past Coding Is Warranted

Hospitals may wish to evaluate whether a review of their past pneumonia coding practices is warranted. An important component of compliance is to correct past instances of regulatory noncompliance that are known to the hospital. Indeed, if a Medicare provider knows that it has received overpayments by Medicare, it may be required to disclose the overpayment to the fiscal intermediary. The Medicare Fraud and Abuse Statute prohibits the knowing failure to disclose the "occurrence of any event affecting [one's] initial or continued right to ...[a] payment... with intent fraudulently to secure such... payment...either in greater amount than is due or when no such...payment is authorized." 42 U.S.C. § 1320a-7b(a)(3). Though the statute is awkwardly worded, the government has interpreted it to mean that it is a felony for a healthcare provider to fail to disclose an overpayment from a federal health program even if the provider was not the cause of the overpayment. *See* HHS-OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb.23, 1998). As noted, the statute only applies where a provider has "knowledge" that it has been overpaid.

In some cases, past regulatory noncompliance may not necessarily be known, but there may be indications of one kind or another indicating past regulatory noncompliance. If the indications are great enough, then hospitals may feel they are on "inquiry notice" sufficient to warrant a further self-review. Obviously, the particular facts and circumstances will determine whether a self-review is warranted.

Another reason to determine whether a self-review is warranted is to anticipate a possible government investigation of pneumonia coding. A hospital that conducts a self-review of pneumonia coding (or other coding), determines that it has been overpaid, and refunds an

overpayment, ought to be viewed more favorably by the government than an otherwise similarly situated hospital that did not take such compliance measures.[17] Some hospitals and their attorneys, however, report that they did not appear to have received more lenient treatment due to their self-reporting. Indeed, in some instances, internal reviews and disclosures may have provoked investigations that might not otherwise have occurred. The government should be held to its assurances of lenience and should be more accommodating with providers who have taken such affirmative compliance measures, as a matter of fairness and sound public policy.

Following an assessment of current coding practices, a hospital may find a self-review of past coding is warranted. If the hospital's coders do not understand well the intricacies of pneumonia coding and have been at the hospital for some time, there is a possibility of prior inaccurate coding.

In addition, hospitals may wish to compare their utilization of DRG 79 and ICD-9-CM codes 482.83 and 482.89 against national, regional or state norms. Hospitals whose past usage of such codes substantially exceeded national norms may be subject to government investigation, and may wish to conduct a self-review. Many state hospital associations, consulting firms, and Peer Review Organizations have readily accessible information about state and national DRG utilization averages, which can be used by hospitals for compliance comparisons in their state or region. Utilization studies should also consider changes in code utilization from year to year. A significant increase or decrease in the use of a given code may indicate that further review is necessary.

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17 *See* HHS-OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb. 23, 1998); *see also* DOJ Guidelines at 4.

A review of the historic coding process may also indicate that a self-review is warranted. For instance, some hospitals may discover that in the past they outsourced the coding function to a consultant or otherwise relied upon the input or advice of an outside consultant. To the extent the consultant had an incentive under the compensation arrangement to maximize reimbursement without a corresponding financial incentive to identify overpayments, the consultant's advice may have been tainted. Obviously, not all consultants paid on a contingency basis provided faulty advice. Moreover, some consultants have considerable experience and enjoy excellent reputations for high quality work, and their use would not raise concerns. Depending on the facts and circumstances, however, the past use (or non-use) of consultants is a factor to consider in determining whether a self-review is warranted.

Hospitals that used in-house resources to code may also conclude from investigating the historic coding process that a self-review is warranted. Coders may disclose, for example, that they believe that they or their peers did not understand how to code pneumonia cases correctly or that their manner of coding did not conform to the government's current position on coding. Again, depending on the particular facts and circumstances, a hospital may conclude that it should conduct a self-review.

C. Performing A Self-Review

Once it is determined that a self-review of past pneumonia coding is warranted, there are a number of issues that must be considered before such a review is undertaken. For example, should the review be privileged? Who should review the charts? What is the scope of the review? What is the proper standard for reviewing charts? A hospital that launches a self-review without first addressing these issues may incur considerable time and expense later

redoing or fixing an improperly conducted self-review. In addition, a poor experience conducting a pneumonia self-review could have the unfortunate effect of deterring an institution from undertaking important self-reviews in the future.

1. Privileged and Non-Privileged Reviews

An initial issue to consider is whether the self-review should be performed under the direction of legal counsel. Of course, self-reviews can be done without the assistance of counsel, and many compliance reviews are routine business operations that do not involve legal counsel. Many hospitals conduct non-privileged "compliance reviews" as part of their compliance program and may decide to review their pneumonia coding as part of that process. Further, reviews done with the expectation that the results will be disclosed to the government (*e.g.*, reviews mandated by a corporate integrity agreement) are not likely to be privileged, even if done under the direction of counsel.

In the context of a pneumonia coding self-review, engaging legal counsel can add additional protections that may be advisable. Since pneumonia coding is an active area of enforcement, pneumonia self-reviews directed by counsel — unlike routine compliance reviews conducted in the ordinary course of business — would seemingly be protected under both the attorney-client privilege and attorney work product doctrine. As the Supreme Court has noted, the purpose of the attorney-client privilege is to encourage individuals to communicate with and provide information to an entity's lawyer, so the lawyer can provide the best possible legal advice. *See Upjohn Co. v. United States*, 449 U.S. 383, 390 (1981). Communications with internal legal resources, such as the General Counsel's office, are also afforded the protections of

the attorney-client privilege as long as the lawyers can demonstrate that they were acting as attorneys and not as business advisers.[18]

2. Identifying The Review Team

After determining whether the self-review will be conducted on a privileged basis, hospitals must decide who will conduct the review. Should it be performed using internal resources or external resources? Issues of expense and professional competence are obviously relevant. The use of hospital employees may pose some problems if the reviewers are too close to the individuals who did the original coding or set historic coding practices. Even where such a concern is not justified, some hospitals prefer to use an outside consultant rather than internal resources in the belief that the findings of the self-review would have greater credibility if investigated by the government. When the review is being conducted under the direction of counsel, the attorneys need to engage and give instruction to either the internal or external reviewer.

The review team should include individuals with expertise in coding, auditing, and the relevant clinical issues. A single coder, nurse or physician may have all the necessary skill sets, but in some instances it may be preferable to have a team conduct the review.

3. Setting The Review Parameters

Before commencing the review, the review team should discuss and agree upon the parameters of the review. The parameters of the review should be recorded in a work plan that clearly identifies the codes to be reviewed, the standards to be applied by the reviewers, the time

[18] Some courts, however, have noted difficulty in determining whether an in-house attorney is providing (privileged) legal advice or whether the attorney is providing business or operational advice (which would not be privileged). *See, e.g., United States Postal Service v. Phelps Dodge Refining Corp.*, 852 F. Supp. 156, 160 (E.D.N.Y. 1994).

period under scrutiny, sampling and extrapolation plans, fact gathering beyond medical record reviews, and the format of the final report.

The work plan should clearly identify the coding standards that the reviewers will apply. As discussed above, coding guidance has not been consistent as to whether coding may be based on a review of the entire medical record to determine the most specific pneumonia code or whether coding must be based solely on the physician's written diagnostic statement which may not have the necessary specificity to allow for coding for the patient's actual pneumonia pathogen. Since pneumonia coding conventions have changed over time, the reviewers should apply the correct standards for the time period in question. Otherwise, the self-review would be either too lenient or too harsh. Guidance on pneumonia coding from the local PRO and FI should also be considered to assist in determining the standards for review. Both PRO and FI general communications and memoranda, and specific communications to the hospital (*e.g.*, correspondence and results of audits and reviews) should be considered.

The work plan should also identify the time frame for review. As a general rule, HCFA's Hospital Manual suggests that in the absence of fraud, hospitals are liable for recoupment of Medicare overpayments within four years of the payment determination. *See* Hospital Manual § 488. This is not to say that all self-reviews should go back four years, but that period has a reasonable basis in the regulations. A hospital's particular facts and circumstances may point to a particular time frame to review, such as a time period determined by changes in hospital operations or personnel, the presence of particular coding consultants, or sudden shifts in the frequency of DRG 79 or particular ICD-9-CM codes.

Sampling and extrapolation decisions should be made before the commencement of a self-review. The hospital's reviewers should determine whether they will be reviewing all cases under review, or just review a sample that will be projected over a wider universe of claims. While situations vary, it may make sense to review initially a probe sample to determine whether a full review is necessary.

The work plan should also identify the facts to be gathered beyond the medical records. Hospitals should consider interviewing coders, those involved in the hiring and management of coding consultants, as well as others who may have relevant knowledge within the hospital. These individuals' accounts of how pneumonia cases were coded may help determine the nature of any disclosure to be made and will also help a hospital understand its potential vulnerability. If attorneys are hired to provide legal advice and direct these interviews, the attorney-client privilege and work product doctrine protections will be available. Conducting interviews and taking notes of such interviews outside of a privileged context can unnecessarily result in the creation of inculpatory evidence and may require disclosure of sensitive information. Consider also whether employees are more willing to be candid where their statements are not subject to the privilege. Beyond the coder interviews, prior consulting advice and prior PRO audits (if any) should be reviewed.

Finally, consultants or in-house personnel preparing reports should be cautioned against reaching legal conclusions, such as whether the hospital committed "fraud," or violated the FCA. Whether the hospital committed fraud or violated the FCA are legal conclusions, not factual findings. Internal review reports should focus on objective facts and analysis (*e.g.*, does the medical record and/or physician's diagnostic statement support the code selected or another code

leading to the same DRG payment?). Needlessly stating in a report that the hospital may have violated the FCA, without full consideration of all facts and potential defenses, can be unfairly prejudicial to a hospital. Similarly, recommendations for employee discipline or legal claims against previous consultants are generally inadvisable in such reports.

D. Disclosing and Refunding Overpayments to Medicare

If a hospital determines, following a self-review, that it has been overpaid, there are a number of means by which the hospital may disclose the overpayment. Repayments related to the correction of mistakes, absent fraud and or intentional misconduct, can and should be made promptly to the entity responsible for claims processing and payment (*i.e.*, the fiscal intermediary in the case of Medicare). Repayments under these circumstances can be made without the involvement of law enforcement agencies. Such a disclosure should identify the claims for which the refund is being made or at least the relevant time period. If the refund was calculated based on a projection of the review of a sample of claims, then the methodology for making the calculation should be disclosed as well. The disclosure should also discuss the training, monitoring and other affirmative compliance measures being undertaken to ensure accurate pneumonia coding in the future and/or identify reasons why the hospital believes there is no basis for continuing concern regarding pneumonia coding.

If the hospital's pneumonia coding conduct potentially involved fraud or FCA violations, however, it may be appropriate or prudent to disclose to the local United States Attorney's Office and to the OIG, either under the OIG's formal Self-Disclosure Protocol or otherwise. Qualified counsel can advise hospitals on the "who, what, when and how" of such self-disclosures.

IV. CONCLUSION

The government is devoting considerable resources to its Pneumonia Coding Project. Both civil and criminal pneumonia coding investigations are underway. Depending on particular facts and circumstances, hospitals may have a number of defenses to FCA allegations, and should confer with qualified counsel. Hospitals may be able to contest the coding standards and approaches applied by the government or develop defenses from the particular facts within the hospital. In addition, there are a number of affirmative compliance measures that hospitals may wish to consider implementing before any government inquiry begins. Prompt repayment of any determined overpayments, however, should always be made by the hospital.

EXHIBITS

1. Complaint, United States ex. rel. Health Outcomes Technologies v. [under seal], Civ. No. 96-1552 (E.D. Pa.)
2. Deputy Attorney General Eric H. Holder, Jr., Address to The American Hospital Association (February 1, 1999)
3. Redacted contact letter from DOJ
4. Redacted "model" subpoena from OIG
5. Deputy Attorney General Eric Holder,"Guidance on the Use of the False Claims Act in Civil Health Care Matters" (June 3, 1998)
6. Letter to F. Keifer from S. Meads, dated April 8, 1992
7. United States Department of Health and Human Services Office of Inspector General, "National DRG Validation Study — Special Report on Coding Accuracy," No. OIA-12-88-01010 (Feb. 1, 1988)
8. St. Anthony's Publishing, *Premier ICD-9-CM Codebook*, 6th ed. (2001) (selected pages)
9. F. Brown, ICD-9-CM Coding Handbook, With Answers (1991) (selected pages)
10. F. Brown, ICD-9-CM Coding Handbook, With Answers (1994) (selected pages)
11. F. Brown, *ICD-9-CM Coding Handbook, With Answers* (1997) (selected pages)
12. Official ICD-9-CM Guidelines for Coding and Reporting (2000)

Attachment: Question 4

In October 1999, the Department of Justice advised York Hospital, York, Pennsylvania, that it had decided to decline prosecution of a case involving allegations of inappropriate billings from the emergency department. The case originated as a qui tam action by a former emergency department physician. A nuisance settlement in the amount of $5,000.00 was entered into with the physician. The DOJ and hospital entered into a settlement agreement and agreed to a voluntary dismissal.

> This decision followed an investigation by DOJ lasting approximately a year-and-a-half, with the full cooperation of the hospital, and included the review of 204 emergency department patient records, submission of additional information regarding the emergency department physicians and residents, a tour of the hospital to observe its supervision, coding and billing processes, and the opportunity to interview any of the hospital's employees.
>
> The investigation was conducted by the DOJ with investigators and auditors from the Office of the Inspector General.

In May 2000 the OIG subpoenaed an additional 180 medical records of emergency department patients pursuant to its authority under the Civil Money Penalties Law. York Hospital again cooperated fully with the OIG and provided all documents and information requested.

In September 2000 the OIG advised the hospital that it had made a preliminary determination that the hospital could be subject to civil monetary penalties of $910,000.00, an assessment of $28,575.00 and program exclusion. This was based on 91 alleged false claims, 75 of which were from the very same records that had previously been provided to the DOJ as part of the case they declined to pursue.

In December 2000 the hospital provided extensive additional information to the OIG substantiating the billings in all but nine of the cases. Those nine appear to be situations attributable to routine clerical error. There is nothing in the records to suggest York Hospital had knowingly submitted false or fraudulent claims.

Between March 2001 and June 2001 the hospital has been in negotiation with the OIG in an attempt to resolve differences. The OIG's claim is premised on the alleged inadequacy of the documentation as opposed to the reckless submission of a false or fraudulent claim, the essence of what is required to impose a CMP. The OIG has rejected York's offer to pay $100,000.00 (absent any recognition of wrongdoing) to avoid further litigation, and rejected any internal hospital compliance program other than a hospital-wide Corporate Integrity Agreement developed by the OIG.

Unless the hospital capitulated to the OIG, the OIG threatened to bring a CMP action that could result in huge money penalties, exclusion from the Medicare program, and other punitive sanctions.

Attachment: Q4 cont'd/2

On June 11, 2001 the OIG rejected the hospital's request to meet with the acting Inspector General and the OIG's chief legal counsel.

On June 15, 2001 the OIG served Notice of Final Determination in the amount of $726,938.00 based solely on the extrapolation of 67 claims of alleged inadequate documentation. These same 67 claims were included within the 204 records originally audited and declined for prosecution by the DOJ.

On August 9, 2001 the hospital filed its request for a hearing with an administrative law judge of the Departmental Appeals Board to contest the proposed imposition of a civil monetary penalty and assessment.

Attachment: Question 7

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Congress should ask tough questions about...

The government's chilling raid on a TN hospital

Some tough questions are in order from Congress to government investigators in light of deeply disturbing events at Woods Memorial Hospital in Tennessee, reported in this newspaper and elsewhere.

Both media reports and local accounts by health officials indicate heavy-handed government agents needlessly frightened, intimidated and bullied hospital staff as they searched for evidence of Medicare fraud.

The 37 agents from several different government agencies, including the Health and Human Services Office of Inspector General and the Federal Bureau of Investigation, **raid**ed the hospital, home health facilities and two warehouses in Etowah, TN.

While they took away files as part of their investigation, the agents stomped through the hospital wearing handguns and bulletproof vests. Agents entered the dialysis center treatement area wearing no protective clothing that guards patients against infection.

No one disputes the government's right to get records relevant to an investigation. But handguns in a hospital? Did the federal government really believe its agents were in immediate danger of bodily injury or death? Did the agents expect to be met by gun-toting billing clerks or armed nurses?

Tennessee hospital officials have every reason to be upset with these cowboy tactics. Besides unfairly tarnishing a hospital's reputation and endangering patient care, these antics fly in the face of a civil, cooperative relationship between hospitals and the government over Medicare's billing mess.

The government's own guidelines for evenhanded enforcement of the False Claims Act in Medicare billing probes should prevent just this sort of behavior. If it cannot, Congress should act to make sure these tactics are not repeated.

The nation's hospitals know the importance of public trust and confidence. But trust and confidence works both ways. Raiding a community hospital as if it were a criminal hideout is inexcusable. For starters, the agencies responsible should apologize to the hospital staff, its patients and the community and return the needed patient records as soon as possible.

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Agents acted recklessly in raid on TN hospital, reports claim

Government fraud investigators have come under fire for the way they conducted a search of a rural Tennessee hospital in February.

Local media reports and some health care officials say the conduct of some agents endangered patients' lives.

On Feb. 24, 37 agents from several different government agencies, including the Office of the Inspector General and the Federal Bureau of Investigations, **raid**ed a hospital, home health facilities and two warehouses owned by the Woods Memorial Hospital District, Etowah, TN, and took away files as part of a Medicare fraud investigation.

Among the potentially dangerous conduct cited by local media and others, agents reportedly entered a dialysis area during a treatment session without wearing protective clothing that guards patients against infections.

"If the government is allowed to do this, then this country is in trouble," said Craig Becker, president of the Tennessee Hospital Association.

AHA Chief Washington Counsel Mary Grealy said no one disputes the government's right to get records needed to conduct an investigation.

However, she asked, "unless you are concerned about patients being in immediate danger of bodily injury or death, do you need to have 40 armed agents descending upon a hospital to obtain billings or records?"

Judy Holtz, spokeswoman for the Office of the Inspector General, confirmed there is an investigation about alleged Medicare fraud and that the investigation is in its early stages.

'Get in and get out'

When a search is necessary, Holtz said, agents complete it as quickly and efficiently as possible.

"First and foremost, it is done to be as least disruptive as possible, to treat people with respect and to do what you need to do, and get in and get out," she said. "My understanding is that that's what was done."

The U.S. attorney's office for the Eastern District of Tennessee wouldn't confirm or deny that a investigation is under way, and declined to comment on the search.

Hospital officials said they plan to cooperate with the investigation.

"We're asking them to let us know what else we can do," said Alvin Hoover, Woods Memorial Hospital District's assistant administrator. "We feel that at the end of this investigation, we'll be exonerated."

This article first appeared in the April 5 1999 issue of AHA News

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Feds tight-lipped after raids on El Paso facilities

Federal investigators armed with search warrants March 19 **raid**ed the offices of several Columbia/ HCA Healthcare facilities and doctors associated with Columbia in El Paso, TX, and removed records and documents.

Officials from the FBI, the Internal Revenue Service, the Department of Health and Human Services, and the Defense Department's Criminal Investigation Service carried out the searches.

Columbia officials released a brief public statement confirming the **raid**s and stating that the company had not been informed of the allegations underlying the search warrants.

Company officials stated they believed the scope of the investigation is limited to the El Paso facilities.

Judy Holtz, spokeswoman for the Office of the Inspector General at the Department of Health and Human Services confirmed that the searches were limited to the El Paso market and involved "potential federal violations."

Otherwise, federal officials were tight-lipped about the scope and focus of the investigation.

Holtz said she was not even aware of whether the investigation involved Medicare or Medicaid, despite the involvement of Health and Human Services.

The Department of Defense's involvement has raised speculation that the investigation could involve Champus insurance for military personnel.

In cases in which search warrents are used, investigators must prove to a judge that there is probable cause to believe evidence is contained in the place to be searched, Holtz said.

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