

**PREVENTING HEALTH CARE FRAUD: NEW TOOLS
AND APPROACHES TO COMBAT OLD CHALLENGES**

HEARING

BEFORE THE

**COMMITTEE ON FINANCE
UNITED STATES SENATE**

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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MARCH 2, 2011
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**PREVENTING HEALTH CARE FRAUD:
NEW TOOLS AND APPROACHES
TO COMBAT OLD CHALLENGES**

WEDNESDAY, MARCH 2, 2011

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:10 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Wyden, Carper, Cardin, Hatch, Grassley, Snowe, Ensign, and Coburn.

Also present: Democratic Staff: Russ Sullivan, Staff Director; John Angell, Senior Advisor; David Schwartz, Acting Chief Health Counsel; Chris Law, Investigator; and Berenise Nunez, Fellow. Republican Staff: Chris Campbell, Staff Director; Kim Brandt, Chief Health Care Investigative Counsel; and Jay Khosla, Chief Health Counsel.

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

The CHAIRMAN. The committee will come to order. I apologize for the late delay; something came up. But we will proceed.

Warren Buffett once said, "Rule number one: never lose money. Rule number two: never forget rule number one." Unfortunately, the Federal Government loses an estimated \$60 billion to fraud in Federal health care programs every year. We must do a better job of ensuring that these programs do a better job of following Buffett's rules.

Before health care reform, our system let criminals into our programs and paid fraudulent claims without enough review. The health reform law provides law enforcement with an unprecedented set of new tools. These tools prevent fraud from occurring in the first place. Specifically, health care reform creates new ways for Medicare to screen health care providers before they are accepted into the program.

The new law also creates one singular database for Medicare billing information. With all this information in one place, HHS and the Department of Justice can compare notes and help each other identify criminals, fraudulent schemes, and other abuses.

Before the new health care law, even suspicious claims were paid and only investigated later. The Affordable Care Act gives law en-

forcement officials the authority to suspend payments and investigate suspicious claims before that money goes out the door.

The law increases civil and criminal penalties for those who commit fraud, penalties that will make criminals think twice before committing fraud in Medicare or Medicaid. And the new law expands the use of recovery audit contractors to Medicare Parts C, D, and Medicaid. Medicare uses these independent investigators to look closely to find out if over-payments are being committed.

Recently, we have seen and read good news on efforts to prevent fraud. We can read the headlines here. I will try to myself. This one is, "Twenty-six Arrested in Three States in Medicare Fraud Schemes." That is December 15, the *New York Times*. "Drug Makers Pay \$400 Million in Medicare and Medicaid Fraud Case," December 7, *Boston Herald*. Here is an earlier one in 2010, July 16, *New York Times*, "Dozens Arrested Totaling \$251 Million in Fraud." *L.A. Times*, "Two U.S. Agencies Team Up To Crack Down on Health Care Fraud." That is dated August 27, 2010.

Over here, these are all 2011: "U.S. Charges 111 in Largest Medicare Fraud Crackdown." That is Reuters. "U.S. Recovers \$4 Billion From Health Care Fraud Cases." That is a lot of money. That was January 24, the *Washington Post*. And then AP, "Feds Recover \$2.5 Billion in Health Care Fraud." *New York Post*, "Medicaid Crackdown Paying Off." So there is a lot of progress. That is good news.

These posters list some of the headlines we have seen regarding our success. In January, we learned that our fraud prevention and enforcement efforts recovered \$4 billion in 2010. This is the highest number of taxpayer dollars ever recovered by efforts to fight health care fraud.

Two weeks ago, the Departments of Justice and Health and Human Services announced the largest fraud bust in U.S. history: 114 defendants arrested. Arrests were made in nine cities, including Los Angeles, Brooklyn, Detroit, and Miami. The defendants were allegedly involved in more than 40 schemes to defraud the government. This bust recovered more than \$240 million.

One of those arrested was a Brooklyn physical therapist named Aleksandr Kharkover. Aleksandr billed Medicare \$11.5 million over 4½ years. He is accused of billing for physical therapy services that were either never performed, or not medically necessary.

Now we are expanding the Medicare Fraud Strike Force through Dallas and Chicago. Today we want to hear from our witnesses about how these new tools are being implemented: are they up and running, are they effective, when do you expect to see results? We want to know if any additional tools are needed and if you have enough resources to do the right job.

The Finance Committee also will continue to investigate fraud. We will look for new places where we can enact laws to strengthen our efforts. Last December, the committee released the findings of our investigation on the connection between a stent manufacturer, Abbott Labs, and a Maryland doctor who allegedly implanted 600 medically unnecessary stents.

Mr. Levinson, yesterday I sent you a letter raising concerns about Medicare contractors along with Senators Carper and McCaskill. Medicare hires contractors to cut the checks that reim-

burse many of the doctors, hospitals, and other providers. Medicare hires contractors to oversee that process to prevent fraud, waste, and abuse. But many of these entities are owned by the same parent company. One division of the company overseeing another raises a conflict of interest. Many of the anti-fraud provisions in the health care law were bipartisan ideas. I am confident that both Democrats and Republicans can work together to prevent fraud as we move forward.

So we thank you both for your hard work and for coming to visit us today.

[The prepared statement of Chairman Baucus appears in the appendix.]

The CHAIRMAN. Senator Hatch?

**OPENING STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH**

Senator HATCH. Well, thank you, Mr. Chairman. We welcome our witnesses here today. We appreciate you taking time to be up here with us. There is no doubt that this is a challenging time. We are in the midst of one of the greatest fiscal crises ever to confront our country. This week, Congress is making tough choices regarding spending to keep the Federal Government's doors open. It is fitting that we are here today to talk about risk to our health care dollars.

Specifically, as the number of Medicare and Medicaid beneficiaries escalates and funds to pay for those services become preciously stretched, it is imperative that we take a critical look at how tax dollars are being spent to reduce the amount of fraud, waste, and abuse.

I am really pleased to welcome Inspector General Daniel Levinson and Dr. Peter Budetti today to speak on this important topic and share with us what efforts are being made to ensure that dollars entrusted to HHS are being spent wisely.

Medicare and Medicaid make up the bulk of the Federal health care programs, with nearly 100 million participants and more than \$800 billion in outlays in 2010, more money than the whole Defense Department spends. When the State's Medicaid matching amounts are added in, these Federal programs spend over \$1 trillion per year.

Estimates of the amount of fraud, waste, and abuse in these programs vary greatly, but CMS has reported that improper payments for Medicare alone in 2010 may have been nearly \$48 billion, and some estimates have said that the amount of fraud, waste, and abuse could be nearly 10 percent of the total Federal entitlement program outlays.

While there is much to be explored today in how HHS, OIG, and CMS are spending the money entrusted to them to curb fraud, waste, and abuse, I also wish to point out that the path to recovering these monies is a path fraught with peril. If the methods used to ferret out fraud, waste, and abuse are not just respectful of due process and recognize distinctions between the truly "bad actors" and errors that are the result of confusing rules and ambiguous regulations, then the agencies will lose their credibility with the health care organizations they monitor and the taxpayers who expect vigorous, but fair, vigilance.

Figuring out how much fraud exists is the first step to better being able to determine how to address it. Determining how to effectively fight it is the next step. In the past year, Congress has given additional tools and appropriated significant new resources to the agencies testifying here today, but it remains to be seen how effective those tools and resources ultimately will be in curbing improper payments.

Recent reports seem to indicate that there are reasons to be optimistic about successes such as the over \$4 billion in recoveries cited by HHS and the DOJ in their 2010 Health Care Fraud and Abuse Control Fund, the HCFAC, report. Moreover, the recovery reports and figures do not address what portion is the result of intentional fraud or is attributable to mistakes due to regulations that are tripping up health care organizations by the sheer size and complexity of those regulations.

I am sincerely concerned about the helter-skelter approach being taken to implement the new health care law's tools to address improper payments. For example, the recent stop and start and then reverse guidance by CMS to States and health care organizations on Medicaid RACs is mind-boggling. The Patient Protection and Affordable Care Act required CMS to establish a Medicaid Recovery Audit Contractor (RAC) program by December 31, 2010. Last month, CMS sent a letter to States which effectively says, "Don't worry about it," and promised to take up Medicaid RACs at an unspecified time "later this year."

Now, the examples abound in which CMS has issued guidances only to retract, amend, or postpone them indefinitely. Is it a wonder that health care organizations think that trying to comply with agency rules can seem like stacking papers in the middle of a tornado?

Lastly, I must address the way the President's budget for fiscal year 2012 uses health care fraud recoveries to suppress the real cost of health care reform and seeks a substantial increase in "fraud-fighting funds," when this administration has not yet shown sustained progress in reducing improper payments.

I see that there is a request for a nearly \$581-million increase in discretionary spending for health care fraud efforts. This is a significant increase over the \$311 million contained in the fiscal year 2011 continuing resolution, and more than double the \$259 million spent in fiscal year 2010.

Now, this is a sizeable increase at a time when there are scant extra dollars to be spared in the Federal budget. Just 2 weeks ago, at the Senate Appropriations Committee, Labor and HHS Subcommittee, Dr. Budetti stated that any spending reduction would be a "major impediment" for CMS's program integrity efforts. And while I appreciate the need for more resources, I wonder why that money cannot come from the \$1 billion implementation fund set up under health care reform rather than from additional appropriations.

I think it is essential we look at the real return on investment of dollars specifically targeted towards implementation of the fraud-fighting provisions of PPACA and determine their effectiveness before committing to additional spending.

Ensuring the integrity and fiscal longevity of our Federal health care programs is an essential priority for all of us, and I look forward to working with both of you, and others as well, to find ways to achieve that goal. You both have very difficult jobs, I acknowledge that, and I appreciate the efforts that you make. I want to thank you both for all the work you and your staffs do on behalf of our taxpayers. This is a tough set of jobs you have, but we have to find some way to be even more successful than we are now.

Thank you so much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hatch.

[The prepared statement of Senator Hatch appears in the appendix.]

The CHAIRMAN. I am very pleased to welcome our witnesses. Today we hear from Deputy Administrator and Director for the Center of Program Integrity, Peter Budetti; and Inspector General for the Department of Health and Human Services, Daniel Levinson.

You probably know the custom here. That is, your statements will automatically be included in the record, and you can summarize within 5, 6, 7 minutes, whatever seems to make most sense. All right?

We will start with you, Dr. Budetti.

STATEMENT OF DR. PETER BUDETTI, DEPUTY ADMINISTRATOR AND DIRECTOR OF THE CENTER FOR PROGRAM INTEGRITY, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. BUDETTI. Chairman Baucus, Ranking Member Hatch, other members of the committee, thank you very much for this invitation to discuss the efforts of the Centers for Medicare and Medicaid Services to reduce fraud, waste, and abuse in the Medicare, Medicaid, and CHIP programs, and the new tools and authorities provided in the Affordable Care Act and other recent legislation.

I am particularly pleased to be sharing the table with my distinguished colleague and tireless fraud fighter, the Inspector General of HHS, Dan Levinson, who is a close colleague in this fight.

From the first day that I had the privilege to take this job on a little over a year ago, I have repeatedly been asked two key questions: why do we let crooks into the Medicare and Medicaid programs, and why do we pay fraudulent claims?

I am pleased to tell you that, with the new authorities provided in the recent laws and the continued commitment of this administration to fighting fraud in our programs, we are making progress on both fronts. We will be keeping the people out of our programs who do not belong there, and we will be screening out fraudulent claims before they are paid. We now have the flexibility to tailor our resources to the most serious problems and to quickly initiate activities in a transformative way.

Under the leadership of Secretary Sebelius, CMS has taken several administrative steps to better meet the emerging needs and challenges of fighting fraud and abuse. CMS consolidated the Medicare and Medicaid program integrity groups under the unified Center for Program Integrity, which I have the privilege of directing.

This allows us to pursue a more coordinated and strategic set of program integrity policies and activities across both programs. This change in structure has served our purposes well and has also facilitated our collaboration with our law enforcement partners.

The Affordable Care Act enhances this organizational change by providing us an opportunity to jointly develop Medicare and Medicaid and CHIP policy on these new authorities. For example, the enhanced screening requirements under the Affordable Care Act apply equally to providers and suppliers across both programs. This provides a basis for assuring better consistency in our approach to fraud prevention across our programs.

Now, you might question whether reorganization within an administrative structure is of real value, but I can tell you that creating a center within CMS that is on a par with the other centers has sent a powerful message about the commitment that we have made to fighting fraud and also put the bad actors on notice as to the seriousness of that commitment.

To explain how we have been transforming our fraud detection and prevention work, I would like to draw your attention now to the new approach shown on this poster. I believe you all have copies of it as well, if it is difficult to read at a distance.

First of all, central to our goal is a shift towards identifying fraud before it happens, preventing it from taking shape, and moving away from pay-and-chase, the approach that we have relied on in the past.

Second, we are committed not to take a monolithic approach to dealing with fraud. Instead, we are focusing on the bad actors who pose elevated risks of fraud.

Third, we are taking advantage of sophisticated new technology and other innovations as we move quickly to take action, to lead to prevention of fraud when possible.

Fourth, consistent with this administration's commitment to being transparent and accountable, we are developing performance measures that will specify our targets for improvement.

Fifth, we are actively engaging our public and private partners from across the spectrum because we know there is much to learn from others who are engaged in the same activity of fighting fraud. We know the private sector is victim of many of the same schemes that we see in our public programs, and collaboration and communication with them will further enhance our fraud fighting.

Finally, we are committed to coordinating and integrating all of the CMS fraud-fighting programs and initiatives when possible. As we move from the old ways to more modern and sophisticated approaches, we are concentrating our actions so that we do a better job of preventing bad actors from enrolling in the first place, while assuring that the good actors are, if anything, less bothered by our activities; second, acting quickly to prevent fraudulent or otherwise improper payments from being made, in collaboration with our colleagues in the Office of Inspector General; third, taking steps to achieve the President's goal of reducing the claims payment error rate by 50 percent; and fourth, using new and different kinds of tools to identify bad actors against whom we need to take action.

One point bears stressing: as we crack down on those who would commit fraud, we are mindful of the necessity to be fair to health

care providers and suppliers who are our partners in caring for beneficiaries and to protect beneficiary access to necessary health care services. This requires striking the right balance between preventing fraud and other improper payments without impeding the delivery of critical health care services to beneficiaries.

We will always respect the fact that the vast majority of health care providers are honest people who provide critical health care services to millions of CMS beneficiaries every day. With the powerful new anti-fraud tools provided to CMS and our law enforcement partners, which I have detailed in my written testimony, we are putting into place these measures that will shift from our previous approach of pay-and-chase to the new approach of preventing fraud, and we are confident that this will be successful as we move forward.

I look forward to working with you as we implement our responsibilities and to answering any questions that you might have. Thank you very much.

The CHAIRMAN. Thank you, Dr. Budetti, very much.

[The prepared statement of Dr. Budetti appears in the appendix.]

The CHAIRMAN. Mr. Levinson, you are next.

STATEMENT OF HON. DANIEL LEVINSON, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. LEVINSON. Thank you, and good morning, Chairman Baucus, Ranking Member Hatch, and members of the committee. Thank you for the opportunity to testify about the efforts of OIG and our partners to combat health care fraud, waste, and abuse. I appreciate your support for OIG's mission to protect the integrity of HHS programs and their beneficiaries.

OIG has been leading the fight against health care fraud for more than 30 years in collaboration with the Justice Department and CMS. Thanks in part to the Health Care Fraud Prevention and Enforcement Action Team or HEAT initiative, we are making strides in preventing fraud, catching and prosecuting criminals more quickly, and assisting well-intentioned providers in complying with the law. Our efforts will be bolstered by the additional funding providing through the Affordable Care Act for the Health Care Fraud and Abuse Control, or HCFAC, program.

The HCFAC program is a prudent investment of taxpayer dollars. In fiscal year 2010, this program's activities returned an unprecedented \$4 billion in fraudulent and misspent funds. Over the past 3 years, for every dollar spent on the HCFAC program, the government has returned an average of \$6.80. The Affordable Care Act further enhances our program integrity efforts by addressing vulnerabilities, strengthening enforcement, and encouraging greater coordination among Federal agencies.

Despite our successes, there is more to be done. Those intent on breaking the law are becoming more sophisticated, and their schemes are more difficult to detect. Some fraud schemes go viral, they replicate quickly, and they migrate. As law enforcement cracks down on a particular scheme, the criminals may redesign it or relocate to a new city. When detected, some perpetrators have become fugitives, fleeing with stolen Medicare funds. To combat

this fraud, the government's response must be swift, agile, and well-organized.

My written statement describes in more detail our collaboration with CMS and DOJ, enhanced program integrity tools in the Affordable Care Act, and OIG fraud-fighting initiatives, but this morning I would like to highlight a few of those initiatives.

Our Medicare Fraud Strike Forces are cracking down on criminals in fraud hot spots around the country. Since 2007, Strike Force operations have charged nearly 1,000 individuals, involving more than \$2.3 billion in Medicare billing. Just last month, Strike Force teams engaged in the largest Federal health care fraud takedown in history. The teams charged more than 100 defendants in 9 cities, including doctors, nurses, and health care company owners and executives for fraud schemes involving more than \$225 million in Medicare billing.

OIG has referred credible evidence of fraud to CMS to implement payment suspensions, helping to turn off the spigot to prevent dollars from being paid for fraudulent claims. OIG excludes fraudulent or abusive providers from Federal health care programs, cutting them off from Federal funds. We are now focusing on holding responsible those individuals who are accountable for corporate misconduct. This exclusion authority is a powerful deterrent to corporate fraud.

However, enforcement alone is not enough. We are also engaging health care providers to help prevent fraud and abuse. For example, we are conducting free training seminars in six cities, including one today in Tampa, FL, to educate providers on fraud risks and share compliance best practices. We recently published a road map for physicians. It provides guidance on how doctors should comply with fraud and abuse laws in their relationship with payers, vendors, and fellow providers.

We are also asking the public to help us track down Medicare fraud fugitives. We have posted online our 10 Most Wanted Health Care Fraud Fugitives, including photographs and details on their fraud schemes. You can see our current Most Wanted list on display right here.

We hope the public will help us bring these individuals to justice by reporting any information about their whereabouts to our website or fugitive hotline, and that is also posted right there on our enlarged poster.

In conclusion, OIG is committed to building on our successes, employing all oversight and enforcement tools available to us, and maximizing our impact to protect our health care programs, the people served by them, and American taxpayers. We very much appreciate your support of our mission, and I am happy to take your questions. Thank you.

The CHAIRMAN. Well, thank you all very much.

[The prepared statement of Mr. Levinson appears in the appendix.]

The CHAIRMAN. I have a sense, and I think the American public has a sense, that there is a lot of fraud in Medicare and Medicaid, and maybe even in CHIP. There is a lot. I think the American people believe that our government is not doing a very good job in rooting it out and preventing it in the first place. I appreciate the

recent developments, especially the most recent one, where a lot of bad actors were rounded up. But still, I think there is a sense that we are only at the tip of the iceberg. I do not know if that is accurate. I know it is accurate that the American people think that, but I do not know if it is accurate that you are not doing what you could be doing.

I would like to ask, of all the health care dollars spent today, your best judgment as to what percent is fraudulent. Either one of you.

Mr. LEVINSON. Mr. Chairman, I have always gone almost out of my way never to provide a specific figure. And it is not because I am trying to elude the question. It is regularly posed.

The CHAIRMAN. Why do you go out of your way?

Mr. LEVINSON. This is such a clandestine type of activity, and in order to try to provide some exact figure about what might be going on with any particular line within the health care industry, or any individual or collection of providers, is almost a distraction from our looking at exactly what the patterns we see are and acting aggressively.

The CHAIRMAN. Let me ask a different question: do you internally have an idea what the answer to that question is, without disclosing it? Do you, in your own mind, have a sense of how much?

Mr. LEVINSON. Well, we certainly know from our own practice, and we are 1,700 strong, and of course we are overseeing the largest department financially in the Federal Government. I have 1,700 people, if I include everybody, looking over \$900 billion.

The CHAIRMAN. That is a different question, sir. I am asking you a different question. I am asking you, Mr. Levinson: do you have an idea of how much of the health care dollar spent today is fraudulent or wasted? Do you personally have an idea, irrespective of whether you have one person working for you or you have 2 million people working for you?

Mr. LEVINSON. I believe it is a significant dollar figure.

The CHAIRMAN. You think it is significant?

Mr. LEVINSON. It is a significant dollar figure. I am hard-pressed to give you a percentage. It is a significant dollar figure.

The CHAIRMAN. Now, what I would like you to do is give us quarterly reports on your progress. How do you internally measure your progress and whether you are doing a good job or not? Do you have benchmarks? Do you have dates by which you want to accomplish certain objectives?

Mr. LEVINSON. Well, we certainly do valuable risk assessments. We have enormous expertise, both on the investigative and on the audit end of our work. Where we see suspicious billing patterns, where we look at those kinds of dollars, we know that that is an area that deserves concentrated attention.

But I would hasten to add that it is not always a matter of looking at exact dollars and cents. It is also a matter of examining quality of care issues as they develop, because many of our investigators uncover patterns of work that indicate that there are significant patient safety issues that are being raised that do not necessarily accompany large dollar figures. That makes the equation more complicated. You are looking certainly at dollars, because these are taxpayer dollars, these are the dollars used for bene-

ficiaries. You are also looking at what the dollars are supposed to mean, and that is high quality of care.

The CHAIRMAN. That was not the case in this latest round, though. That was just a pure rip-off. Not many people were being cared for in that one.

Mr. LEVINSON. That is exactly right. I think it is helpful to address this area in the sense of two separate pillars. One is, who is entitled to get into the program? What kind of provider should be allowed to participate? Historically, entry into the program was too relaxed. There are some serious enrollment issues, people masquerading as health care providers who do not belong in the program in the first instance.

The CHAIRMAN. Right. Right.

Mr. LEVINSON. That is really where the Strike Force work has been so important.

The CHAIRMAN. There is some talk in the Congress on how far it has gotten over at HHS or CMS. A credit card company, let us take, for example, American Express. If it sees an outlier, a charge that is out of your usual pattern of purchases, it calls you up and asks, "Did you charge this or not?" They call you up, and you respond, "Yes, I made that purchase."

Someone suggested—in fact, a couple of Senators here suggested—that the government adopt a similar procedure. That is, look at the billing practices of companies like American Express, and incorporate similar procedures to root out fraud. Are you doing that?

Mr. LEVINSON. Well, I would defer to CMS about how the program actually is being operated here. But it is unquestionably true that our investigators would benefit enormously from being able to obtain real-time data so that we can act far more aggressively as the fraud actually unfolds, and we are seeing improvements in being able to get data in real time. But I would defer to CMS.

The CHAIRMAN. But is the program I just outlined being pursued or not?

Dr. BUDETTI. My two words would be my poster.

The CHAIRMAN. And it says what?

Dr. BUDETTI. Yes, Senator. The short answer is that we are developing, within the Center for Program Integrity, a new approach that takes into account not only claims patterns, but many other sources of information, so that we can identify patterns and problems prospectively and put administrative actions and referrals to law enforcement into place before the claims are paid. That is where we are going, using the latest technology and sophisticated tools.

The CHAIRMAN. All right.

Dr. BUDETTI. I would be happy to discuss that in more detail if you would like.

The CHAIRMAN. I would like for you, Mr. Levinson, and your whole team, and I guess that includes the Justice Department, CMS, and others, to send this committee a quarterly report on your progress, with data, with numbers. I asked the SIGTARP to do that, the Special Inspector General for the TARP program. It worked wonderfully. He did a very good job. A very good job. So, I am asking you to do the same, to do a quarterly report with data,

numbers, dates, benchmarks, so you can show what your progress is or is not on a quarterly basis. See, we want to help you. If you give us the information, then we can help you, help each other here, to get these bad guys, the bad people.

Mr. LEVINSON. Mr. Chairman, we welcome the opportunity to work with you and your staff to provide exactly the information that you are looking for.

The CHAIRMAN. And you will do this?

Mr. LEVINSON. In whatever form that is appropriate.

The CHAIRMAN. A quarterly report. You will send a quarterly report to this committee?

Mr. LEVINSON. Yes.

The CHAIRMAN. And with numbers, and benchmarks, etc.

Mr. LEVINSON. We will provide the information that you are looking for.

The CHAIRMAN. All right. Thank you very much. I appreciate that.

Senator Hatch?

Senator HATCH. Well, thank you, Mr. Chairman.

I agree with the chairman that we have to have more information. We need to know what is going on, and we need to have you really keep us informed at all times. We also need your suggestions on what we can do to help you to do a better job—or the best job, I will put it that way. We are serious about it, because it is just pathetic that we have so many crooks who are in these industries.

Now, Dr. Budetti, we have discussed the anti-fraud provisions that were included in the Patient Protection and Affordable Care Act. As I noted in my opening statement, it seems that the implementation of the anti-fraud provisions has run into a number of delays. For instance, the provisions implementing the order and referring requirement for providers have been delayed multiple times, and most recently there have been additional delays in the implementation of the Medicaid RAC provisions.

Now, in both instances the reasons cited for the delays are operational issues by either CMS or the States. Now, can you explain to me why CMS did not assess or anticipate these operational delays before issuing guidance and beginning down the pathway toward implementation? How can providers be expected to be compliant if CMS itself is not able to effectively implement these provisions?

And one last question on this: what is being done to ensure that these types of start-stop implementation issues will not occur with other provisions as they are rolled out?

Dr. BUDETTI. Thank you for the question, Senator Hatch. We have certainly been engaged in meeting the statutory deadlines that were provided in the Affordable Care Act with great diligence. We just recently published a major regulation on provider screening and enrollment, on suspension of payments, on moratoria, and on termination of providers from both Medicare and Medicaid that will take effect on March 25 of this year.

The final rule will take effect March 25. That is a significant step towards implementing some of the key provisions of the Affordable Care Act, and we look forward to that being implemented aggressively and quickly over the coming year.

On some of the other items that you mentioned, as far as the State Recovery Audit Contractor program under the Medicare program, the requirement, we believe, was met by publishing a Notice of Proposed Rulemaking before the end of last year to the States. We have had a lot of interaction back and forth with the States. We have provided guidance to the States.

We are in the process of preparing the final rule for implementing that. We want to be responsive to our partners in the States in fighting fraud and get it right, so we have had some interaction—extensive interaction—on this, and we believe that we are moving forward with full implementation of that provision, as well as all of the other provisions. So this is a big job. We are on it with a great deal of effort and diligence. I believe that so far we have, in fact, met our statutory deadlines. I would be happy to discuss any particular issues with you, Senator.

Senator HATCH. We will send you a list of questions that you can answer.

Dr. BUDETTI. Sure.

[The questions appear in the appendix.]

Senator HATCH. Mr. Levinson, in the OIG's top management challenges, the first challenge discussed is health care reform implementation and the challenge HHS faces with respect to successfully implementing health care reform.

Now, can you please elaborate on some of the challenges and how well-prepared you think HHS is to meet these challenges?

Mr. LEVINSON. Well, Senator Hatch, I think that we have a rather robust collection of important assignments to do just in terms of the ACA itself, which mandates certain studies for us to do. But as the program unfolds, we are going to want to do a list of items that include how the expedited time frames will actually be addressed in terms of the roll-out.

Of course, we can draw upon our experience from the Medicare prescription drug benefit law and the American Recovery and Reinvestment Act, programs involving data collection, to ensure accuracy and completeness of the data. That will be a major challenge.

The grant programs. We are already the largest grant-making department in the government, but we have new significant grant program responsibilities that we will endeavor to oversee as quickly as possible, ensuring the accuracy of payments involving risk corridors, reconciliation payments, or similar payment structures, changes to Part D and other Medicare and Medicaid payments, and, of course, the potential for scams, such as insurance scams that target beneficiaries. So, we have a very robust collection of issues that we need to address.

Senator HATCH. Well, thank you.

My time is up, Mr. Chairman.

The CHAIRMAN. Senator Ensign? Thank you.

Senator ENSIGN. Thank you, Mr. Chairman.

Just a couple of questions. I have several questions I can submit for the record as well.

[The questions appear in the appendix.]

Senator ENSIGN. When you were talking with the chairman, and he was asking for a specific figure, have we looked back over time? Do we have estimates? Are there studies that you have looked at,

either one of you have looked at, what the estimates are, or have been at least in the past several years on the percentage of Medicare dollars or Medicaid dollars that we think are in fraud?

Dr. BUDETTI. Senator Ensign, yes. In fact, there have been two different sets of numbers that have circulated. One is the one that we are required to report under the Improper Payments Act, and those are improper payments. That is the figure of what was cited earlier. Improper payments are improper, and they should not occur the way that they have occurred, but they are not necessarily equated to fraud.

Senator ENSIGN. Right. Some of those are just, somebody did not fill out the form right, or whatever.

Dr. BUDETTI. Right. Anywhere from honest billing mistakes, to apparent lack of documentation, to delivering the right care but in the wrong setting. There are a number of different ways that there can be improper payments, and those can be corrected, and should be corrected.

On the other hand, as far as real fraud is concerned, I would say that the estimates that have been circulated most widely are 3 percent and 10 percent; 3 percent is principally a figure that was developed by the National Health Care Anti-Fraud Association by interviews with the investigative units of private health plans, and it is an estimate—that is all it is—that cuts across both private and public sector potential fraud. The 10-percent figure is one that the General Accounting Office, when it was the General Accounting Office, the Government Accountability Office now, produced, maybe 20 years ago, also by interviews with executives in the health care industry, so it is also an educated guess at best.

I will tell you that our experience is that there are plenty of indicators that there is a lot of fraud and that we need to do something about it, indirect indicators, even if we do not, as the Inspector General said, have the number. The biggest indicator to me is that the more we look for, the more we find. The return on investment of fighting fraud goes up the more we spend to fight fraud. That is both, as far as I am concerned, good news and bad news. It means that we are getting a good recovery for the investments that we are making in fighting fraud, but it also means there is still a lot there to find.

Senator ENSIGN. In that study that went across public and private, how much was public, how much was private?

Dr. BUDETTI. I do not recall that they made any effort to separate those, Senator.

Mr. LEVINSON. My best recollection is that the figures of 3 to 10 percent were actually sought by Congress during the deliberations on the Kennedy-Kassebaum HIPAA law in 1996, and that played, actually, a very crucial part in establishing this whole HCFAC program because the 104th Congress was so concerned about the fraud risk. My best recollection is that it was done by the private sector, in effect saying there is bound to be fraud risk. No matter what you do with big dollars, there is going to be fraud risk.

Senator ENSIGN. I was on the Ways and Means Committee at the time on the Health Subcommittee, and I was part of those hearings. As I recall, the 10-percent number, though, included fraud, waste, and abuse, so lot of the improper payments, a lot of that

stuff. So the bottom line is, we do not really have good numbers. Obviously we have to go after it.

You mentioned, Dr. Budetti, the system, the credit system that you all are developing. I did not hear a time table when you thought that that would be completed and functional. Completed and functional.

Dr. BUDETTI. So what we are running right now, Senator, is a pilot to test the use of swipe card technology, as in credit cards, in a limited area with Durable Medical Equipment (DME) suppliers in order to get experience with this new technology and to confirm that it is going to work. That is going on through the course of this year and will be completed this year as a pilot, and it is going to help us direct where we are going to go in the future with similar approaches to identifying securely who is ordering and who is providing the supplies on the DME side, and it also will give us a good basis for expanding such efforts in the future.

We are doing other kinds of technology that are under way right now besides the credit card approach. We are using the same kind of analytic that many of the industries are using—banking and telephone and so forth are using—to identify problems across a wide range of data.

Senator ENSIGN. But the chairman asked you a question on that type of a system. Do you have a plan put in with goals, benchmarks of when it would be fully functional? In other words, the old saying is, if you do not shoot for a target, you will never hit it.

Dr. BUDETTI. We are doing two things. One is, we are doing this pilot so that we get our experience with this kind of technology so we can see how promising it is, going forward. I think that is a very important first step for us to take.

The second thing is that we are using the same kinds of technologies, not the swipe card, per se, but we are using those, and that is on a time table. We put out bids. We solicited bids for those kinds of technologies late last year. We are in the process right now of reviewing the applications that came in. That system will be in place later this year and will be fully integrated into our systems next year. So it is very much on a specific timetable, and I would be happy to share that with you in more detail.

Senator ENSIGN. Yes. If you could get that to us so we can at least see what your goals are, and so we can at least, when you come back before the committee, we can say—

Dr. BUDETTI. See whether we got there or not.

Senator ENSIGN [continuing]. See whether you got there, what are the problems, and things like that, because it seems to me that this is an important part of eliminating—credit cards, they live off wiping out fraud and things like that, and that is why they have such robust systems, because it is their money. It is out of their profits. The government does not have nearly as much motivation, but we should be as vigilant because this is the taxpayers' money, and especially the types that we are dealing with today, the huge deficits that we are dealing with today, every dollar is precious and we have to go after those dollars in every way we possibly can.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Carper? First, I want to say what a great job Senator Carper has been doing in this area. He has been working hard to root out a lot of fraud here, and that is probably because in his earlier life he was Governor of his State.

Senator CARPER. Thanks very much, Mr. Chairman. I want to be your partner in all this. To my other partners across the aisle here, Tom Coburn and John Ensign, we have worked on this stuff together. People, particularly those behind me, Peter, Tyler, and Heather, have been just great in providing staff support.

The CHAIRMAN. Thank you all for your work, all of you.

Senator CARPER. We appreciate very much the ability to work with your staff and the Republican staff, too.

It is very nice to see you both, and thank you for appearing. I just want to say, as John Ensign was speaking I was thinking that I could not have agreed more with what he said.

I would like to say, and I have said this to you before, everything I do, I know I can do better. I think that is probably true for all of us. One of the things that we have sought to do is introduce what I call a culture of thrift in the Federal Government. A lot of people think we operate under a culture of spendthrift. We need to look in every nook and cranny of the Federal Government, all of our operations, whether they are domestic spending, defense spending, entitlements, even work we do at the IRS, look at everything we do and see if there is a way to get a better result for less money, or a better result for not a lot more money.

One of the things you suggested in your testimony today to us is that we get a really good bang for the buck in terms of fraud recovery for the monies that we invest, so we want to make sure that you have the resources, the access to resources to get that bang for the buck.

The other thing we want to make sure of is that you are using good ideas, good ideas of what works around the country. In Delaware, we have a lot of financial services industries there. We have a lot of credit card banks and those that do debit card operations. I remember in the early 1990s, talking to a fellow who was then the CEO of MBNA Bank. They had been hiring a lot of folks in fairly senior positions who are former FBI, former law enforcement people. I would say, well, what do they know about credit cards? He said they do not know a lot about credit cards, but they know about fraud. They have focused 24/7 on fraud. They have very smart people who do this, and they are pretty good at it.

Some of the debate we are hearing on the issue of interchange that sort of cropped up again, you buy stuff with a debit card and there is a fee that is paid by the merchants, if you will, to the issuer of the debit card. But one of the issues that comes out of that is, in recovery, one of the reasons why there is an interchange fee is because fraud costs are so large.

But I just want to make sure that we are having a good dialogue between CMS and the folks who literally do this for a living, because they have been working on it for years and years, and they have the technology, the ideas, and they can be a great resource. They have a dog in this fight, because they are all taxpayers, too.

The question I would like to ask is, we have had the opportunity, Dr. Budetti, to talk about, I call it post-audit cost recovery. It is

something that Senator Coburn and I have worked a whole lot on, in improper payments, the idea of how we harness market forces to be able to recover some of this money. We use these private contractors: they collect a dollar, they keep a dime, and that incentivizes them and keeps people off your payroll, and we get money.

There was, as you know, a ramp-up for a number of years, for about 4 years, where we actually did this in like 5 States, and I think eventually maybe all 50 States. As we are prepared to go to all 50 States, I think we are expecting to collect, frankly, maybe less money in all 50 States, or certainly not a lot more money in all 50 States, as we extend the scope of what had been a demonstration. I think we clocked about \$1 billion over maybe 3, 4 years in 5 States, and we are expecting not to do much more than that in 50.

I would really appreciate the opportunity for you again to visit with us and say, why can we not do a whole lot better than \$300 million a year, \$400 million a year? I realize we are going from, what do you call it, pay-and-chase? We are going to kind of move away from pay-and-chase to be able to stop the problem up front, but it would still seem to me that we could do better than that. Could you just talk about that for me?

Dr. BUDETTI. Sure, Senator. Thank you. Yes, the Recovery Audit Contractor program in Medicare fee-for-service was implemented as you described in a step-wise fashion, first as a series of initial States, and now nationwide. There has been some adjustment, because there were lessons learned in the original implementation that we wanted to be sure were taken into account in the final version that was put into place.

So the initial year of recoveries may appear to be lower because of the phasing in of the program nationwide, but we believe that the recoveries will continue to grow over the next few years substantially back into the order of magnitude that I think we all expected from the pilot program. So we see that very much as an area that will in fact have those kinds of returns.

As far as the expansion of the contingency fee Recovery Audit Contractor program, fondly known as the RAC, in the Affordable Care Act to both Medicaid and to Medicare Parts C and D, we are in the process of implementing all of that. That raises very different implementation issues because Medicare Parts A and B, of course, being fee-for-service, C and D being structured differently with payments to plans, and with Medicaid largely being under managed care in most States, we are looking very carefully at exactly how that should be implemented. But this is a priority for us. It is something that we are implementing very actively, and we believe that it will be extremely useful on the recovery side of things. Does that address your question, sir?

Senator CARPER. Yes. That is helpful.

My time is expired. Mr. Chairman, as you know, you said you tried to get our witnesses to provide an actual range or cost estimate. This is huge. I think one of the things that Senator Coburn and I learned on the Improper Payments Act is just that, improper payments for CMS for fraud, for last year, I think were about \$47 billion. We are not sure how much is fraud or just mistakes, that

kind of thing, but it is huge. I really compliment you for taking this time today to put this before the full committee.

I would ask that we maybe have a chance to talk later on in a roundtable. I mentioned this to Russ Sullivan, the idea of a roundtable, where members of our committee, our staffs, could have the opportunity to really drill down on this stuff in a more informal way in the weeks to come. There is just so much that could be done. Thank you.

The CHAIRMAN. That is a good idea. You bet.

I think, Senator Coburn, you are next.

Senator COBURN. Thank you.

The CHAIRMAN. Thank you for your efforts, too, Senator.

Senator COBURN. Yes, sir.

Thank you both for being here. Just to give you a little background, AARP's CEO, Barry Rand, and Newt Gingrich estimate that Medicare and Medicaid may lose \$100 billion every year. That is their estimate. Thomson Reuters, who actually did a thorough study, said \$120 billion. We had a hearing in the Federal Financial Management Subcommittee where we could document \$100 billion. GAO participated in that hearing, as well as CMS, and we pulled that data together. So we know it is a big problem.

Just a small question. When you do provider exclusions, do you notify Indian Health Service and VA of those provider exclusions as well?

Mr. LEVINSON. As far as how that information is——

Senator COBURN. No, no. Do you or do you not?

Mr. LEVINSON. I do not know exactly who gets that——

Senator COBURN. Would you not think that would be a wise thing for us to do, so somebody who is defrauding Medicare or Medicaid does not go over and turn around and start defrauding IHS and VA?

Mr. LEVINSON. I think all of government should be aware of it. Absolutely.

Senator COBURN. So do you all need a piece of legislation to do that, or can you not just do that internally?

Mr. LEVINSON. I would hope that that would not require any additional legislation.

Senator COBURN. Would you get back to me on that?

Mr. LEVINSON. Yes.

Senator COBURN. All right.

The second thing is, on physicians and licensed personnel, do you notify the State boards of your exclusions?

Mr. LEVINSON. I know that has been a challenge, because there are so many different authorities at the State and local level.

Senator COBURN. No, no. In all 50 States there are State licensing boards. There is a licensing board for MDs, for DOs, for chiropractors——

Mr. LEVINSON. Right.

Senator COBURN [continuing]. And for nurse practitioners and physician assistants. The question is, if we are not, will you, and will you get back to me on that?

Mr. LEVINSON. Senator Coburn, I think the problem has been historically about the information getting to us as opposed to us sharing results.

Senator COBURN. No, no. I am talking about, when you all exclude a provider, you make that determination. Do you give that information to the State licensing boards?

Mr. LEVINSON. I would think we would, yes.

Senator COBURN. That is every State, on every provider that you—

Mr. LEVINSON. Yes. Yes, we do.

Senator COBURN. Great. Thank you.

Predictive modeling did not come through the Affordable Care Act. It came through the Small Business Act by Senator LeMieux, one of the last things he accomplished before he left here. The private insurance industry has been doing predictive modeling for 20 years. You are new, Dr. Budetti, to this, so we cannot hold you accountable.

But is it not a question that the American people ought to ask, that here is something that the insurance industry is doing that has a 1-percent fraud rate—which we also documented in the Federal Financial Management Subcommittee—why has it taken us so long to get to predictive modeling?

Dr. BUDETTI. Senator, as you said, thank you for letting me off the hook, but I must say this is something that we do feel is going to be extremely valuable. We appreciate what was in the Small Business and Jobs Act, very much support what was in that legislation. We had, in fact, already embarked on the road towards developing predictive modeling and viewed the support that came from the Small Business and Jobs Act as very timely and useful to moving us forward, and also to setting certain time tables for us which we are happy to meet.

Senator COBURN. Can I ask you a question about that? Are you all recreating the wheel here or are you taking something that is already proven in industry and applying it to Medicare?

Dr. BUDETTI. We are doing the latter, sir. We had a solicitation that went out to get the best ideas from the private sector, and we are incorporating those. We are reviewing them right now. We have two different sets of requests for information and for bids that went out. We are putting into place the ideas from the private sector.

I think it is also fair to say, we need to know what we are doing on our end as well. We need to oversee this, and we need to make sure that we know how to use the private sector tools appropriately, because we are responsible for these programs. So we are doing both at the same time, but we are not recreating wheels. We are using the best ideas in the private sector, we are putting them all together in the way that we think serves the interests of the Medicare and Medicaid programs, so it is a mixture of getting the best ideas and putting them into place.

Senator COBURN. Do you have any concern about the new list of diagnostic procedures that is going to be this expansive new volume that you are mandated to now cover? Senator Wyden and I are working on trying to pass some restrictions on that, because what is going to be required in the provider level, what is going to be required for you, is exponentially larger with very little benefit and gain in terms of diagnosis. Most of that is done because the

public health people would like to see that, but not because it makes sense in Medicare or Medicaid to go to that large number.

Would you look favorably on Senator Wyden and I trying to limit utilization of that so it limits your frame of areas? It is a multiplier of about 10 times in terms of diagnostic codes that are going to be required, which is going to cost a ton on the provider side and also cost you a ton in terms of the range of things you have to check. Would you have any interest or recommendation on that?

Dr. BUDETTI. Are you talking about the shift to ICD-10, is that what it is?

Senator COBURN. Yes.

Dr. BUDETTI. That is not really directly under my purview, so I am not really able to comment on that.

Senator COBURN. But you have to carry it out.

Dr. BUDETTI. We at CMS will have to carry it out.

Senator COBURN. Yes.

Dr. BUDETTI. But within the Center for Program Integrity, that is not something that I am directly responsible for.

Senator COBURN. But in the Center for Program Integrity—

Dr. BUDETTI. Yes, sir.

Senator COBURN [continuing]. If we increased the diagnostic codes by 10-fold for you, what that does is magnify tremendously the difficulty in terms of accuracy and your job. It makes it more difficult. It also makes it much more difficult and creates a potential for error—not direct fraud but error—on the providers who are billing you who are innocent.

In other words, what you are going to do is, you are going to get all these flags because they are not perfect. Quite frankly, a coder in an office, they are going to get as close as they can but they are not going to be right, not when you have that number.

So I would love for you to look into that and see what that effect is going to be, the ICD-10, on your efforts, because I am really worried about that, especially in terms of computer storage—just computer storage. You are going to have that with every claim that you get. You are going to have to look through that whole thing and make sure that it is accurate.

So I will not spend any more time on that. I plan on sending you each lots of questions, because I have a limited amount of time, and I am already out of it. I am sorry, Mr. Chairman. I yield back.

[The questions appear in the appendix.]

The CHAIRMAN. Senator Grassley?

Senator GRASSLEY. Inspector General Levinson, your office has posted on the agency website a list of the 10 Most Wanted Health Care Fraud Fugitives. In addition, a research associate at the Institute of Cuban and Cuban American Studies at the University of Miami recently reported that officials from the Cuban government may be facilitating Medicare fraud in South Florida. I intend to follow up on this matter with the Department of Justice, but I would like to ask you, has this come up in any of your investigations, and if so, how did your office handle it?

Mr. LEVINSON. Senator Grassley, I am sure that our investigators work very, very closely with the Justice Department, and when we deal with potentially international issues, I think that gets beyond both the strict portfolios of HHS and DOJ, so we prob-

ably work with the State Department as well. But I would have to get back to you on the particulars of this particular instance.

Senator GRASSLEY. And in getting back to me on the particulars of that, could you consult with the other two departments you just mentioned?

Mr. LEVINSON. Yes.

Senator GRASSLEY. That would avoid my having to do it. But if they do not want to do it for you, will you tell me and tell them that I am going to contact them?

Mr. LEVINSON. Yes, sir.

Senator GRASSLEY. Thank you.

This is also for you. Last year, the House passed a bill, H.R. 6130, by voice vote to expand the permissive authority the Inspector General has to exclude individuals or entities from participating in Medicare or Medicaid. Unfortunately, we ran out of time in the Senate and were not able to get it passed before session end. The bill has been reintroduced in the House this year as H.R. 675. I understand that you believe that this bill would provide valuable tools for combatting fraud and abuse.

Can you discuss for us the types of fraud and abuse that you could address if this legislation were passed?

Mr. LEVINSON. Yes. There have been a variety of problems that have come up in the course of our investigative work in which an individual or a family or a collection of people will—and I will take the South Florida example—open up a sham clinic on one block, and then go down the street and open up another. We wind up with, in effect, a crime ring in which our agents then have to play Whack-a-Mole to close down one, and then not be able to make the obvious connection that an individual or a group of people are actually principals in more than one operation.

So being able to go after those who are affiliated with the entity that needs to be sanctioned would create a far more efficient law enforcement effort in that kind of case. Other examples would be if you had, for example, a national pediatric dental clinic. This comes very close to a real case in which dentists—not just in one clinic, but in many clinics around the country—are performing baby root canals unnecessarily.

Scores of young children are being put on papoose boards and being subject to pulpotomies. The need to close down one clinic at a time seems to be a waste of law enforcement resources when there is plainly something going on at headquarters, up the chain, that a very effective or a more effective law enforcement scheme would be able to address more immediately.

I would also refer to—

Senator GRASSLEY. I think you are telling me it would be a very useful tool.

Mr. LEVINSON. It would be a very useful tool, because it would allow us to go up the chain, and now we can go down based on the principal and agent concept. But so often we find in these larger pattern or practice cases, we need to go up the chain.

Senator GRASSLEY. I would like to ask one more question. This would be for both of you to listen. We had a *Wall Street Journal* article point out how a 3-decade-old court decision from 1979 protects physician privacy by limiting the release of physician Medi-

care billing records. A former Department of Justice official is quoted in this article as supporting making physician billing records public.

At least I think it is time to revisit this decision and make some transparency of payments physicians receive for Medicare payments, pretty much like you can see Chuck Grassley's name in the newspaper sometimes that I have gotten a farm subsidy through the U.S. Department of Agriculture. That sort of transparency is good, to know where the taxpayers' dollars go.

Mr. LEVINSON and Dr. Budetti, do you agree that we should consider making data available from physician billing records in Federal health care programs, and why or why not?

Dr. BUDETTI. Well, Senator, as you mentioned, this has been something that did come up years ago, and there were some issues that we dealt with, so we have not been in the position of doing that. We do need to respect the privacy of everybody involved and look carefully at what is released and what is not released.

There are some provisions in the Affordable Care Act that allow certain qualified entities to have access to certain identifiable data for quality purposes. That is a different provision, but it is something that is in the Act. But as far as the release of the physician billing records, I think that is something we would have to look at very carefully.

Senator GRASSLEY. Do you have an opinion, Mr. Levinson?

Mr. LEVINSON. Senator Grassley, our default position always is, we like transparency. I think that is very important, to shine as much light on people and issues as possible. But of course, we cannot always do that within OIG itself, given our important investigative responsibilities and the need to protect innocent people. There are plainly conflicting policy issues that I think—

Senator GRASSLEY. I think I got a non-answer from both of you, so we will let it go at that.

The CHAIRMAN. Thank you very much.

We have about two minutes left on a vote. Senator Cardin?

Senator CARDIN. I would take one minute.

The CHAIRMAN. Do what you want to do. Senator Wyden is supposed to have voted and is on his way back so he can close us out.

Senator CARDIN. I will take one.

The CHAIRMAN. You go right ahead.

Senator CARDIN. Thank you.

First, let me point out that when we deal with the unnecessary treatments, such as stents, in Maryland, there are people who are directly impacted by it. It is not just the fraud of expenditures, it is people who have gone through unnecessary medical procedures and unnecessary medical risks. So I would hope that we would be also highlighting the fact about the fraud having a negative impact on people's lives and people's health outcomes.

The second thing—and if necessary I will supplement this via questions for the record—is that, where you have third party responsibility for Medicare costs and settlements are reached, it is necessary to get forms from Medicare in order to pay off those forms. This can amount to significant funds to the Federal Treasury. I have been told over and over again that the bureaucracy to get that number straight takes a long time, hours on the phone.

I would just ask that you look into this issue, because I think it is denying the Federal Government the flow of money at a more efficient rate, which also can save us dollars.

Dr. BUDETTI. Senator, I would particularly like to comment on your first point, which is of great importance to us. Our central mission at CMS is to provide services to beneficiaries to make sure that they receive the services that are appropriate and necessary, and we never forget that that is at the core of our mission. When even one dollar is stolen and it detracts from the ability to provide those services, we think that is a very serious problem.

Senator CARDIN. But it is also those getting services they should not be getting that is putting them at risk.

Dr. BUDETTI. And that as well. So we always remember that there is a human being at the other end of what we are doing, sir.

Senator CARDIN. Thank you. And, if you could get back on the secondary payer issues, on where there is third-party responsibility, I would appreciate it. Thank you.

I will now yield to Senator Wyden.

Senator WYDEN. I thank my friend from Maryland. Good to see both of you. I remember fondly my days working with Dr. Budetti when he was at the Commerce Committee; I had a full head of hair and rugged good looks. I am just very glad to have both of you here.

I want to pick up on two questions that I gather have just been touched on in the last couple of minutes while I was running to vote. I share Senator Grassley's concern with respect to this lawsuit that has been brought by the *Wall Street Journal* and the Center for Public Integrity.

I think it is very clear that that 1979 Federal court injunction that prevents public disclosure of what medical procedures a health care provider bills Medicare for and how much they are reimbursed for these procedures, this is something that has to be dealt with. I am going to be working on legislation. I am now in the process of drafting legislation that will ensure access and disclosure of this information. In fact, I intend to talk with Senator Grassley about seeing if we can team up, because the two of us have for some time.

Dr. Budetti, would you be supportive of legislation like that? I think this is essential in terms of really having the disincentives that are needed to deal with those who commit fraud, and it seems to me that making this data available to a wider variety of individuals and groups is going to encourage accountability. So I have this legislation now in process of being drafted. You heard from my colleague that there is bipartisan concern. Dr. Budetti, would you be supportive of that?

Dr. BUDETTI. Senator Wyden, just let me say it is also very good to see you again and to be working with you again on fighting fraud issues and related topics. This is something that, as you know, is a long-standing and complicated issue. It is something I would be delighted to work with you on and to explore what could be done here. It is not something that I am in a position to speak directly at the moment, but it is something that we would be happy to discuss with you and your staff at any time, sir.

Senator WYDEN. I appreciate that. Conceptually, would you have any problem with legislation like that? I understand that there is

a departmental review process, but one of the reasons that I want us to send a stronger message is that this issue has gone on for so long. I mean, some of these battles in health care seem like the longest-running battle since the Trojan War. They just go on and on and on. It seems to me, I think the lawsuit that is being brought is certainly a powerful message, but you sure get people's attention by having it carry the force of law.

So conceptually, recognizing that you cannot state an official departmental position, would you have a problem with this?

Dr. BUDETTI. The concept itself, Senator Wyden, is something that really has a lot of ramifications, so I would want to really explore all of those, both in terms of what the effects might be on physicians, what the effects would be on the physician community, what the benefits would be in terms of the information that would be provided.

So I think that we need to take a very careful look at all of the ramifications in order to decide. It is not a concept that I have yet explored. Even myself, I have been busy with other things. But I would be happy to begin that discussion with you, sir.

Senator WYDEN. I will tell you, it strikes me that the benefits are pretty obvious. I mean, the benefits are the benefit of sunlight, and sunlight has always been the best disinfectant. I mean, this information is going to be out there to a broader array of people. I think that is why the Center for Public Integrity wants it; I think it is why the *Wall Street Journal* wants it.

There would be a very strong message sent that, if you are going to try to rip off the government for millions of dollars—the press has been investigating these physicians who have allegedly perpetrated fraud that amounts to millions of dollars—you are going to face a new set of hurdles. There is going to be a very substantial disincentive for you doing that because this information is going to get out.

So why do we not close this part of my questioning. Can you get back to me within, let us say, 2 weeks, because I would like to go forward with this legislation. Knowing of my colleagues' interest, I want us to work in a bipartisan way. Senator Grassley and I have done this. Could you get back to me within, say, 2 weeks with respect to what you just mentioned? You are going to have to look at the ramifications. That way you do not have to take a position on a bill within 2 weeks, but I would like to know what you call the ramifications. Would that be acceptable, within 2 weeks?

Dr. BUDETTI. I would be delighted to work on that, sir.

Senator WYDEN. All right.

Let me ask you one other question. I think my colleagues talk about it. That is this new coding system, ICD-10 system, which is estimated to cost something in the vicinity of \$30 billion. Dr. Coburn and I have been working on this, and I gather he has talked about it. My big concern is that this is fighting the last war. This is propping up the fee-for-service system.

One of the most troubling parts of the discussion about health reform is that, as we went forward and looked at the various issues, people did not really think through some of the ramifications for fee-for-service and just paying for each individual service. Is this not going to have to be part of the debate in terms of scrutinizing

wasteful kinds of payments and getting away from a system that just constantly rewards volume?

I mean, Democrats and Republicans, through the course of health reform, had disagreement on lots of stuff. Lots and lots of stuff. But almost everybody, at least on this committee, said we really have to have payment reform. We need to start moving away from fee-for-service. Yet, the department is looking at fighting the last war and propping up the fee-for-service system. Would moving away from that not take away some of the incentives for over-billing and just continually putting the focus on the volume of services rather than quality?

Dr. BUDETTI. Senator, I think, as you know, the department is in fact looking at some alternatives in terms of reorganization of both the delivery and financing of care, creating Accountable Care Organizations, health homes, and other approaches to organizing care to achieve many of the goals that you are talking about.

So I think in that context there are some very important innovations that are moving forward. As far as ICD-10, I have to tell you, that is not something that I consider myself an expert in. But to the extent that you would also like to be discussing that with us, I would be happy to explore that with you.

Senator WYDEN. I like the fact that the department is moving ahead with payment reform and Accountable Care Organizations. These were consensus features in terms of health reform, and the department, to its credit, is moving ahead. What is striking is, having moved ahead with payment reform, particularly under Secretary Sebelius, who constantly champions it, I do not understand why the department then would be talking about this kind of step backwards in propping up fee-for-service through ICD-10.

I continue to believe that those kinds of billing arrangements invite the payment for each specific service and volume, and that as we continue to look at how inventive people—luckily a small minority—try to take advantage of these programs, they can use the fee-for-service system in a volume-driven kind of system in order to do it.

So I hope that you all will get involved in those discussions. Secretary Sebelius has talked with me about it. She has been very gracious in terms of her time. I think the department is clearly thinking through how it wants to handle it. But we are talking about coding for 150,000 procedures. I do think that this is propping up yesteryear.

Given the fact that the department is moving thoughtfully in just the opposite direction on payment reform, we can do better here. I mean, if we are talking about trying to describe various services, that is an electronic medical records issue. That is an issue for a description of services, not the same as coding and getting us away from paying for value and bundling and a lot of the other things that you would like to do.

I will give you the last word. Anything you want to add?

Dr. BUDETTI. I do want to say that we are very appreciative of the support that this committee and the Congress has provided us with the new tools and authorities in the Affordable Care Act and with the resources as well that expanded it. I think that it is unfortunate that we have a problem of this magnitude, but we are up

to the task, and we are taking it on. I believe that you will continue to see a great return on your investment. Thank you, sir.

Senator WYDEN. Mr. Levinson?

And we will leave it for you, Dr. Budetti, 2 weeks in terms of getting your assessment on the pros and cons of the legislation on disclosure. That is very helpful.

You have been spared here, Mr. Levinson. Anything you want to add?

Mr. LEVINSON. No. I would certainly second what Dr. Budetti has said about the support of the committee for our work. It is extremely vital. No matter what figure you put on fraud, waste, and abuse, we know it is a significant challenge for the program. So much of both financial and public health is at stake. The fact that we get the kind of support we do from you and your colleagues is instrumental in being able to tackle that challenge.

Senator WYDEN. A good point to close on. I do not think a session goes by when the chairman has committee members together when he does not talk about how we can come up with new ways to work together in this area. We will continue to do that.

With that, the committee is adjourned.

[Whereupon, at 11:29 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.) Regarding Health Care Fraud Prevention

Warren Buffett once said:

“Rule number one: never lose money. Rule number two: never forget rule number one.”

Unfortunately, the federal government loses an estimated \$60 billion to fraud in federal health care programs every year. We must do a better job ensuring that these programs do a better job of following Buffett’s rules.

Before health reform, our system let criminals into our programs and paid fraudulent claims without enough review. The health reform law provides law enforcement with an unprecedented set of new tools. These tools prevent fraud from occurring in the first place.

Specifically, health care reform creates new ways for Medicare to screen health care providers before they are accepted into the program.

The new law also creates one, singular database for Medicare billing information. With all of this information in one place, HHS and the Department of Justice can compare notes and help each other identify criminals, fraudulent schemes, and other abuse.

Before the new health care law, even suspicious claims were paid, and only investigated later, but the Affordable Care Act gives law enforcement officials the authority to suspend payments and investigate suspicious claims before the money goes out the door.

The law increases civil and criminal penalties for those who commit fraud - penalties that will make criminals think twice before committing fraud in Medicare or Medicaid.

And the new law expands the use of Recovery Audit Contractors to Medicare Parts C and D, and Medicaid. Medicare uses these independent investigators to look closely at payments to find out if fraud is being committed.

Recently, we have seen and read good news on efforts to prevent fraud. These posters list just some of the headlines we’ve seen regarding our success. In January, we learned that our fraud prevention and enforcement efforts recovered \$4 billion in 2010. This is the highest number of taxpayer dollars ever recovered by efforts to fight health care fraud.

Two weeks ago, the Departments of Justice and Health and Human Services announced the largest Medicare fraud bust in U.S. history. One hundred and fourteen defendants were arrested. Arrests were made in nine cities, including Los Angeles, Brooklyn, Detroit and Miami. The defendants were allegedly involved in more than 40 schemes to defraud the government. This bust recovered more than 240 million dollars.

One of those arrested was a Brooklyn physical therapist named Aleksandr Kharkover. Aleksandr billed Medicare \$11.9 million over four and a half years. He is accused of billing for physical therapy services that were either never performed or not medically necessary.

Now we are expanding the Medicare Fraud Strike Force to Dallas and Chicago.

Today, we want to hear from our witnesses about how these new tools are being implemented. Are they up and running today? Are they effective? When do you expect to see results? We want to know if any additional tools are needed and if you have enough resources to do the job right.

The Finance Committee will also continue to investigate fraud. We will look for new places where we can enact laws to strengthen our efforts.

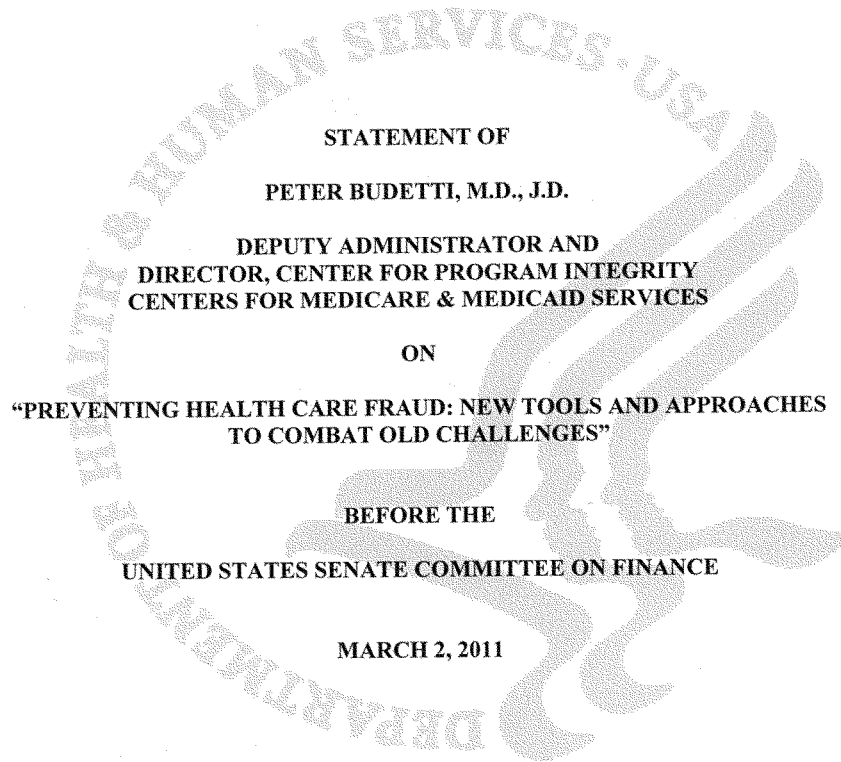
Last December, the Committee released the findings of our investigation on the connection between a stent manufacturer, Abbott Labs, and a Maryland doctor who allegedly implanted 600 medically unnecessary stents.

Mr. Levinson, yesterday I sent you a letter raising concerns about Medicare contractors, along with Senators Carper and McCaskill. Medicare hires contractors to cut the checks that reimburse many of the doctors, hospitals and other providers, and Medicare hires contractors to oversee that process to prevent fraud, waste and abuse, but many of these entities are owned by the same parent company. One division of a company overseeing another raises a conflict of interest.

Many of the anti-fraud provisions in the health care law were bipartisan ideas. I'm confident that both Democrats and Republicans can work together to prevent fraud as we move forward.

Thank you for your hard work and for coming before the Committee today.

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STATEMENT OF

PETER BUDETTI, M.D., J.D.

DEPUTY ADMINISTRATOR AND
DIRECTOR, CENTER FOR PROGRAM INTEGRITY
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

“PREVENTING HEALTH CARE FRAUD: NEW TOOLS AND APPROACHES
TO COMBAT OLD CHALLENGES”

BEFORE THE

UNITED STATES SENATE COMMITTEE ON FINANCE

MARCH 2, 2011

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

U.S. Senate Committee on Finance
Hearing on “Preventing Health Care Fraud: New Tools and Approaches to Combat
Old Challenges”
March 2, 2011

Chairman Baucus, Ranking Member Hatch, and Members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services’ (CMS) efforts to reduce fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) and the new tools and authorities provided in the Affordable Care Act.

As CMS implements the new authorities in the Affordable Care Act, we have a significant opportunity to enhance our existing efforts to combat fraud, waste, and abuse in Federal health care programs. These new authorities offer more front-end protections to keep those who are intent on committing fraud out of the programs and new tools for deterring wasteful and fiscally abusive practices, identifying and addressing fraudulent payment issues promptly, and ensuring the integrity of Medicare, Medicaid, and CHIP. CMS is pursuing an aggressive program integrity strategy that seeks to prevent payment of fraudulent claims, rather than chasing fraudulent providers after a payment has been made. CMS now has the flexibility to proactively tailor resources and quickly initiate activities in a transformative way. We believe the Affordable Care Act provisions will greatly support the effectiveness of our work. This historic moment also presents CMS with a valuable opportunity to partner with the private sector and collaborate on fraud detection efforts based on tools and methods that are already succeeding in other sectors.

CMS recognizes the importance of having strong program integrity initiatives that will deter and end criminal activity that attempts to defraud Federal health care programs. I share your commitment to ensuring taxpayer dollars are being spent on legitimate items and services, which is at the forefront of our program integrity mission.

Bringing Activities Together into the Center for Program Integrity

CMS has taken several administrative steps to better meet the Agency's future needs and challenges. CMS realigned its internal organizational structure last year, consolidating the Medicare and Medicaid program integrity groups under a unified Center for Program Integrity (CPI). This centralized approach has enabled CMS to pursue a more strategic and coordinated set of program integrity policies and activities across the Federal health care programs and has formed a bridge that facilitates collaboration on anti-fraud initiatives with our law enforcement partners, such as the Health and Human Services Office of Inspector General (OIG), the Department of Justice (DOJ), and State Medicaid Fraud Control Units. We are also working closely with our colleagues in the Office of the Secretary at HHS, as they implement the Secretary's program integrity initiative across the department. We are actively sharing best practices and lessons learned as we move forward together.

The Affordable Care Act enhances this organizational change by providing CMS with the ability to improve and streamline its program integrity capabilities by providing us with an opportunity to jointly develop Medicare, Medicaid and CHIP policy on these new authorities. For example, many Affordable Care Act provisions, such as enhanced screening requirements for new providers and suppliers, apply across the programs. The new integrated operation of program integrity activities within CMS ensures that there is better consistency in CMS' approach to fraud prevention across all of our programs.

Strategic Principles for Program Integrity Operations

As we continue the process of implementing these authorities and strengthening the integrity of the Federal health care programs, we are mindful of the impact our new rules have on health care providers and suppliers, who are our partners in caring for beneficiaries and have the awareness needed to assist us in continuing to protect beneficiary access to necessary health care services, supplies or medication. CMS is committed to improving care for our beneficiaries and engaging States and law-abiding providers and suppliers to ensure our activities reflect their interests. As we seek to reduce fraud, waste, and abuse in Medicare, Medicaid, and CHIP, we are mindful of

striking the right balance between preventing fraud and other improper payments without impeding the delivery of critical health care services to beneficiaries. At their core, Federal health care programs are designed to provide affordable health care to families in need, people with disabilities, and aging Americans. Additionally, the vast majority of health care providers are honest people who abide by their legal and professional duties and provide critical health care services to millions of CMS beneficiaries every day. CMS is committed to providing health care services to beneficiaries, while reducing the burden on legitimate providers, targeting fraudsters and saving taxpayer dollars.

This Administration is committed to minimizing fraud, waste, and abuse in Federal health care programs. While improper payments are not necessarily indicative of fraud, CMS is committed to reducing all waste within our programs. In order to focus on the prevention of improper payments while remaining vigilant in detecting and pursuing problems when they occur, we have increased provider education on proper documentation and are reexamining our claims payment and enrollment systems. With these efforts and others, we are confident that we will meet the President's goal to reduce the Medicare fee-for-service error rate in half by 2012. Moreover, we are implementing a number of measures that will shift our enforcement and administrative actions from a "pay and chase" mode to the prevention of fraudulent and other improper payments. This shift involves many different activities, which we are carrying out with the powerful new anti-fraud tools provided to CMS and our law enforcement partners under the Affordable Care Act.

We are steadily working to incorporate targeted screening and prevention activities into our claims and enrollment processes where appropriate. Our goal is to keep those individuals and companies that intend to defraud Medicare, Medicaid, and CHIP out of these programs in the first place, not to pay fraudulent claims when they are submitted, and to remove such individuals and companies from our programs if they do get in. The first step to preventing fraud in the Federal health care programs is to appropriately screen providers and suppliers who are enrolling or revalidating their enrollment to verify that only legitimate providers and suppliers who meet our stringent enrollment standards are providing care to program beneficiaries.

CMS' Efforts to Implement the Affordable Care Act**New Actions – Medicare, Medicaid, and CHIP Screening and Fraud Prevention Rule (CMS-6028-FC)**

On January 24, 2011, HHS and CMS announced rules that implement new Affordable Care Act tools to fight fraud, strengthen Federal health care programs, and protect taxpayer dollars. This rule puts in place prevention safeguards that will help CMS move beyond the “pay and chase” approach to fighting fraud.

Enhanced Screening and Enrollment Protections: The Affordable Care Act requires providers and suppliers who wish to enroll in the Medicare, Medicaid, or CHIP programs to undergo a level of screening tied to the level of risk of fraud, waste, or abuse such providers and suppliers present to the programs. This new rule will require high-risk providers and suppliers, including newly enrolling suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and home health agencies, to undergo a higher level of scrutiny based on CMS' and law enforcement's experience with these provider and supplier types. CMS has also established certain triggers that would move a provider or supplier into the highest screening level.

In addition, CMS-6028-FC implements the Affordable Care Act provision that authorizes CMS to require that providers who order and refer certain items or services for Medicaid beneficiaries be enrolled in the State's Medicaid program; this is similar to the new Medicare requirement included in an interim final rule published this past spring, CMS-6010-IFC, described in more detail below.

This new rule implements the statutory authority for CMS to impose a temporary enrollment moratorium if the Secretary determines such a moratorium is necessary to prevent or combat fraud, waste, or abuse. We will assess the impact of any proposed moratorium on beneficiary access and take this into consideration. We will publish a notice of the moratorium including a rationale for the moratorium in the *Federal Register*. Other preventive measures include new levels of coordination between

Medicare and State Medicaid agencies. For example, State Medicaid programs are now required to terminate a provider that has been terminated for cause by Medicare or another State Medicaid agency.

Stopping Payment of Suspect Claims: CMS-6028-FC allows Medicare payments to be suspended from providers or suppliers if there is a credible allegation of fraud pending an investigation or final action. The law also requires States to suspend payments to Medicaid providers where there is a credible allegation of fraud. This enhanced authority will help prevent taxpayer dollars from being used to pay fraudulent providers and suppliers.

New Resources to Strengthen Program Integrity: The Affordable Care Act provides an additional \$350 million over 10 years, plus an inflation adjustment, to ramp up program integrity efforts in HHS' Health Care Fraud and Abuse Control program (HCFAC) account, including the Medicare Integrity Program, as well as the Medicaid Integrity Program. These dedicated Affordable Care Act funds provide important financial resources for government-wide health care fraud and abuse efforts for the next decade, which will be used along with discretionary funding sought in the President's Budget to pursue critical new prevention-focused activities, place more "feet on the street" by hiring more law enforcement agents, and facilitate other efforts to reduce improper payments and address emerging fraud schemes in the health care system.

Other Implementation Steps – CMS-6010-IFC

CMS published an interim final rule with comment period (CMS-6010-IFC) in the *Federal Register* on May 5, 2010 that implemented some new anti-fraud authorities and provisions of the Affordable Care Act. This rule, which took effect July 6, 2010, requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in Federal health care programs and to also include their NPI on all claims for payment submitted to Medicare and Medicaid. CMS-6010-IFC also requires that physicians and eligible professionals who order or refer home health services or most Medicare Part B-

covered items and services for Medicare fee-for-service beneficiaries be enrolled in Medicare. In addition, it adds requirements for providers, physicians, and suppliers participating in the Medicare program to provide access and maintain documentation on orders or requests for payments for items or services at high risk of fraud, waste, and abuse, such as DMEPOS, home health services, and certain other items or services as specified by the Secretary.

Other Affordable Care Act Authorities

There are many other Affordable Care Act program integrity provisions that we will also be busy implementing this year. For example, CMS will be issuing additional surety bond requirements under the Affordable Care Act for DMEPOS suppliers and home health agencies and potentially for certain other providers of services and supplies. These surety bonds are a condition of enrollment and may help ensure that DMEPOS suppliers and home health agencies, and potentially certain other providers of services and supplies, are legitimate and financially solvent.

In addition, providers and suppliers will be required to establish compliance plans that contain certain anti-fraud requirements and reflect good governance practices. Such plans will help ensure that providers and suppliers have incorporated anti-fraud protections into their operations. Other preventive measures focus on certain categories of providers and suppliers that historically have presented concerns to our program including DMEPOS suppliers, home health agencies, and Community Mental Health Centers (CMHCs). For example, as an additional safeguard to address longstanding concerns with CMHCs, such facilities will be required to provide at least 40 percent of their items and services to non-Medicare beneficiaries.

Expanded Use of Recovery Audit Contractors

CMS is drawing from the lessons learned from the Medicare Fee-For-Service (FFS) Recovery Audit Contractor (RAC) Program to implement the new statutory authority given in the Affordable Care Act to expand the program to Medicare Parts C and D and Medicaid. In order to address the fundamental differences in payment structure between

FFS, Medicare Part C (managed care), Medicare Part D and State-run Medicaid programs, CMS has taken a multi-pronged approach to implementation of the new Affordable Care Act authorities. In January, CMS awarded a contract to identify incorrect payments and recoup overpayments in Medicare Part D. Additionally, we are seeking public comment through a solicitation issued on December 27, 2010 in the Federal Register on innovative strategies for review of additional Medicare Parts C and D data, including the effectiveness of sponsors' anti-fraud plans.

In the Medicaid program, CMS issued a State Medicaid Director letter in October 2010 that offered initial guidance on the implementation of the Medicaid RAC requirements and published a Notice of Proposed Rulemaking on November 10, 2010. CMS has provided significant technical assistance to States through all-State calls and webinars and has begun the coordination with States that have RAC contracts in place, as required by the statute. CMS will also work to ensure that States and their Medicaid RACs coordinate recovery audits with other entities to minimize the likelihood of overlapping audits. On February 17, CMS launched a Medicaid RACs At-A-Glance web page on the CMS website. The page provides basic State RAC information to the public and interested stakeholders about each State's RAC program. As States fully implement their programs and additional elements are added to the site in the future, the site will help States to monitor the performance of their own RAC program and find information on other States' programs that may assist them.

Increased Flexibility in Medicaid Recovery Rules

CMS issued a State Medicaid Director letter in July 2010, providing initial guidance on the recovery of Medicaid overpayments as required by the Affordable Care Act. States now have up to one year from the date of discovery of an overpayment in Medicaid to recover, or attempt to recover, such overpayment before being required to refund the Federal share of the overpayment. Prior to passage of the Affordable Care Act, States were allowed only up to 60 days from the date of discovery of an overpayment to recover such overpayment before making the adjustment to the Federal share. CMS appreciates this new flexibility for States. The additional time provided under the Affordable Care

Act will enable States to more thoroughly root out fraud and overpayments. However, for overpayments resulting from fraud, if an ongoing administrative or judicial process prevents a State from recovering an overpayment within one year of discovery, the State has an additional 30 days after a final judgment is made to recover the overpayment before making the adjustment to the Federal share.

Guidance on Self-Disclosure of Actual or Potential Violations of Physician Self-Referral Statute

In September 2010, CMS published the Voluntary Self-Referral Disclosure Protocol (SRDP) on its website to enable providers and suppliers to disclose actual or potential violations of the physician self-referral statute (Section 1877 of the Social Security Act). The SRDP contains instructions for providers and suppliers who make self-disclosures, and advises that the Affordable Care Act gives the Secretary the discretion to reduce the amount due and owing for a violation of the physician self-referral statute. The SRDP states the factors CMS may consider in reducing the amounts due and owing, including: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.

Fraud Detection and Reporting

CMS has improved the processes for fraud detection by our contractors and for reporting, analyzing, and investigating complaints of potential fraud from beneficiaries.

In order to take a more holistic approach to detecting and addressing fraud, CMS has worked to integrate the activities of the Program Safeguard Contractors (PSCs) into more comprehensive Zone Program Integrity Contractors (ZPICs). Before these reforms, each PSC focused on benefit integrity in limited parts of the Medicare program, making it possible for providers and suppliers to continue to submit fraudulent claims to one part of the Medicare program even after questionable claims had been identified in another part of the program. Instead, CMS is currently in the process of contracting with one ZPIC in

each of seven separate geographic zones, with an emphasis on designated high fraud areas. Unlike PSCs, ZPICs perform program integrity functions for all parts of Medicare. These contracting reforms have allowed CMS to break down silos in program integrity work and better identify potentially fraudulent behavior across all parts of the Medicare program.

Another of these fraud detection improvements involves modifications to the 1-800-MEDICARE call center procedures. In the past, if a caller reported that they did not recognize a provider or did not receive the service documented on their Medicare Summary Notice form, they were asked to follow up with the provider prior to filing a fraud complaint. However, now 1-800-MEDICARE will review the beneficiary's claims records with them and if the discrepancy is not resolved, we will take action and file a complaint immediately, regardless of whether the caller has attempted to contact the provider. Also, CMS is using the information from beneficiaries' complaints in new ways. For instance, CMS is generating weekly "fraud complaint frequency analysis reports" that compile provider-specific complaints and flag providers who have been the subject of multiple fraud complaints for a closer review. This is just one example of CMS shifting our use of available data in more intuitive ways.

As part of our commitment to applying innovative analytics to existing data sources to prevent fraud, CMS has developed the capability to map shifts and trends in fraud allegations reported to 1-800-MEDICARE over time using geospatial maps and sophisticated data tools. These tools will allow CMS to gather more information from 1-800-MEDICARE calls for data analysis. The various parameters include claim type, geographic location, and fraud type. CMS is also exploring new options for streamlining the process and timeframe for investigating fraud complaints, while seeking to preserve the efficiencies and cost-effectiveness of a single call center like 1-800-MEDICARE.

Fiscal Year 2012 Budget Request

To continue the Administration's focus on fraud prevention and to build on the new authorities and resources provided by the Affordable Care Act, the President's Fiscal

Year 2012 Budget Request includes a package of program integrity legislative proposals across Medicare, Medicaid and CHIP that will save \$32.3 billion over 10 years. These proposals, if enacted, would provide CMS with additional tools to reduce and prevent improper payments and ensure that those committing fraud are held responsible and cannot easily discharge their debts or reenter our programs to commit additional offenses.

In addition, the FY 2012 Budget Request also includes a little over \$1.85 billion for the HCFAC account, including mandatory and discretionary sources, divided between CMS' programs and our law enforcement partners at the OIG and DOJ. The FY 2012 discretionary HCFAC request is \$581 million, a \$270 million increase over the FY 2010 enacted level. Described in more detail below, these new HCFAC resources would support and advance the goals of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, a joint Cabinet-level effort established by the President and led by Secretary Sebelius and Attorney General Holder. The Budget Request is necessary to continue expanding the Medicare Fraud Strike Force—an integral part of HEAT, described below—to as many as 20 areas, as well as civil health care fraud enforcement activities. Further, if provided by Congress, this discretionary HCFAC funding will allow us to expand prevention and detection activities and work to reduce improper payments with aggressive pre-payment review, increased provider education, and the development of a national pre-payment edit module.

HCFAC Program Successes

HCFAC has been steadily growing since it began in 1997 and, as shown in the recently released FY 2010 HCFAC report, this investment in fraud fighting resources is paying dividends. The HCFAC report demonstrates the value of this program; since its inception and through FY 2010, HCFAC has resulted in the return of \$18 billion to the Medicare trust funds. In FY 2010 alone, \$2.8 billion was returned to the Medicare trust funds and \$683 million was returned to the Federal Treasury from Medicaid recoveries. The HCFAC return-on-investment (ROI) is currently the highest it has ever been; the 3 year rolling ROI (FY 2008- FY 2010) averaging all HCFAC activities is \$6.8 to \$1; this is

\$1.9 more than the historical average. Additionally, the ROI for the Medicare Integrity Program's activities is 14 to 1.

HCFAC funds support HEAT and many complementary anti-fraud initiatives, including:

- **DOJ-FBI-HHS-OIG-Medicare Strike Forces:** This coordinated effort is needed in order to focus enforcement resources in geographic areas at high risk for fraud. Strike Force cases are data driven, using technology to pinpoint fraud hot spots through the identification of unusual billing patterns as they occur.
- **Increased Prevention and Detection:** CMS is committed to working with law enforcement to efficiently use existing systems and collaborate on future improvements, and has provided numerous training sessions for law enforcement personnel on CMS data analytic systems. Further, CMS will do rapid response projects as well as long-term in-depth studies.
- **Expanded Law Enforcement Strategies:** HCFAC will further expand existing criminal and civil health care fraud investigations and prosecutions, particularly related to fraud schemes in areas such as pharmaceutical services, medical devices, and durable medical equipment, as well as newly emerging schemes. It will allow the use of cutting-edge technology in the analysis of electronic evidence to better target and accelerate enforcement actions. Finally, the increase will expand Medicare and Medicaid audits and OIG's enforcement, investigative, and oversight activities.
- **Oversight:** HCFAC will help to further strengthen oversight in Medicare, Medicaid, and CHIP.

We are excited about the tools and resources available to CMS through HCFAC. In particular, because of changes in the Affordable Care Act, we will now have flexibility to utilize HCFAC funds to enhance our own expertise for pursuing fraud, waste, and abuse in Medicare.

Engaging Our Beneficiaries and Partners

Meanwhile, HHS and CMS continue to work with and rely on our beneficiaries and collaborate with our partners to reduce fraud, waste, and abuse in Medicare, Medicaid and CHIP. The Senior Medicare Patrol (SMP) program, led by the Administration on Aging (AoA), empowers seniors to identify and fight fraud through increased awareness and understanding of Federal health care programs. This knowledge helps seniors protect themselves from the economic and health-related consequences of Medicare and Medicaid fraud, waste, and abuse. In partnership with State and national fraud control/consumer protection entities, including Medicare contractors, State Medicaid Fraud Control Units, State Attorneys General, the HHS OIG, and CMS, SMP projects also work to resolve beneficiary complaints of potential fraud. Since the program's inception, the program has educated over 3.84 million beneficiaries in group or one-on-one counseling sessions and has reached almost 24 million people through community education outreach events. CMS is partnering with AoA to expand the size of the SMP program and put more people in the community to assist in the fight against fraud.

In addition to working with AoA on expanding the SMPs, CMS is implementing a number of new mechanisms to better engage beneficiaries in identifying and preventing fraud. As part of that effort, CMS encourages its beneficiaries to check their Medicare claims summaries thoroughly. Medicare Summary Notices (MSNs) are sent to beneficiaries every 90 days; CMS is working with beneficiaries to redesign the MSNs to make them easier to understand so beneficiaries can spot potential fraud or overpayments on claims submitted for their care. Additionally, some 10 million beneficiaries are enrolled into www.mymedicare.gov, a secure website, and can now check their claims within 24 hours of the processing date. This information is also available through the 1-800-MEDICARE automated system. A fact sheet and informational card have been developed to educate and encourage beneficiaries or caregivers to check their claims frequently and to report any suspicious claims activity to Medicare. These materials are being used at the regional fraud prevention summits (described below) and have been shared with both State Health Insurance Plans (SHIPs) and SMPs.

Further, CMS is implementing a number of new educational and awareness initiatives in identifying and preventing fraud among those Americans who receive services under the Medicaid program.

Collaborating with Law Enforcement Partners

CMS is committed to working with our law enforcement partners, who take a lead role in investigating and prosecuting alleged fraud. CMS provides support and resources to the Strike Forces, which investigate and track down individuals and entities defrauding Medicare and other government health care programs. Strike Force prosecutions are “data driven” and target individuals and groups actively involved in ongoing fraud schemes. These efforts started in Miami in 2007 and expanded to Los Angeles in 2008. In 2009 and 2010 under the HEAT initiative, we continued expanding the Strike Force to Detroit, Houston, Brooklyn, Tampa and Baton Rouge using the additional discretionary funding that Congress provided in response to the President’s budget requests. On February 17, 2011, we announced further expansion of Medicare Fraud Strike Force operations to Dallas and Chicago. HEAT has enhanced coordination of anti-fraud efforts of DOJ’s Civil and Criminal Divisions and U.S. Attorneys’ Offices, FBI, HHS/OIG and CMS. The HEAT task force is working to identify new enforcement initiatives and areas for increased oversight and prevention, including how to increase efficiency in pharmaceutical and device investigations.

The Strike Force model has been very successful. Since its inception, Strike Force operations in nine cities have charged more than 990 individuals who collectively have falsely billed the Medicare program for more than \$2.3 billion. This figure includes the Medicare Strike Force’s latest successes, announced on February 17, 2011, charging 111 individuals with more than \$225 million in false Medicare billing.

Sharing information and performance metrics broadly and engaging internal and external stakeholders requires establishing new partnerships with government and private sector groups. Because the public and private sectors have common challenges in fighting fraud and keeping fraudulent providers at bay, it makes sense that we should work together to

develop common solutions. In addition to the HEAT initiative, agencies including HHS, CMS, OIG, and DOJ have co-hosted a series of regional summits on health care fraud prevention.

Building on the momentum generated by the National Health Care Fraud Summit in January 2010, regional health care fraud prevention summits have been held across the country. These summits, held to date in Miami, Los Angeles, New York, and Boston with plans for additional cities, brought together Federal and State officials, law enforcement experts, private insurers, beneficiaries, caregivers, and health care providers to discuss innovative ways to eliminate fraud within the nation's health care system. These summits also featured educational panels that discussed best practices for providers, beneficiaries and law enforcement in preventing health care fraud. The panels included law enforcement officials, consumer experts, providers and representatives of key government agencies. CMS looks forward to continuing these summits in 2011 as well as more opportunities to bring these stakeholder communities together in other cities to continue this important dialogue and strengthen our cooperative efforts across the Federal government and with the private sector.

Data Analytics

The Affordable Care Act also requires increased data sharing between Federal entities to monitor and assess high risk program areas and better identify potential sources of fraud. CMS is expanding its Integrated Data Repository (IDR) which is currently populated with five years of historical Part A, Part B and Part D paid claims, to include near real time pre-payment stage claims data; this additional data will provide the opportunity to analyze previously undetected indicators of aberrant activity throughout the claims processing cycle. CMS intends to develop shared data models and is pursuing data sharing and matching agreements with the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential waste, fraud, and abuse throughout Federal health care programs. Also, the Affordable Care Act requirement that States report an expanded set of data elements from their Medicaid Management Information System (MMIS) will

strengthen CMS' program integrity work both within State Medicaid programs and across CMS. This robust State data set will be harmonized with Medicare claims data in the IDR to detect potential fraud, waste and abuse across multiple payers.

CMS will implement an innovative risk scoring technology that applies effective predictive models to Medicare. Innovative risk scoring technology applies a combination of behavioral analyses, network analyses, and predictive analyses that are proven to effectively identify complex patterns of fraud and improper claims and billing schemes. CMS is integrating the advanced technology as part of an end-to-end solution that triggers effective, timely administrative actions by CMS as well as referrals to law enforcement when appropriate. Prior to applying predictive models to claims prepayment, CMS will rigorously test the algorithms to ensure a low rate of false positives, allowing payment of claims to legitimate providers without disruption or additional costs to honest providers; confirm that the algorithms do not diminish access to care for legitimate beneficiaries; and identify the most efficient analytics in order to appropriately target resources to the highest risk claims or providers. Given the changing landscape of health care fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as they appear.

As we pursue and test new technology, CMS is working to involve the private sector and State partners to incorporate strategies that have already proven successful. As the first phase of partnership building with private sector entities, CMS held an industry day in October 2010 that was attended by approximately 300 industry representatives. This event highlighted CMS' strategic goals, priorities, and objectives in the use of information technology solutions for fraud prevention in our programs and provided an opportunity for attendees to determine whether their firm's services, methods and products fit with CMS' mission and vision. In December 2010, CPI issued a Request for Information asking vendors to identify their capabilities in the areas of provider screening/enrollment and data integration. CMS will review the responses and incorporate innovative ideas into the strategy for integrated, automated, providers screening and data integration.

Further, the Small Business Jobs Act of 2010 provided \$100 million, beginning in FY 2011 to phase-in the implementation of predictive analytics in Medicare FFS, Medicaid, and CHIP over four years. The new predictive modeling technology will incorporate lessons learned through pilot projects. For example, in one pilot, CMS partnered with the Federal Recovery Accountability and Transparency Board (RATB) to investigate a group of high-risk providers. By linking public data found on the Internet with other information, like fraud alerts from other payers and court records, we uncovered a potentially fraudulent scheme. The scheme involved opening multiple companies at the same location on the same day using provider numbers of physicians in other states. The data confirmed several suspect providers who were already under investigation and, through linkage analysis, identified affiliated providers who are now also under investigation.

Delivery System Reforms

Beyond the traditional program integrity initiatives, the delivery system reforms created by the Affordable Care Act will further help to deter and prevent fraudulent activities within Medicare. When there are large disparities between the cost of goods and services, as compared to the allowed reimbursement, we know that these excessive payments often make Medicare a more attractive and lucrative target for those attempting to commit fraud. For instance, OIG, the Government Accountability Office (GAO), and other independent analysts have repeatedly highlighted that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or cash customers. These inflated prices in turn increase the potential profits of those intending to defraud the Medicare program. To that end, CMS implemented supplier contracts and new payment rates based on the Round 1 rebid of DMEPOS competitive bidding on January 1, 2011 in nine Metropolitan Statistical Areas. The Office of the Actuary estimates that once fully implemented this program is projected to save more than \$17 billion in Medicare expenditures over ten years. Outside of DMEPOS, CMS is working to redesign our Medicare payment systems and institute delivery system reforms that will realign

Medicare payments with market prices and thereby reduce the incentive for “bad-actors” to target Medicare.

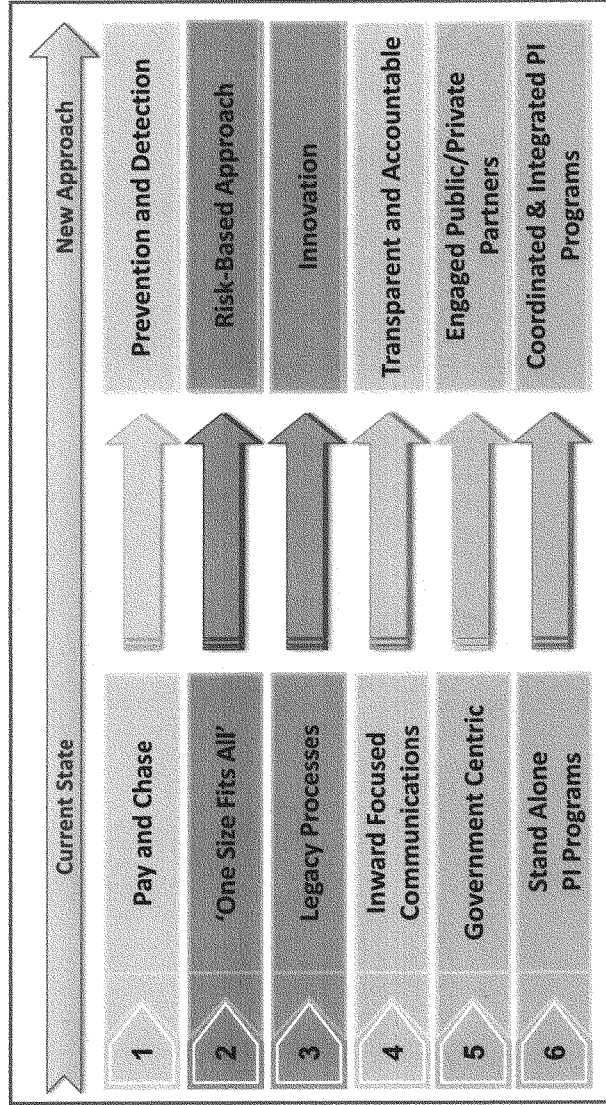
All of these new authorities and analytical tools will help move CMS beyond its historical “pay and chase” mode to a prevention-oriented approach with strong fraud deterrents and increased enrollment screenings, new disclosure and transparency guidelines, and early identification of high-risk providers and suppliers.

Conclusion

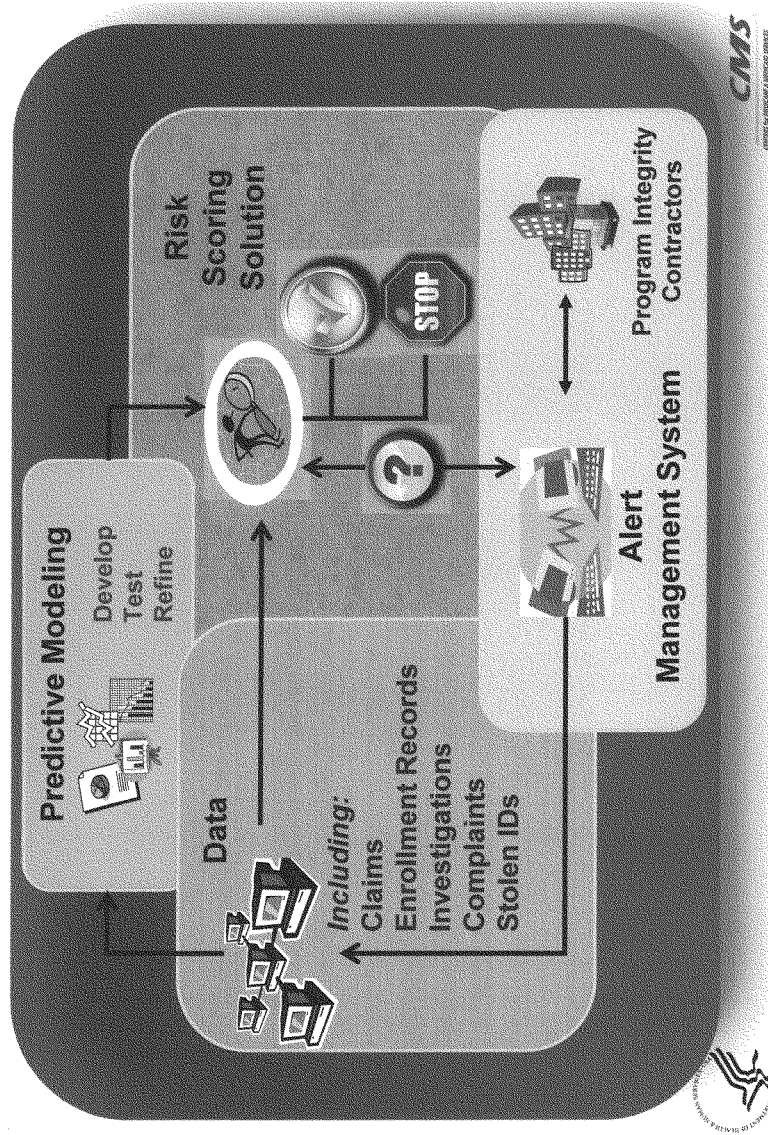
Health care fraud and improper payments undermine the integrity of Federal health care programs. Taxpayer dollars lost to fraud, waste, and abuse harm multiple parties, particularly some of our most vulnerable seniors, not just the Federal government. Eliminating the problem requires a long-term, sustainable approach that brings together beneficiaries, health care providers, the private sector, and Federal, State, and local governments and law enforcement agencies, in a collaborative partnership to develop and implement long-term solutions. New authorities in the Affordable Care Act offer additional front-end protections to keep those who intend to commit fraud out of Federal health care programs, as well as new tools for deterring wasteful and fiscally abusive practices, and promptly identifying and addressing fraudulent payment issues, which will ensure the integrity of Medicare, Medicaid and CHIP.

This Administration has made a firm commitment to rein in fraud and wasteful spending, and with the Affordable Care Act, we have more tools than ever before to implement important and strategic changes. CMS thanks the Congress for providing us with these new authorities and resources, and looks forward to working with you in the future as we continue to make improvements in protecting the integrity of Federal health care programs and safeguarding taxpayer resources.

Center for Program Integrity



National Fraud Prevention Program



United States Senate Committee on Finance
Public Hearing
“Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges”
March 2, 2011

Responses to Questions Submitted for the Record From Peter Budetti

Senator Max Baucus:

Questions for the Witness:

HCFAC Successes

The Health Care Fraud and Abuse Control (HCFAC) program funds the major health fraud prevention activities conducted by HHS, OIG, DOJ, and the FBI. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established the HCFAC Program under the joint direction of the Attorney General and the Secretary of HHS, designed to coordinate Federal, state and local law enforcement activities to combat health care fraud and abuse. Since 2009, HCFAC's return on investment has been \$6.80 per every \$1. In total, HCFAC has returned more than \$18 billion to the Medicare Trust Fund. In January of this year, HHS announced that the Health Care Fraud and Abuse Control Program (HCFAC) recovered over \$4 billion in fraudulent payments in 2010—the largest annual recovery ever.

I was impressed to see that last year, the combined efforts by HHS and DOJ, through the HCFAC program, recovered over \$4 billion. I understand this is the highest annual recovery under this program.

1. Please describe what was done differently to allow such a high recovery.

Answer: A combination of factors contributed to last year's record high recoveries, especially the additional discretionary resources that Congress provided to HHS and DOJ for program integrity and the Health Care Fraud Enforcement Action Team (HEAT) initiative to enhance our joint enforcement and prevention activities. In FY 2009, Congress provided \$198 million in new discretionary funding to HHS for health care fraud enforcement and prevention activities, of which about \$19 million (approximately 9.6%) was designated for DOJ. Last year, Congress provided \$311 million to HHS for health care program integrity activities of which DOJ received \$29.8 million in dedicated health care fraud enforcement funding. These additional prevention, investigation and prosecution resources have enabled HHS and DOJ to handle additional cases leading, in part, to greater total recoveries.

Since its creation in May 2009, the joint HHS-DOJ HEAT task force has focused on key areas for coordination and improvement. HEAT members are working to expand existing enforcement initiatives and to identify new areas for increased oversight and prevention. DOJ and HHS have expanded data sharing and improved information sharing procedures in order to get critical data and information into the hands of law enforcement to track patterns of fraud and abuse, and increase efficiency in investigating and prosecuting complex health care fraud cases.

2. With the new tools provided in the health reform law becoming effective this year, should we expect a higher number next year?

Answer: Predictions of future collections based on the provision of “new tools” is difficult. Even when new resources or authorities are provided, cases still take a number of months and often years to develop. As a consequence it is difficult to predict the number and amount of case resolutions for any particular year. The HCFAC ROI calculation is the result of a three-year rolling average of collections, since it can take several months or longer to detect fraud, build a case for prosecutions, and then achieve settlements or collect recoveries. Further, authorities and activities that are focused on preventing fraudulent individuals and entities from enrolling in our programs and avoiding making payments on fraudulent claims will not translate into increased collections, despite being key and important fraud-fighting investments. As we implement these tools and become increasingly effective in using them to prevent fraud, it is possible that there may be a slowing in the growth of the dollar amount of recoveries from fraud as a result of more effective prevention measures. We are currently exploring the adoption of measurement tools which will provide a reliable picture of avoided fraud costs in order to provide a complete picture of the positive effects of our integrated fraud and abuse prevention and recovery efforts. Nevertheless, we are committed to reducing fraud in our Federal health care programs, and stewarding taxpayer resources appropriately, and are exploring ways to measure the effects of such prevention activities, as well as recoveries.

3. What else can we do to improve the effectiveness of HCFAC?

Answer: In FY 2012, the Administration has requested historic levels of funding to support CMS’ program integrity work and our HHS and DOJ law enforcement partners’ criminal, civil and administrative enforcement activities. The Administration is seeking \$581 million in HCFAC discretionary funds, a \$270 million increase in discretionary funds compared to FY 2011, which have shown a strong return-on-investment (ROI) and successful recoveries to the Trust Funds. CMS’ Actuaries have determined that the multi-year discretionary HCFAC investment, starting with \$581 million in FY 2012, is estimated to save \$4.6 billion over five years and \$10.3 billion over ten years.

The increase in funds for FY 2012 will be split among CMS and its law enforcement partners and be used to continue and expand program integrity efforts. It supports ongoing efforts by the Administration to reduce the Medicare FFS error rate, expansion of HEAT Strike Force and civil pharmaceutical fraud and medical device enforcement activities, and will also be used to deploy new and innovative efforts such as: (1) State-of-the-art data analytics and national pre-payment edits to prevent potentially wasteful, abusive, or fraudulent payments before they occur; (2) The build-out of the Compromised Beneficiary and Provider Numbers database; (3) Further expansion of the Integrated Data Repository; (4) Enhancements to the Do Not Pay list; (5) Development of HEAT complaint maps to help target priorities and identify geographic “hot spots.”

4. Does HCFAC have the resources necessary?

Answer: The Administration’s FY 2012 Budget Request continues to make fighting health care fraud and reducing improper payments a top priority. These efforts will safeguard public funds and send a clear message that fraud and waste in our Federal health care programs will not be tolerated.

The Budget Request includes \$581 million, a \$270 million increase in discretionary program integrity resources compared to FY 2011 levels as part of a multi-year investment to enable HHS and its partners to take ground-breaking steps to detect, prevent, and prosecute health care fraud. The Budget also proposes a series of new legislative changes that will strengthen existing program integrity oversight in Medicare and Medicaid. These legislative changes will show real, measurable results, saving \$32.3 billion over ten years.

Fully funding the Administration's FY 2012 Budget Request will provide needed additional resources for CMS and its law enforcement partners.

State Fraud Enforcement Actions

States are under enormous financial stress as a result of the economy. Because revenues have fallen and Medicaid expenditures have grown, states are under pressure to find ways to save money. Many of the tools included in the Affordable Care Act (ACA) apply to both Medicare and Medicaid, including increased screening requirements and an expansion of the recovery audit contractors. In addition, the ACA requires a state Medicaid program to terminate any provider that has been terminated due to fraudulent activity by Medicare or a different state's Medicaid program. This prevents criminals from simply moving from state to state perpetrating similar schemes. Finally, the President's Budget proposed additional policies aimed at reducing fraud in Medicaid.

The great recession has put states under enormous pressure to balance their budgets. As a result, they are looking for a variety of ways to reduce spending. As you well know, one way to reduce spending is to root out fraud.

5. Can you talk about ways the Affordable Care Act allows states to prevent fraud and in turn reduce spending on Medicaid?

Answer: The Affordable Care Act provided numerous new authorities that allow States to prevent fraud and reduce their spending on Medicaid. These new authorities include:

- Enhanced screening and other enrollment requirements that will keep fraudulent providers from entering the Medicaid program and remove those who are defrauding it.
- Expanded overpayment recovery efforts that extends the Recovery Audit Contractor program to Medicaid and requires Medicaid providers to report and return overpayments within 60 days of identification.
- Improved data exchange and program coordination between the Federal and State governments through mutual reporting of terminated providers from Medicare, Medicaid, CHIP or another State Medicaid program.
- Elevated barriers to deter the defrauding of the Medicaid program by prohibiting program payments to institutions or entities located outside of the United States.
- Increased scrutiny of provider claims and payments by incorporating the National Correct Coding Initiative (NCCI) into the Medicaid program to reduce improper payments.

6. Have you identified certain states that have excelled in preventing and fighting fraud and what lessons can be learned from those states?

Answer: The Medicaid Integrity Program has two mechanisms by which it identifies States that have excelled in program integrity and the lessons States can learn from those leader States.

First, CMS conducts annual comprehensive program integrity reviews of one-third of the States (including Puerto Rico and Washington D.C.) each year. The objectives of the reviews include identifying effective practices. We publish a Program Integrity Review Annual Summary, which is a compendium of data collected from the comprehensive reviews conducted each year since FY 2008. In the *Effective Practices* section of the report, practices identified by both the CMS review team and the States are discussed. Please note that the report is not intended to be a *report card*. Rather it is a vehicle to share program integrity practices and other information with all States. The reports are available on the CMS website at http://www.cms.gov/FraudAbuseforProfs/05_StateProgramIntegrityReviews.asp#TopOfPage.

Second, CMS implemented the State Program Integrity Assessment (SPIA). SPIA is an annual activity to collect State Medicaid program integrity data, develop profiles for each State based on these data, determine areas to provide States with technical support and assistance, and develop measures to assess States' performance in an ongoing manner. SPIA represents the first national baseline collection of data on State Medicaid integrity activities for the purposes of program evaluation and technical assistance support. In FY 2009, CMS completed the first national collection of SPIA data. With this information, States and CMS can identify areas of opportunity to build on already effective practices and to identify areas for improvement. Individual State reports, a complete dataset, and a high-level executive summary of the results are available on the CMS website at http://www.cms.gov/FraudAbuseforProfs/11_SPIA.asp.

Deficient Hospital Peer Review Problem

One contributing factor to the alleged unnecessary cardiac stent utilization at St. Joseph Medical Center was a breakdown in the hospital's peer review process. The doctor accused of implanting unnecessary stents was also responsible for picking and choosing which cases were reviewed by his peers. The hospital has since reformed its peer review process to include monthly random reviews to evaluate medical necessity.

Dr. Budetti, the Committee's investigation looking at the overutilization of cardiac stents raised the issue of enhanced peer review at hospitals as a way to curb unnecessary procedures.

7. Can you comment on any ongoing efforts at CMS to examine or strengthen hospital peer review?

Answer: The Centers for Medicare & Medicaid Services (CMS) is committed to improving the quality of care furnished to Medicare beneficiaries and we agree that the peer review process plays an important role in this effort. In fact, Medicare's hospital Conditions of Participation (CoPs) include a number of requirements that recognize the need for effective peer review and, through the survey and certification process, these requirements are monitored on a routine basis. For example, the CoPs include requirements to ensure that medical staff is accountable to the governing body for the quality of care provided to patients and that medical staff periodically conduct appraisals of its members.

At the same time, CMS recognizes the importance of linking quality improvement techniques with peer review efforts. The Quality Improvement Organizations (QIOs) function as peer review organizations and review professional activities of physicians and other health care

practitioners to determine if the services they furnished are reasonable and medically necessary and whether such services and items are allowable. The QIOs also perform case reviews to ensure the quality of such services meets professionally recognized standards of health care and perform reviews to identify trends and patterns. When these reviews reveal unnecessary medical procedures, the QIOs work with the practitioners/providers to develop and implement a quality improvement corrective action plan to address the issues, and the practitioners/providers are placed under routine monitoring to ensure demonstration of corrective and sustainable actions.

Peer review mechanisms also play a role in focusing and enhancing our program integrity efforts. The Medicare Administrative Contractors (MACs) and Zone Integrity Program Contractor (ZPICs) perform claim reviews to identify possible over-utilization of procedures by comparing providers to peers. If providers are identified as having questionable billing through this process, further analysis is conducted of specific billing procedures and frequency. If quality of care issues, such as inappropriate procedures, are identified through this process, the provider is referred to the QIO for investigation. All medically unnecessary procedures represent quality of care issues as well as utilization issues. Therefore, the MACs refer these issues to the QIO for quality review.

Senator Orrin Hatch:

Questions for the Witness:

Antifraud Provisions in the ACA

We've discussed the antifraud provisions that were included in the Patient Protection and Affordable Care Act. As I noted in my opening statement, it seems that implementation of the antifraud provisions have run into a number of delays. For instance, the provision implementing the ordering and referring requirement for providers has been delayed multiple times and most recently there have been additional delays to implementation of the Medicaid RAC provisions. In both instances, the reason cited for the delays are operational issues by either CMS or the states.

- 1. Can you explain to me why CMS did not assess or anticipate these operational delays before issuing guidance and beginning down the path toward implementation?**

Answer: The Affordable Care Act included many program integrity provisions with aggressive implementation timelines, and CMS has worked expeditiously to meet all statutory deadlines within the Affordable Care Act. CMS issued an interim final rule with comment (IFC) on May 5, 2010 requiring physicians and eligible professionals who order and refer to enroll in Medicare; this provision had an effective date of July 6, 2010. In keeping with the law, CMS is committed to ensuring that we only pay for services that are ordered and referred by eligible physicians and other practitioners who are enrolled in Medicare. We acknowledge delays in enforcing the requirement through automated edits due to operational concerns; however we have been clear since the rule was issued that the law is in effect and that we expect such physicians and eligible professionals to comply with the enrollment requirement. We plan to issue a final rule incorporating the comments received from the IFC and at that time will issue advance notification as to when the automated edits will be operational.

In regards to the Medicaid Recovery Audit program, in line with our interpretation of the statute, States were required to submit a State Plan Amendment to CMS to establish their recovery audit programs by December 31, 2010. This is an important program and we intend to promulgate final regulations as expeditiously as possible.

2. How can providers be expected to be compliant if CMS itself is not able to effectively implement these provisions?

Answer: As stated above, no deadlines have been missed in our implementation of these provisions. CMS is committed to implementing the provisions of the Affordable Care Act and is mindful of burdens on providers in these situations. We will continue to work with providers to make sure that they are informed on the status of all new program integrity provisions.

3. What is being done to ensure that these types of start/stop implementation issues will not occur with other provisions as they are rolled out?

Answer: CMS is committed to implementing the provisions of the Affordable Care Act in a timely fashion. The Affordable Care Act included many program integrity provisions that included aggressive timelines; CMS is committed to implementing these authorities within statutory deadlines.

Strategic Principals for Program Integrity

In your testimony and other public statements you have spoken at length about your strategic principals for Program Integrity and articulated a wide-ranging number of actions your office is pursuing,

4. but do you have a coordinated plan for how all those actions fit together?

Answer: Yes. CMS' Center for Program Integrity has aligned the Center's strategic principles with budgetary and staff resources to ensure that CPI is implementing an integrated program strategy.

5. How will you assess which of those efforts are effective and how well they are all working together?

Answer: CMS' Center for Program Integrity is in the process of developing and implementing new performance metrics that will assist us in evaluating the effectiveness of new activities as well as ongoing ones. Additionally, we are continually looking for opportunities to coordinate program integrity activities across Medicare and Medicaid to make an effective strategy even more valuable.

6. Rather than asking for more resources, would it not be more prudent to assess how well what you are doing is working before spending even more money or assuming that more resources are needed?

Answer: The annual Health Care Fraud and Abuse Control Program (HCFAC) report demonstrates that resources spent on program integrity activities have a very high return on investment. The most recent HCFAC report demonstrated the highest recovery in the history of

the program \$4 billion; and a three year average return on investment of \$6.80 per every \$1 spent. For these reasons, CMS is confident that the program integrity efforts we are making are effective and vital to the federal health care programs.

New Tools and Approaches

In your testimony and other public statements, you have indicated the array of new tools and approaches CMS is utilizing to do more on the front end to prevent fraud, waste and abuse from occurring. While there is certainly much to point to in terms of enforcement results over the past year, I am curious as to what tangible and quantifiable results CMS has seen from the money and tools specifically given to them.

7. Can you please give me some specific examples of where CMS has seen actual return on investment from the money provided from the Patient Protection and Affordable Care Act?

Answer: Predictions of future collections based on the provision of “new tools” is difficult. Even when new resources or authorities are provided, cases still take a number of months and often years to develop. The mandatory HCFAC resources allocated in the Affordable Care Act are already being utilized to increase and improve program integrity efforts. At this time, it would be premature to comment or speculate on the return on investment from these allocations because the process of investigating and prosecuting fraud takes many months and often years. An updated return-on-investment calculation and recovery figures will be available in the FY 2011 HCFAC report. Furthermore, as we implement these tools and become increasingly effective in using them to prevent fraud, it is possible that there may be a slowing in the growth of the dollar amount of recoveries from fraud as a result of more effective prevention measures.

8. What other types of results can this Committee expect to see from this investment and how will you be measuring the success of those efforts?

Answer: As part of routine, statutorily mandated reporting on HCFAC, CMS in coordination with HHS and the Attorney General submit a joint consolidated annual report to the Congress which identifies both: (1) the amounts appropriated to the Medicare Trust Funds for the previous fiscal year under various categories and the source of such amounts; and (2) the amounts appropriated from the Trust Funds for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts. Additionally, the report is required to “include measures of the operational efficiency and impact on fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program for the funds provided by this appropriation.” We are currently exploring the adoption of measurement tools which will provide a reliable picture of avoided fraud costs in order to provide a complete picture of the positive effects of our integrated fraud and abuse prevention and recovery efforts.

9. Why do you believe that these new approaches will deter or prevent the rampant fraud that has continued unabated over the last 20 years?

Answer: The FY2012 Budget makes fighting health care fraud and reducing improper payments a top priority. These efforts will safeguard public funds and send a clear message that fraud and waste in our health care programs will not be tolerated. The Budget includes \$581 million for HCFAC discretionary activities, a \$270 million increase in discretionary program integrity resources as part of a multi-year investment to enable HHS and its partners to take ground-

breaking steps to detect, prevent, and prosecute health care fraud. Although fraud has been a long-term problem in the Federal health care programs, in the four years since the inception of the Strike Force Model, Strike Force prosecutors filed 530 cases charging more than 1,000 defendants who collectively billed the Medicare program more than \$2.3 billion; 551 defendants pleaded guilty and 52 others were convicted in jury trials; and 465 defendants were sentenced to imprisonment for an average term of 42 months.

The Affordable Care Act provides additional tools to help prevent fraud. The Affordable Care Act requires providers and suppliers who wish to enroll in the Medicare, Medicaid, or CHIP programs to undergo a level of screening tied to the level of risk of fraud, waste, or abuse such providers and suppliers present to the programs. The statute also provides the authority for CMS to impose a temporary enrollment moratorium if the Secretary determines such a moratorium is necessary to prevent or combat fraud, waste, or abuse, in addition to allowing Medicare payments to be suspended from providers or suppliers if there is a credible allegation of fraud pending an investigation or final action. These changes help CMS move from a “pay and chase” model of fraud fighting to being more prevention-focused.

Center for Program Integrity

In October of 2010, the Center for Program Integrity (CPI) held an Industry Day event. During that event, CPI described their challenges and priorities related to managing waste, fraud, and abuse within the Medicare, Medicaid, and CHIP programs. It was stated that CPI was looking to industry for fresh, innovative ideas, practices, and technologies to help fight fraud.

10. How is CMS able to get these things from industry when they limit procurements to existing contractors, whom one could argue are part of the current state vs. the future state?

Answer: As we pursue and test new technology for data analytics, CMS is working to involve the private sector and State partners to incorporate strategies that have already proven successful. As the first phase of partnership-building with private sector entities, CMS held an Industry Day in October 2010 that was attended by approximately 300 industry representatives. CMS then issued two formal requests for information to obtain industry guidance and innovative ideas on the development of fully integrated approaches to provider screening and data matching. CMS received responses from a variety of companies, and is using this information to better inform future solicitations. For example, after reviewing the responses to the provider screening RFI, CMS issued a Sources Sought Notice on April 14, 2011 to further assess the ability of innovative small businesses to meet the requirements for an integrated provider screening solution. Based on that assessment, CMS will issue a provider screening solicitation open to all companies that qualify as an 8a Small Business this summer.

CMS opted to leverage its existing umbrella contract for Enterprise Systems Development in order to meet the aggressive statutory schedule milestones of the Small Business Jobs Act of 2010 (SBJA). In order to be eligible to compete for awards under an umbrella contract, industry leading companies undergo open competition to become “pre-qualified” for future solicitations. This specific umbrella contract is tailored around the ability to provide information technology solutions that are compatible with CMS system requirements. CMS awarded the predictive modeling contract on April 30, 2011, and anticipates the award of the second developer contract in the near future as required by the SBJA. The prior verification of vendor capabilities required

by the umbrella contract enabled the timely award of these contracts and CMS is on track to meet the July 1, 2011 SBJA implementation date.

At a later date, CMS intends to launch a full and open competition for an additional umbrella contract for Program Integrity solutions. This competition will identify vendors who are capable of developing and supporting additional anti-fraud complex applications, and permit CMS to more quickly adopt innovative technologies and respond to emerging threats.

Predictive Modeling Solutions

In your testimony, Dr. Budetti, you mentioned that there were proposals being reviewed now for predictive modeling solutions. You also stated that CMS expects to make an award by the end of June and have a solution in place by the end of the year.

11. Given that proposals are still being evaluated and implementation of this type of technology is complex, how would this even be feasible without having already decided upon some sort of solution?

Answer: The solutions to be implemented will come from the successful bidders. The Evaluation Criteria associated with the Predictive Modeling acquisition were carefully selected to help CMS select the most qualified and capable developer that is able to meet technical requirements while mitigating risks associated with the aggressive schedule. For example, contractors were instructed that proposals are evaluated on technical understanding of the new requirements and integration into CMS claims processing systems, predictive modeling methodology, clinical knowledge and experience with payment rules and regulations, the contractor's performance-based work plan and relevant past performance. CMS believes these factors encouraged new innovative partnerships during the strategic proposal development and planning stage to meet these requirements. Proposals meeting these criteria are more likely to meet the aggressive schedule.

12. Why is CPI placing the majority of their emphasis on predictive modeling of claims data?

Answer: CMS intends to aggressively implement and use all of the tools and statutory authorities provided by the Affordable Care Act and the Small Business Jobs Act, including enhanced provider enrollment screenings, payment suspension when a credible allegation of fraud exists, and data analytics.

Section 4241 of the Small Business Jobs Act of 2010 requires the Secretary to "use predictive modeling and other analytics technologies...to identify improper claims for reimbursement and to prevent the payment of such claims under the Medicare fee-for-service program." CMS is integrating the advanced technology as part of an end-to-end solution that triggers effective, timely administrative actions by CMS as well as referrals to law enforcement when appropriate. Innovative risk scoring technology will apply a combination of behavioral analyses, network analyses, and predictive analyses that are proven to effectively identify complex patterns of fraud and improper claims and billing schemes.

For too long, the Federal claims payment system has operated primarily as a "pay and chase" system, *i.e.*, paying providers and suppliers now, and asking questions later, regardless of the risk of fraud, waste and abuse. The purpose of predictive modeling technologies is to prevent

improper payments from being made in the first place by flagging questionable claims for additional review and potential payment suspension. The results of the predictive modeling will be applied to claims that are submitted, but the data that will be used to develop the models and that will be analyzed go well beyond claims data.

13. Wouldn't it make more sense to enhance provider enrollment screening processes and controls, ensuring that no more bad actors infiltrate the system?

Answer: There is no question that strong provider enrollment screening processes and controls are a foundation of our efforts to prevent fraud in Medicare and other Federal health care programs. Each month CMS receives 18,000 new requests from providers and suppliers wishing to participate in Medicare.

We are appreciative of the new enrollment screening tools provided by the Affordable Care Act and are steadily working to incorporate targeted screening and prevention activities into our claims and enrollment processes where appropriate. This new authority requires high-risk providers and suppliers, including newly enrolling suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and home health agencies, to undergo a higher level of scrutiny based on CMS' and law enforcement's experience with these provider and supplier types. CMS has also established certain triggers that would move a provider or supplier into the highest screening level. Our goal is to keep those individuals and companies that intend to defraud Medicare, Medicaid, and CHIP out of these programs in the first place, not to pay fraudulent claims when they are submitted, and then to remove such individuals and companies from our programs if they do get in.

Prescreening enrollment applications using innovative technology has substantial value, as demonstrated through a pilot project. CMS partnered with the Federal Recovery Accountability and Transparency Board (RATB) to investigate a group of high-risk providers. By linking public data found on the Internet with other information, like fraud alerts from other payers and court records, we uncovered a potentially fraudulent scheme. The scheme involved opening multiple companies at the same location on the same day using provider numbers of physicians in other states. The data confirmed several suspect providers who were already under investigation and, through linkage analysis, identified affiliated providers who are now also under investigation.

The first step to preventing fraud in the Federal health care programs is to appropriately screen providers and suppliers who are enrolling or revalidating their enrollment to verify that only legitimate providers and suppliers who meet our stringent enrollment standards, enhanced by the Affordable Care Act, are providing care to program beneficiaries. However, even with strong enrollment controls, there is still a need for subsequent claims analytics to ensure that fraudulent claims can be identified and not paid.

14. Additionally, as part of that same process, why wouldn't CPI want to utilize analytic processes and technologies to identify and prosecute potential bad actors that are already in the system?

Answer: Per the requirements of the Affordable Care Act, CMS is focusing initial efforts on enrollment protections for new providers and suppliers, but we are still monitoring existing providers for aberrancies and subjecting them to new screening procedures when they

periodically revalidate their enrollment. As our system develops, CMS intends to use predictive analytics to help determine whether CMS should target additional review to certain providers, suppliers, or certain high-risk claims activity. This technology will improve CMS' ability to stop paying claims once they are determined to be fraudulent, even if the claims come from a provider legitimately enrolled in the program. In addition to stopping payment, CMS will refer these providers to the OIG for action.

CMS is also automating the validation of information providers submit during their enrollment process and identifying providers with risk factors prior to enrollment. For example, data submitted on the application form, such as licensure and ownership information, will be validated against existing data sources.

Indian Health Service and Veterans Affairs

It was noted that organizations like the Indian Health Service and Veterans Affairs are not notified when a provider is flagged as excluded.

15. Because collaboration and sharing of information with other government agencies is vitally important, can you tell us how CMS has made improvements in this area?

Answer: CMS agrees that data sharing with governmental partners is extremely important, and is working on implementing the new Affordable Care Act requirement that CMS enter into data sharing and matching agreements with Indian Health Service, the Department of Veterans Affairs, as well as the Social Security Administration and the Department of Defense.

However, CMS does not maintain the Office of Inspector General exclusion database that is the publicly available repository of data on providers who have been excluded from all federal health care programs.

16. Has CMS gotten access to other governmental data sources that can be incorporated into the edits process?

Answer: As noted above, CMS is in the process of implementing the Affordable Care Act requirement to enter into data sharing agreements with other agencies. CMS will explore the possibility of implementing such information in the claims edit process. Moreover, CMS believes that such information pertaining to individuals, including information captured by the Federal "Do Not Pay" list, is also likely to be extremely valuable during the enrollment screening process, allowing CMS to deny enrollment to bad actors before they are ever able to submit a claim to CMS.

Change Management

17. There's been great mention of predictive modeling and various innovative technologies, but how is CMS addressing change management?

Answer: Sound, secure, effective, and maintainable business applications and systems that respond to CMS' changing needs are essential to the successful support of the CMS IT Modernization Program. The demands of the modernized CMS environment necessitate an enhanced approach to configuration management, system and software development and a contracting vehicle that facilitates the acquisition of these services. To help address these

business and technology issues, CMS established the ESD initiative to improve how the Agency acquires, implements, and maintains its systems and software across CMS. The ESD Contractor's configuration management, project management and reporting, and risk management systems have been approved and determined to be interoperable with the CMS' framework.

To foster enhanced focus on the major changes underway in CPI, we have recently reorganized and retooled our staffing allocations. Rather than concentrating vast responsibilities in only two staff divisions, we have divided into five groups that are aligned along major functional lines of 1) Enrollment Operations, 2) Data Systems and Analytics, 3) Enforcement, 4) Medicaid, and 5) Medicare Policy and Contractor Operations functions. We have regrouped staff into smaller more focused programmatic priority areas, and we have added some additional staff to areas responsible for new initiatives such as predictive analytics. We have aligned our resources to be consistent with the changes necessary in our work, both to take advantage of new technology and analytics and also to foster meaningful change in the work and working of our contractors that are charged with benefit integrity assurance. These recent changes coupled with the initial creation of the Center for Program Integrity as an equal partner with other operating centers at CMS, position us to succeed in our fight against fraud, abuse, and waste in Medicare and other Federal health care programs.

18. CMS has traditionally focused on payment accuracy and timeliness in making payments. How will CMS take on more of a law enforcement and intelligence mindset as opposed to an operational mindset?

Answer: Due to prompt-pay requirements in the Medicare program, our systems were originally designed with a primary goal to process claims efficiently and effectively. While CMS pays more than 4 million claims every day, we recognize the need to do more than simply pay claims quickly in our systems.

Already, CMS is making progress in screening claims for data aberrancies. Automated edits in our systems screen out coding errors, medically unlikely events, and other claims payment errors. CMS has implemented edits to stop the payment of claims with a date of service after a beneficiary's date of death, stop the payment of durable medical equipment while the beneficiary is receiving care in an inpatient setting, and to stop the payment for individual services that should have been bundled into another payment. In addition, the claim processing contractors have been able to implement local system edits to stop improper payments relating to durable medical equipment bundling (wheelchair and accessories and knee prosthetics) and drugs paid exceeding recommended dosages.

As systems integration continues and more complex analytic capabilities are integrated into our claims processing efforts, CMS will be able to detect patterns in aberrancies, then determine whether to target additional review to certain providers, suppliers, or certain high-risk claims activity. This technology will improve CMS' ability to stop paying claims once they are determined to be fraudulent, even if the claims come from a provider legitimately enrolled in the program. There are currently stringent screening enrollment standards in place for existing providers, these procedures are being enhanced for certain high-risk providers CMS has also established certain triggers that would move a provider or supplier into the highest screening level.

CMS Audits

Congress took an unprecedented step in allowing CMS to contract with private companies to audit health care organizations and allow those companies to take a percentage of the overpayments they find. I understand the demonstration project returned a considerable amount of money to the trust funds.

19. What is the success rate of the permanent Recovery Audit Contractor (RAC) program?

Answer: Between January 1, 2010, and March 1, 2011, the permanent Medicare FFS Recovery Audit program corrected a total of \$261.5 million in improper payments, including \$43.6 million in underpayments corrected and \$217.9 million in overpayments collected.

20. At what point in the future do you expect the RACs to reach their full potential?

Answer: We believe the national Medicare FFS Recovery Audit program will continue to produce recoveries; FY 2010 outreach and education has occurred and we expect that this will result in increased recoveries and continued success.

Recovery Auditors are already helping CMS to identify areas where policy changes, systems changes, and provider education and outreach can help prevent future improper payments. CMS employs a robust system to identify patterns in the vulnerabilities identified by Recovery Auditors and to undertake appropriate corrective actions. In the national program, Recovery Auditors have identified several areas where payment system edits can be helpful in preventing improper payments. CMS has implemented edits to stop the payment of claims with a date of service after a beneficiary's date of death, stop the payment of durable medical equipment while the beneficiary is receiving care in an inpatient setting, and to stop the payment for individual services that should have been bundled into another payment. In addition, the claim processing contractors have been able to implement local system edits to stop improper payments relating to durable medical equipment bundling (wheelchair and accessories and knee prosthetics) and drugs paid exceeding recommended dosages.

As you would expect with a program based on contingency fees, contractors have a financial incentive to focus their work on high dollar amount claims and areas of medical care. Thus far, low dollar claims have been less likely to be reviewed by Recovery Auditors. For example, contractors have not yet reviewed many Medicare Part B claims, which cover outpatient care provided to beneficiaries. FY 2010 outreach and education has occurred and we expect that this will result in increased recoveries and continued success.

21. With limited monies being returned to CMS, do you have any sense of the cost to health care organizations in trying to work with and respond to the RACs?

Answer: CMS is committed to minimizing the burden on providers and healthcare organizations. One of the major lessons we learned during the Recovery Audit demonstration was the importance of communication with providers. CMS continues to work very closely with the provider community and associations to get feedback prior to instituting large-scale changes and continues to value their ongoing participation and feedback.

Before implementing the nationwide Recovery Audit program, CMS made a number of changes in response to direct feedback from providers. For example, every RAC is required to hire a physician medical director, which gives providers additional assurance that the reviews of their medical decisions are accurate and handled appropriately. Providers expressed concerns that filling multiple requests for medical records for review created a burden. As a result, CMS created sliding scale limits, based on provider size, for the number of medical records that can be requested by RACs from a provider. In order to ensure accurate determinations of payments made in error, RACs must now also secure pre-approval from CMS of issues they wish to pursue for review, meaning that before a RAC can proceed with large numbers of reviews, CMS staff, and if necessary, a third party independent reviewer, must examine and approve the proposed provider type, error type, policy violated and potential improper payment amount per claim to ensure that the review is appropriate.

CMS believes that these changes strike an appropriate balance between minimizing the burden on providers and allowing Recovery Auditors to perform their work and ensure that Medicare payments are accurate.

Self-disclosure Protocols

Both of your agencies have self-disclosure protocols. The OIG has a general self-disclosure process for providers and CMS recently adopted a self-disclosure protocol for non-compliance with the physician self-referral law (also known as the Stark Law).

22. Could both of you tell me how long it takes for an organization to resolve a matter which uses your respective self-disclosure protocols?

Answer: The Centers for Medicare & Medicaid Services (CMS) published the self-referral disclosure protocol on the CMS website on September 23, 2010. Due to our limited experience with the protocol thus far, we are unable to provide an estimate concerning the amount of time needed to resolve a disclosure. However, we believe that there will be considerable variation in the amount of time it takes for an organization to resolve a matter through the process. Some of the factors that will bear on this include the cooperation of the disclosing party, differences in the nature and extent of the disclosed conduct, the size of the entity, and the number of non-compliant arrangements.

23. Are there any estimates in how much it costs health care organizations to go through the self-disclosure process?

Answer: We estimate the average cost per disclosure to be roughly \$1,500 to \$2,000.

24. That is, how many personnel hours are needed, or what types of costs do organizations incur to work through the process?

Answer: We estimate that an average disclosure will require approximately 15 hours of legal review with an associated cost of roughly \$1,000 to \$1,500. In addition, we estimate an average disclosure will require roughly nine hours of accounting review for the financial analysis at a cost of approximately \$400.00 to \$500.00.

Senator Chuck Grassley:

Questions for the Witness:

President's FY 2012 Budget

Dr. Budetti, the President's FY 2012 Budget includes \$1.27 billion in mandatory funds for the Health Care Fraud and Abuse Control Program (HCFAC). In addition, the Budget requests \$581 million in discretionary HCFAC funding, an increase of \$270 million over FY2010. Of the discretionary funds, CMS would be allocated \$389.9 million, nearly 70 percent of the total.

Similarly, in FY 2009 and FY 2010, CMS received 80 percent of the HCFAC discretionary total (\$160 million and \$251.4 million, respectively).

On December 17, 2010, I sent a letter to Secretary Sebelius and Attorney General Holder seeking information regarding the way HHS and DOJ allocate and utilize taxpayer monies appropriated for HCFAC in FY 2009. Specifically, I asked for a detailed breakdown of how HCFAC monies are allocated within each subordinate agency of HHS (Office of Inspector General, Office of the General Counsel, Administration on Aging, and Centers for Medicare and Medicaid Services) and what activities those monies funded.

I received a response to my letter on January 24, 2011. With such a significant portion of funds going to CMS, I asked for and expected a detailed breakdown of the programs and activities supported by these funds. Instead, I received a chart with vague descriptions next to very large amounts in funding (see attached). For example, \$36 million went to "Part C & D Oversight" and \$8.2 million went to "Other Activities."

Dr. Budetti, as you stated in your written testimony, Congress has made substantial investments to help fight health care fraud. With that comes a constitutional duty to conduct oversight and I need to be confident that CMS and HHS will provide me with the necessary information to fulfill this duty.

1. I request that you provide me with a detailed breakdown of the CMS projects and activities that were funded by HCFAC monies in FY 2009 for the line items listed below:

- a. Part C & D Oversight (\$36.2 Million)**
- b. Fraud Response Initiatives (\$34.77 Million)**
- c. Other Activities (\$8.23 million)**
- d. Medicaid Oversight (\$24.98 million)**

The following chart lists the CMS projects which were provided funding:

Project Area	Funding Level (in millions)
Part C & D Oversight	\$36.62
Part B, D, Medi-Medi Integrated Data Repository (IDR)	\$21.55
Part D Claims - Drug Data Processing System	\$2.09
Part C & D IT Compliance System Support	\$15.91
Medicare Drug Integrity Contractors (MEDIC)	\$19.22
Fraud Response Initiatives (Edits, Rapid Response, Target Provider Oversight)	\$34.77
Other Activities (Special Projects)	\$8.23
Provider Verification Systems: Provider Enrollment & Chain Ownership System (PECOS)	\$7.47
Provider Statistical Reimbursement Report (PS&R)	\$0.60
Payment Error Rate Measurement (PERM)	\$13.03
Medicaid Oversight	\$24.98
Carry Over of Two-year Funding to FY 2010	\$0.56
TOTAL	\$185.04

Answer to 1a-d: In FY 2009, CMS funded the following projects with HCFAC discretionary funds:

Part C & D Oversight (\$36.62M)

- *Health Plan Management System (HPMS) (\$4.85M)* – HPMS is a web-enabled information system that supported ongoing business operations of Medicare Advantage (MA) and Prescription Drug (Part D) programs. This system provided automated solutions for MA and Part D contracting and oversight. HPMS software modules collected data for and managed the following MA and Part D plan enrollment and compliance processes: application submission, formulary submission, bid and benefit package submissions, marketing material reviews, plan monitoring and oversight, complaints tracking, plan connectivity, financial reporting, financial and plan bid audits, plan surveys, operational data feeds for enrollment, payment, and premium withhold, and data support for the Medicare & You handbook and the www.medicare.gov website.
- *Part C & D Performance Report Cards (\$4.85M)* - The Part C & D Performance Report Cards project provided CMS with critical infrastructure to enable data collection and analysis. It included performance metrics and data to support, monitor and provide oversight for Part C and D programs. It ensured Part C and D sponsors

were complying with program requirements and protected the programs against fraud, waste, and abuse.

- *Marketing Investigation and State Referral (\$0.98M)* – Funding provided CMS with a mechanism to track agent/broker activities, marketplace monitoring services, complaints tracking, enrollment issues and marketing misrepresentation. This funding also supported oversight for Cost Plan Sponsor contractors and PACE (Program of All-Inclusive Care for the Elderly) Organizations, which offer drug and health plans but are governed by other provisions of the SSA.
- *Retiree Drug Subsidy (RDS) Compliance, Audit, and Payment Error Reduction Activities (\$2.71M)* – Provided funding to conduct audits of plan sponsors participating in the RDS program. Audits evaluated the accuracy of sponsor’s actuarial equivalency attestations, creditable coverage disclosures, payment requests, and compliance with other program rules.
- *Accrediting Organization (AO) Validation Studies of MA (\$2.50M)* – Provided funding for CMS to perform required “look-behind” audits of all AOs, who perform reviews of MA Deeming applicants. In addition, CMS reviewed tools used by AO for deeming reviews to ensure they met or exceeded CMS standards. This evaluative work was necessary in order to ensure the entities that were granted AO status, were compliant with CMS standards and regulations.
- *Audit, Compliance, and Enforcement (\$1.14M)* - The Audit, Compliance, and Enforcement activities included technical, clinical, and non-clinical support, which assisted CMS in conducting Managed Care and PDP audits. These activities helped redesign the program compliance audit process, which needed major restructuring in order to support effective oversight.
- *Compliance Training, Education, and Outreach (\$2.68M)* - This project provided compliance training, education and outreach to CMS staff, internal and external stakeholders. The complexities associated with the Medicare managed care program required CMS staff, the managed care industry and audit assistance contractors to be continually updated on CMS’ expectations regarding compliance and enforcement activity. In addition, CMS continues to provide technical assistance for all MA Plans and PDPs on the development and improvement of their own compliance plans.
- *Encounter Data (\$4.74M)* – Beginning in 2009, CMS required funds to begin implementation of this large scale project to collect risk adjustment “encounter” data as defined under 42 CFR § 422.310. This initiative requires collection, editing, storage, and pricing of new data for more than 11 million beneficiaries enrolled in MA. This data collection effort will give CMS the capacity to measure costs and utilization for all enrollees in MA, while including various risk adjusting payment factors into the methodology.
- *Plan Fee For Service (PFFS) Adjudication (\$1.40M)* – PFFS plans are required to have accessible and understandable provider payment terms/conditions and a dispute resolution process. Funding allowed CMS through a contractor to adjudicate PFFS

Plan payment disputes and allowed CMS to test PFFS plan payment systems to assure consistency with Medicare reimbursement policies and practices.

- *Managed Care Payment Validation (\$.77M)* – This activity was necessary because CMS received a high volume of member transactions from MA organizations and Part D Prescription Drug Plans (PDPs) that could not be processed through the normal batch systems. These transactions required manual processing. These transactions affected the enrollment of members and the payment for the plan requesting the action.

Fraud Response Initiatives (\$34.77M)

- *Fraud and Abuse Customer Service Initiative (\$5.98M)* – This project created a dedicated geographically specific fraud hotline in South Florida. In addition to the equipment and staff to maintain the hotline, a team was established to follow up on leads received from the fraud hotline and then working with CMS and/or law enforcement to pursue appropriate follow up action.
- *Enhanced Provider Oversight (\$10.42M)* – Through a special project in South Florida, this initiative provided for onsite verifications of providers before enrollments were issued. Revalidation of existing providers/suppliers that were due to update their Medicare enrollment information in accordance with 42 CFR § 424.515 was also addressed.
- *Zone Program Integrity Contractors (ZPICs) (\$10.21M)* – This additional funding for ZPICs was used to support field offices dealing with “hot issues”. Special projects included a task order to examine fraudulent billing for home health services in Texas and a project targeting the billing of power mobility devices. ZPICs in high fraud risk areas also worked with subcontractors to pilot test various software products to perform proactive data analysis.
- *Durable Medical Equipment (DME) Initiative (\$5.28M)* - The DME Stop Gap Plan was initiated in 7 High Risk States (CA, FL, IL, MI, NC, NY & TX). CMS and its contractors (Pricing Data Analysis and Coding Contractor (PDAC), National Supplier Clearinghouse (NSC), DME Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs)) (1) identified/interviewed and/or conducted site visits to highest paid/highest risk durable medical equipment, prosthetics, and orthotics supplies (DMEPOS) suppliers, highest ordering physicians and highest utilizing beneficiaries and (2) identified and scrutinized the highest billed/highest risk DMEPOS equipment and supplies.
- *Automated Fraud Edits (\$2.88M)* - This project, more appropriately titled Fraud System Enhancements, funded projects that included the expansion of the Services Tracking, Analysis and Reporting System (STARS) National Database to accommodate the increasing law enforcement user base and the early stages of development work on a national compromised Health Insurance Claimant National database.

Other Activities (\$8.23M)

- Comprehensive Error Rate Testing Program (CERT) (\$3.81M) – This project provided additional funding for the CERT program, which produced national, contractor-specific, and service-specific paid claim error rates. Independent reviewers periodically reviewed representative random samples of Medicare claims that were paid and claims that were denied to ensure that the decision was appropriate. The outcomes were a provider compliance error rate, paid claims error rate, and error rates for specific contractors, services, and provider types.
- Medicare Secondary Payer Recovery Contractor (MSPRC) (\$2.97M) – The primary purpose of this contract was to recover MSP debts owed to the Government. This action was necessary to fulfill the agency’s fiduciary responsibility to recover those debts to safeguard the integrity of the Medicare Trust Funds.
- Medicare Automated Deny Edit Pilot (\$1.45M) – This funding was used to implement, in the prepayment claims stream, a modified product that will evaluate all claims marked for payment approval, as an additional protective mechanism for Medicare Program Payments.

Medicaid Oversight (\$24.98M)

- Payment Error Rate Measurement (PERM) (\$13.10M) – Program funding was provided for CMS to measure and report improper payments in Medicaid and Children’s Health Insurance Program as required by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) which amended the Improper Payments Information Act of 2002 (IPIA).
- Medicaid/CHIP Financial Oversight Project (\$11.88M) – This project (Medicaid FTE funding specialist positions) has enhanced Medicaid’s oversight of the fiscal integrity of the Medicaid program. The funding specialists are involved in the “up-front” financial management review process of Medicaid expenditures and other proposals that impact Medicaid expenditures, which has ensured that States were making proper claims for Federal dollars and that post-payment recoveries were minimized.

Suspended Payments

Under the Patient Protection and Affordable Care Act, the Secretary may suspend payments pending an investigation of credible allegations of fraud in Part A and B. In Medicare Part D, a prescription drug plan must pay a clean claim within 14 days. However, I have been told that the plans are not able to suspend payments even when they have evidence of potential fraud, such as claims being filed from empty storefronts.

2. **Please specify the number of times prescription drug plans have reported to CMS that payments should be suspended as a result of evidence of potential fraud in Part D for FY 2010 and FY 2011.**

Answer: Part D plan sponsors can deny payment to pharmacies when they have evidence of potential fraud. As a result, Part D plans are not required to seek permission from CMS before the plan sponsor suspends payments to pharmacies as a result of evidence of potential fraud. Further, CMS regulations at §423.520, which require prompt payment of clean claims by Part D plan sponsors, define a clean claim as “a claim that has no defect or *impropriety* (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section” (emphasis added). Thus, plan sponsors already have the ability to pay only those claims that are proper.

3. Please describe how CMS handled each report.

Answer: Part D plans are not required to seek permission from CMS before the plan sponsor suspends payments to pharmacies as a result of evidence of potential fraud.

4. What is your position on statutory changes to allow prescription drug plans to suspend payments when there is suspicion of fraud?

Answer: Part D plan sponsors can currently deny payment or suspend payment to pharmacies when they have evidence of potential fraud. As a result, no statutory change is needed.

FDA Verification

On February 25, 2011, the *Los Angeles Times* reported that the Food and Drug Administration (FDA) is struggling to keep unapproved drugs off the market. It reported, “In many cases, the agency doesn’t even know what the drugs are, or where they are.” Under current law, Medicaid pays for many of these drugs until FDA identifies a drug or class of drugs as not approved for marketing and takes formal action.

On March 2, 2011, I introduced the Strengthening Program Integrity and Accountability in Health Care Act of 2011, which includes a provision that amends Section 1927 of the Social Security Act to require State Medicaid programs to first verify with the FDA that a drug or class of drugs is being legally marketed before payment is made.

5. What is your position on my proposal?

Answer: CMS appreciates the opportunity to comment on the section 1927 portion of the Strengthening Program Integrity and Accountability in Health Care Act of 2011 and agrees with your goal of ensuring drugs are legally marketed. As you may know, the President’s FY 2012 Budget included a proposal to restrict Medicaid reimbursement to only those drugs that are properly listed with the FDA.

My staff will continue to review your legislation and provide additional, specific feedback as appropriate to ensure that it meets your stated goal.

6. What other statutory changes should be made to prevent illegal, unapproved drugs from being sold on the market?

Answer: We would also encourage the consideration of the proposal outlined in the President’s Budget to require drug manufacturers to repay States for improperly reported items for

Medicaid-covered prescription drug coverage. The proposal would require full restitution to States for any covered drug improperly reported by the manufacturer on the Medicaid drug coverage list. The adoption of the proposal would ensure that manufacturers are financially responsible for errors in reporting. Additionally, as CMS is responsible for just a portion of the compliance and enforcement activities around the Medicaid Drug Program, we would encourage you to solicit the thoughts of our other Federal partners.

Sunshine Act

As part of health reform, Senator Kohl and I included provisions that would require drug and device companies to report to the public all payments and gifts made to physicians and teaching hospitals, also known as the Physician Payments Sunshine Act (Sunshine Act). We believed that disclosure in this area would reduce conflicts of interest and improve patient care. Dr. Budetti, I understand that your office has been tasked with overseeing the implementation of the Sunshine Act.

7. The sooner the pharmaceutical and device companies know the format and type of information that CMS will want in establishing the database, the lower the cost of compliance and the sooner consumers will have access to this information. What steps are you taking to meet the October 1, 2011 deadline for rules and regulations on procedures the companies must follow?

Answer: CMS is working hard to meet the requirements and the deadlines of the law to provide this information to consumers. The Agency is in the process of rulemaking to establish procedures for reporting, and more information will be forthcoming as the process moves forward. We expect that manufacturers will have sufficient notice to meet the Sunshine Act's reporting obligations, which do not begin until March 31, 2013.

8. What is CMS's process for engaging stakeholders in developing this public database?

Answer: On March 24, 2011, CMS held a Special Open Door Forum to seek stakeholder input on a variety of topics related to the implementation of the Sunshine Act. In addition to seeking general comments, we plan to specifically ask the public for input on the following topics:

- Additional forms and natures of payments and transfers of value to be considered by the Agency.
- Methods to ensure the reported data are accessible and usable by consumers.
- Mechanisms for accurate, efficient, and cost-effective reporting of data.

The Agency plans to engage in notice and comment rulemaking regarding the implementation of the Sunshine Act, including the database. We will use information obtained during the Special Open Door Forum to inform the rulemaking. The rulemaking will address the Agency's proposed procedure for making information submitted to the database available to the public through a web site that is searchable and in a format that is clear and understandable. As always, we encourage the public to review the proposed rule once it is available and to submit comments.

Zone Program Integrity Contractors

It is my understanding that CMS will rely on the existing Zone Program Integrity Contractors (ZPIC) to evaluate and investigate alerts from the predictive modeling system.

9. Is that true? And will CMS be relying only on ZPICs to carry out that function? If not, what other contractors or third parties will be involved in implementing the predictive modeling program?

Answer: Yes. The ZPICs will be responsible for evaluating and investigating alerts identified through the risk scoring solution (predictive modeling system).

10. What is the likelihood that the ZPICs will be able to meet their current programmatic obligations as well as provide the additional services necessary to achieve the predictive modeling program?

Answer: The ZPICs will be able to meet their current programmatic obligations. The predictive modeling program will complement the work the ZPICs currently perform. The risk scoring solution will identify high quality leads that will be prioritized within the ZPICs' workload. The ZPICs will continue to conduct specific local analyses in response to complaints, leads, and/or law enforcement requests.

Predictive Modeling

11. To what extent will the pre-screening and enrollment and predictive modeling programs leverage common systems to (1) ensure that findings are shared across the systems and (2) help minimize the likelihood that bad actors are permitted to re-enter the Medicare and Medicaid programs once disqualified by the predictive modeling system?

Answer: We are committed to sharing information between our Federal health care systems and in keeping with the law, ensuring that providers and suppliers excluded from one Federal health care program are not able to operate in neighboring States or other parts of the country. The Affordable Care Act promotes this new level of coordination between Medicare and State Medicaid agencies. For example, State Medicaid programs are now required to terminate a provider that has been terminated for cause by Medicare or another State Medicaid agency.

CMS intends to aggressively implement and utilize all of the tools and statutory authorities provided by the Affordable Care Act, including enhanced provider enrollment screenings, payment suspension when a credible allegation of fraud exists, and predictive analytics.

Section 4241 of the Small Business Jobs Act of 2010 requires the Secretary to "use predictive modeling and other analytics technologies...to identify improper claims for reimbursement and to prevent the payment of such claims under the Medicare fee-for-service program." CMS is integrating the advanced technology as part of an end-to-end solution that triggers a more thorough claims review for high risk claims as well as referrals to law enforcement when appropriate. Innovative risk scoring technology will apply a combination of behavioral analyses, network analyses, and predictive analyses in order to effectively identify complex patterns of fraud and improper claims and billing schemes. Results from the enhanced provider enrollment

screenings and payment suspension will be integrated with the risk scoring technology that is monitoring incoming claims.

There is no question that strong provider enrollment screening processes and controls are a foundation of our efforts to prevent fraud in Medicare, Medicaid, and other Federal health care programs. We are steadily working to incorporate targeted screening and prevention activities into our claims and enrollment processes where appropriate.

For too long, the Federal claims payment system has operated primarily as a “pay and chase” system, *i.e.*, paying providers and suppliers now, and asking questions later, regardless of the risk of fraud, waste and abuse. The purpose of predictive modeling technologies is to prevent improper payments from being made in the first place by flagging questionable claims for additional review and potential payment suspension.

12. To what extent will new entrants be closely tracked following admission to the Medicare and Medicaid programs to prevent attempts by newly admitted providers and suppliers to defraud these programs?

Answer: Our goal is to keep those individuals and companies that intend to defraud Medicare, Medicaid, and CHIP out of these programs in the first place, not to pay fraudulent claims when they are submitted, and to remove such individuals and companies from our programs if they do get in. The first step to preventing fraud in the Federal health care programs is to appropriately screen providers and suppliers who are enrolling or revalidating their enrollment to verify that only legitimate providers and suppliers who meet our stringent enrollment standards are providing care to program beneficiaries. The ongoing work with claims analysis will indicate if further action is needed to monitor the billing practices of a particular provider.

As required by Section 6401(a) of the Affordable Care Act and described in more detail in CMS-6028-FC, high-risk providers and suppliers, including newly enrolling suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and home health agencies, will now be required to undergo a higher level of scrutiny based on CMS’ and law enforcement’s experience with these provider and supplier types. CMS has also established certain triggers that would move a provider or supplier into the highest screening level.

Section 4241 of the Small Business Jobs Act of 2010 requires the Secretary to “use predictive modeling and other analytics technologies...to identify improper claims for reimbursement and to prevent the payment of such claims under the Medicare fee-for-service program.” For too long, the Federal claims payment system has primarily operated as a “pay and chase” system, *i.e.*, paying providers and suppliers now, and asking questions later, regardless of the risk of fraud, waste and abuse. The purpose of predictive modeling technologies is to prevent improper payments from being made in the first place by flagging questionable claims for additional review and potential payment suspension.

13. Is CMS currently using any predictive modeling technologies in its program integrity efforts? If so, please elaborate. Please also describe any initial findings and results from these efforts.

Answer: CMS is in the process of implementing a risk scoring solution that will apply predictive models to claims, as required in the Small Business Jobs Act. Two contractors will be hired

through the procurement: a Development Contractor that will implement the risk scoring solution and develop/test predictive models; and a Modeling Contractor that will develop/test predictive models. CMS is currently developing and testing predictive models through a rapid response project led by the CPI Analytics Lab. Leads identified through the models are communicated to the ZPICs, the ZPICs investigate the leads (including appropriate administrative action or referral to law enforcement), the results are communicated to the Lab, and the models are refined accordingly. We are early in this testing process and expect results within the next few months. The goal of this effort is to produce effective algorithms that may be included in the risk scoring solution once it is implemented.

14. CMS announced that it would award two contracts by April 2011 to expand Medicare's use of predictive modeling tools by July 1, 2011. What is the status of CMS's procurement of predictive modeling capabilities? What steps will CMS be taking to implement these new tools nationwide?

Answer: CMS will implement a single risk scoring solution that applies proven algorithms to national data. The risk scoring solution will be implemented using near real-time data in the first contract year. This is necessary because of the time required to implement a new system in the claims processing system. During the first year, if there are algorithms that are proven to effectively identify bad actors, CMS will work with the MAC in the appropriate area(s) of the country to incorporate the algorithms in their claims system.

15. In light of the accelerated schedule and the fact that these are new technologies, what steps is CMS taking to ensure the successful adoption of predictive modeling tools? To what extent is CMS factoring in the skills and capabilities of prospective contractors in its award decision?

Answer: Section 4241 of the Small Business Jobs Act of 2010 requires the award and implementation of Predictive Modeling technology by July 2011. After careful consideration of a variety of acquisition strategies and options, CMS selected the Enterprise Systems Development (ESD) contract to streamline the evaluation, selection, and implementation processes and meet the aggressive statutory timeframe mandated in the Act.

CMS' ESD Systems Integration and Development contractors were selected based on their ability to integrate solutions into the CMS Services Model, Framework, and Enterprise Architecture Program that complies with the requirements of the Clinger-Cohen Act of 1996 and OMB Circulars A-130 and A-11. These contractors were subjected to a rigorous selection process and were required to meet stringent constraints such as SEI Capability Maturity Model Integration appraisal, establishment of a 32-criteria approved Earned Value Management System and Cost Accounting System. The 16 selected contractors are some of the nation's most experienced and innovative IT Systems Integrators: Northrop Grumman, CGI Federal, EDS, CSC, IBM, Lockheed Martin, SAIC, ViPS, Buccaneer Computer Systems, IDL Solutions, Quality Software Services, Maricom Systems, 2020 LLC, iFed LLC, Alta Systems, DCCA. Throughout this acquisition process, CMS has encouraged industry partnerships with these integrators to provide innovative and comprehensive value added solutions.

The Evaluation Criteria associated with the Predictive Modeling acquisition were carefully selected to help CMS select the most qualified and capable developer that is able to meet technical requirements while mitigating risks associated with the aggressive schedule. For

example, contractors were instructed that proposals are evaluated on technical understanding of the new requirements and integration into CMS claims processing systems, predictive modeling methodology, clinical knowledge and experience with payment rules and regulations, the contractor's performance-based work plan, and relevant past performance. CMS believes these factors encouraged new innovative partnerships during the strategic proposal development and planning stage to meet these requirements. Proposals meeting these criteria are more likely to meet the aggressive schedule.

Senator John Ensign:

Questions for the Witness:

Electronic Health Records

1. **Will the use of electronic health records and e-prescribing systems reduce fraud, waste, and abuse in our federal healthcare programs?**

Answer: While there is no single solution to reducing fraud, waste, and abuse, CMS incentive programs to promote electronic prescribing (e-prescribing) and electronic health records (EHRs) are providing the infrastructure that will facilitate many of our shared goals to reduce waste, fraud, and abuse, pay appropriately, and increase quality and patient safety in Federal health care programs.

E-prescribing programs are designed to reduce drug errors from poor handwriting and adverse drug interactions. Moreover, EHRs promote prompt and secure communications between providers, improve safety, and reduce unnecessary tests and procedures. Taken together, these tools will help hospitals and physicians provide more integrated care and reduce waste through reductions of duplicated services and avoidance of preventable medical errors.

Further, widespread adoption of EHRs and e-prescribing initiatives will help to better track patients and allow for improved electronic data analysis and screening across claims and providers to improve our ability to identify fraudulent claim patterns. Additionally, these electronic records will make it easier to identify duplicative or inappropriate services or prescriptions in the claims process.

2. **What kinds of controls need to be built into these systems to prevent fraud and abuse?**

Answer: CMS is committed to safe and secure technologies that will help prevent fraud and abuse. Each system needs to have robust authentication requirements so that only properly credentialed individuals have access to the system and users are uniquely identified. The systems should be able to restrict users to the functions within the system that pertain to them (role-based access). Additionally audit logs should track who logs in and out of the system as well as all of their activities. In this way all actions can be tracked directly to the individual. Systems should have the capability to generate reports so that entries and changes can be analyzed for patterns and outliers. Systems should also have a time out function so that users are automatically logged out after a period of inactivity.

Pay and Chase

It appears that HHS spends most of its time chasing after providers for dollars after payments have already been made.

3. What kinds of structural and systematic changes can be made on the front end to help prevent fraud and abuse from ever happening and to also achieve cost-savings?

Answer: CMS is aggressively implementing a number of measures that will shift our enforcement and administrative actions from the historical “pay and chase” mode to more prevention of fraudulent and other improper payments. This shift involves many different activities, which we are carrying out with the powerful new anti-fraud tools provided to CMS and our law enforcement partners under the Affordable Care Act. We are steadily working to incorporate targeted screening and prevention activities into our claims and enrollment processes where appropriate. Our goal is to keep those individuals and companies that intend to defraud Medicare, Medicaid, and CHIP out of these programs in the first place, not to pay fraudulent claims when they are submitted, and to remove such individuals and companies from our programs if they do get in.

4. Has CMS established goals and benchmarks in this area?

Answer: CMS is developing performance metrics at this time.

HIPAA Eligibility Transition System

It is my understanding that there is an electronic program, known as the HIPAA Eligibility Transition System. Many providers use this system to verify Medicare eligibility for specific services. I have heard rumors that the system has been experiencing timing out issues. It is also my understanding that the HETS system will be transitioning to a new program called the 5010 system. If these types of glitches remain, there could be an increase in fraud; providers could experience more bad debt; and Medicare beneficiaries could be forced to pay for services up-front.

5. Can you please explain how HHS is responding to these technical issues and how it intends to manage the change to the new 5010 system?

Answer: HHS published two final rules on January 16, 2009 to adopt updated HIPAA standards. In one rule, HHS adopted ASC X12 Version 5010 and National Council for Prescription Drug Programs Version D.0 for HIPAA transactions. For version 5010 and Version D.0, the compliance date for all covered entities is January 1, 2012. This gives the industry enough time to test the standards internally to ensure that the systems have been appropriately updated, and then test between trading partners before the compliance date. CMS plans to continue outreach and education efforts to ensure that providers make an efficient and effective transition.

Senator Tom Coburn**Questions for the Record:**Fraud, Waste, and Abuse

1. **Do you believe the Patient Protection and Affordable Care Act provides CMS/CPI with all the tools it could use to eliminate waste, fraud, and abuse in Medicare and Medicaid – or could it use more?**

Answer: The Administration's FY 2012 Budget continues to make fighting health care fraud and reducing improper payments a top priority. These efforts will safeguard public funds and send a clear message that fraud and waste in our Federal health care programs will not be tolerated.

The Budget Request includes \$270 million increase in discretionary program integrity resources as part of a multi-year investment to enable HHS and its partners to take ground-breaking steps to detect, prevent, and prosecute health care fraud. The Budget also proposes a series of new legislative authorities that, if enacted, would further strengthen program integrity oversight in Medicare and Medicaid. These investments will show real, measureable results, with savings estimated at \$32.3 billion over ten years.

Additionally, as CMS learns more about how and where improper payments occur, as well as uncovers new fraud schemes in partnership with OIG and DOJ, we expect that we will identify additional authorities and tools that will help us reduce waste, fraud, and abuse in Medicare and Medicaid.

Enhance Program Integrity

The Government Accountability Office has a list of more than 30 significant recommendations, based on reports they have done, that would enhance program integrity in Medicare or Medicaid. These recommendations, updated as of January 2011, and have not been implemented.

2. **Have you reviewed this list? If so, which ones do you think Congress should give CMS the tools to implement?**

Answer: CMS is working steadily to implement the new authorities provided by the Affordable Care Act and have identified additional tools to enhance these efforts in the President's budget. Additionally, not all of the recommendations from GAO fall under my direct area of supervision, so I cannot comment on all of the recommendations. However, CMS agrees in general with these recommendations, and is working to reduce improper payments and fraud in the Medicare and Medicaid programs. We appreciate GAO's acknowledgement of our efforts to reduce improper payments and are working to address their recommendations as we continue to implement the Improper Payments and Recovery Act (IPERA) and expand the Recovery Audit program.

Improper Payments

I am very concerned about improper payments. In June, 2010, President Obama set a goal of reducing the Medicare fee-for-service improper payment rate to half of its current level by 2012. You have said this goal will be met. Last year the error rate was 10.5 percent or \$34.3 billion.

3. Are you the accountable federal official for this goal?

Answer: The agency accountable official is Ellen Murray, the Assistant Secretary for Financial Resources for the Department of Health and Human Services. As the Deputy Administrator for Program Integrity at CMS, I am the program accountable official.

4. Are you willing to have a percentage of your salary indexed to the degree of CPI's success in meeting this goal?

Answer: Payment policies and guidelines for all government employees are established by the Office of Personnel Management. However, as the program accountable official at CMS, the Agency's efforts to reduce fraud and improper payments is a component within my annual performance evaluation.

Medicaid Bills

Last year's financial audit of the Department found that CMS does not perform a claims-level detailed analysis for certain Medicaid bills (Entitlement Benefits Due and Payable) to determine the reasonableness of the various state calculations of unpaid claims. According to the independent auditors, this pot of money was about \$27 billion as of September 30, 2010, and is "a significant liability on the financial statements."

5. What is your timeframe and process for implementing a detailed claims look-back analysis?

Answer: The CMS annual financial statements include the calculation of the Medicaid Entitlement Benefits Due and Payable (EBDP) liability to ensure the agency reports all of its liabilities owed in accordance with generally accepted accounting standards. This liability is an estimate of the net Federal share of Medicaid expenses that have been incurred by the states and territories but have not yet been reported to CMS, i.e., Medicaid services have been provided, but the claim has not been submitted for payment. The CMS develops this estimate using specific audited financial data provided by the States and territories who attest to the validity and accuracy of the information provided.

While the independent auditors did report that CMS' FY 2010 financial statements, including the \$27 billion Medicaid EBDP estimate, were fairly stated, they did note that we do not perform a claims-level look back analysis that would determine the reasonableness of the estimate. In order to do this analysis, CMS would need to have access to all the states and territories' Medicaid claims level detail. Currently, the CMS receives claims level data from states through the Medicaid Statistical Information System (MSIS). However, this information is not comprehensive for all states and territories which precludes us from conducting the reasonableness test.

The CMS has several initiatives in progress to move us toward a timely, and more comprehensive data feed from the states, including comprehensive Medicaid and CHIP claims and eligibility data that will allow us to conduct an additional reasonableness test. Under one pilot project currently underway, we will attempt to bring 10 selected pilot states onboard with this new data submission methodology by the end of this fiscal year. We intend to bring onboard

the remaining 40 states thereafter, and to be operational, nationwide, using this new submission process following the conclusion of the pilot.

The pilot initiative is to test implementation of sections 6402 and 6504 of the Affordable Care Act. Section 6402 requires enrollee encounter data to be submitted by the States and section 6504 requires States to submit data elements from their automated data systems that CMS determines to be necessary for program integrity, program oversight and administration. Currently, data extraction is different in each State, but if it could be standardized across States with tools being developed in the pilot that would result in a reduction from numerous feeds to one feed. The data feed would expand from around 350 data elements to around 800. CMS will also create a database using States' data for States to access.

Duplicative and Ineffective Programs

On March 1, 2011 the Government Accountability Office published a large report of duplicative and ineffective programs. For this year's budget, your office has requested an increase of \$270 million above the FY 2010 Budget.

6. Because our national debt is more than \$14 trillion, and the American people want us to cut spending, would you support cutting duplicative programs to fund important program integrity efforts?

Answer: I understand that during pressing economic times, tough choices have to be made. I fully support the President's efforts to consolidate activities and reduce duplicative or ineffective programs as laid out in his FY 2012 Budget request. In line with that effort, we are certainly seeking efficiencies within our existing efforts to reduce unnecessary program growth.

The Health Care Fraud and Abuse Control Program (HCFAC) is an important and prudent investment for the Federal health care programs. Over time our recoveries have demonstrated that the more resources invested into this program, the higher the return on investment has been. The HCFAC account has a three-year ROI rolling average of 6.8 to 1 and the Medicare Integrity Program averages an ROI of 14 to 1. Further, CMS' Actuaries have determined that a multi-year discretionary HCFAC investment, starting with \$581 million for FY 2012, is estimated to save \$4.6 billion over five years and \$10.3 billion over ten years.

Deceased Patient Claims

7. If a provider or supplier under Medicare submits a bill for services rendered to a deceased patient and that claim is denied, are subsequent claims from that same provider or supplier more closely examined or denied? Please offer some detail in your explanation.

Answer: Over the last two years, CMS has made significant progress in eliminating inappropriate payments to Medicare physicians who are not living, or payments made on behalf of dead beneficiaries. Since September 2008, CMS has received monthly updates of deceased individuals from the Social Security Administration, which we compare against our provider and beneficiary enrollment data. Based on this comparison and the subsequent verification by a CMS contractor, CMS has deactivated the National Provider Identifiers of more than 11,500 practitioners who were previously enrolled in Medicare.

As CMS continues its efforts to implement predictive modeling and data analysis in our claims payment process, we will be able to recognize aberrant patterns of billing, including patterns of billings for deceased patients. This is potentially one trigger that could escalate a provider into a high-risk category that would subject them to further scrutiny. If the provider is fraudulent, they will be referred to law enforcement for investigation and prosecution, and/or suspended or terminated from the Medicare program.

Senator John Thune

Questions for the Record:

THE CLASS ACT AND THE POTENTIAL FOR FRAUD

In December 2010, the bipartisan National Commission on Fiscal Responsibility and Reform released its report containing a set of recommendations to address the fiscal situation, which included a recommendation to reform or repeal the new Affordable Care Act entitlement program known as the Community Living Assistance Services and Supports (CLASS) Act. The Commission noted the CLASS Act is financially unsound because beneficiaries will pay modest premiums yet receive significantly higher benefits at payout. I would appreciate if you could provide insight regarding the following questions:

- 1. It stands to reason that any government program that has significant payout in relation to modest premiums is highly vulnerable to fraud. Dr. Budetti and Mr. Levinson, do you feel the CLASS Act is susceptible to fraud?**

Answer: The Secretary has made the determination that the CLASS program will be implemented by the Administration on Aging. CMS does not have any responsibility in establishing, running, or overseeing the program so I cannot speak to the details of this question.

- a. If so, can you elaborate on why you believe it is?**

Answer: N/A

- 2. Dr. Budetti, I'm aware that under the CLASS Act, the Secretary of HHS has to establish a procedure for administering cash benefits to beneficiaries into a Life Independence Account. With an already heavily burdened HHS workforce, how do you expect to monitor for fraudulent long-term healthcare claims submitted under the CLASS Act?**

Answer: The Secretary has made the determination that the CLASS program will be implemented by the Administration on Aging. CMS does not have any responsibility in establishing, running, or overseeing the program so I cannot speak to the details of this question on monitoring against fraudulent long-term healthcare claims. Nevertheless, it is my understanding that the Secretary has the authority to establish standards of conduct for beneficiaries and their representatives including standards related to the quality of services provided, avoiding conflicts of interest, and misuse of benefits.

3. **I'm also aware that once HHS transfers funds electronically to the Life Independence Account, beneficiaries are able to use a debit card to purchase non-medical services that beneficiaries would need to maintain their well-being. Dr. Budetti, how do you intend to ensure funds transferred to the beneficiary's Life Independence Account are, in fact, being spent appropriately by the beneficiary?**

Answer: The Secretary has made the determination that the CLASS program will be implemented by the Administration on Aging. CMS does not have any responsibility in establishing, running, or overseeing the program so I cannot speak to the details of this question on Life Independence Accounts. Nevertheless, it is my understanding that the Secretary has the authority to establish standards of conduct for beneficiaries and their representatives including standards related to the quality of services provided, avoiding conflicts of interest, and misuse of benefits.

FRAUD AT ABERDEEN AREA INDIAN HEALTH SERVICES

A recent Senate Indian Affairs Committee investigation of Indian Health Service's (IHS) Aberdeen Area found three service units in particular have a history of missing or stolen narcotics and that nearly all facilities in the Area have failed to perform consistent monthly pharmaceutical audits of narcotics and other controlled substances. The report also found that between 2006 and 2008, there was a 27 percent increase in prescription volume in that Area. Not only does this raise issues about waste and fraud, but prolonged deficiencies in this area can lead to CMS and other third party reimbursement decertification, a funding source IHS facilities cannot afford to lose. I would appreciate if you could provide insight regarding the following questions:

4. **Mr. Levinson and Dr. Budetti, is there any evidence that this type of criminal activity is occurring in other IHS areas?**

Answer: The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring that Medicare-certified Indian Health Service hospitals meet requirements to participate in the Medicare program (referred to as Medicare Conditions of Participation) as well as emergency treatment requirements mandated under the Emergency Medical Treatment and Labor Act (EMTALA). As you indicate in your question, Indian Health Service hospitals have encountered some difficulties in complying with these requirements, which has put them at risk of termination from the Medicare program. Because oversight responsibility for Indian Health Facilities generally is not within the purview of CMS, I cannot comment specifically on the Senate Indian Affairs Committee investigation or any allegations of waste and fraud in those facilities.

**Prepared Statement of Senator Chuck Grassley of Iowa
U.S. Senate Committee on Finance
Hearing on "Preventing Health Care Fraud: New Tools and
Approaches to Combat Old Challenges"
March 2, 2011**

Chairman Baucus, thank you for calling this hearing today to discuss ways we can prevent health care fraud. I think we can all agree that we need to cut down on health care fraud to ensure the sustainability of Medicare and Medicaid. Over the last nine years, the Finance Committee has held about 20 oversight hearings dealing with Medicare and Medicaid fraud. These hearings have highlighted flaws in how the federal government administers Medicare and Medicaid. They also emphasized the need to create disincentives for those who seek to defraud these vital programs. Every dollar lost to Medicare or Medicaid fraud is a dollar that's not available for beneficiaries.

In addition to my position on the Finance Committee, I now serve as the Ranking Member of the Senate Committee on the Judiciary. In January, the Judiciary Committee held a hearing to discuss with Department of Justice officials what is working, what isn't working, and what more can be done to combat fraud, including health care fraud. Today's hearing is another opportunity to continue that conversation with officials from the Department of Health and Human Services.

The federal government spent \$502 billion on Medicare and \$379 billion on Medicaid in fiscal year 2009. It is estimated between \$40 billion and \$70 billion was lost to fraud that year. Officials from the Department of Health and Human Services and the Department of Justice announced in January that their health care fraud prevention and enforcement efforts recovered \$4 billion in fraud. That means we have a long way to go.

When it comes to public programs like Medicare and Medicaid, it is clear that the federal government needs to be more effective in combating fraud, waste and abuse. The federal government has simply made it too easy for bad actors to steal from these programs. It says a lot when you hear that organized crime groups have moved into health care fraud because it is profitable. Medicare and Medicaid are also attracting more criminals because the consequences of getting caught are significantly less onerous. And then there are those who don't get caught.

Taxpayer dollars should only go to bona fide providers and medical suppliers. But the reimbursement system is set up so that the federal

government pays first and asks questions later; in other words, the program is founded on a "pay and chase" system.

Over the years, Congress has provided the executive branch with additional authorities to improve enforcement of fraud, waste and abuse laws. During health care reform, Chairman Baucus and I developed a bipartisan set of legislative proposals to combat fraud, waste and abuse. Many of these proposals are in the bill I introduced in the last Congress, S. 2964, the Strengthening Program Integrity and Accountability in Health Care Act, and were included in the Patient Protection and Affordable Care Act (PPACA). These provisions did not draw opposition from either side of the aisle. Tackling fraud, waste and abuse in health care is one of the areas where there is widespread agreement.

But our work does not end with reforms we passed last year. Congress needs to keep the pressure on federal officials to do everything possible to prevent and stop fraud. There is also more that Congress should pass in the way of reforms to enhance the government's ability to fight fraud. And there's a lot more the government should do to fully use the tools it has already.

We need to ensure that phantom doctors, pharmacies and durable medical equipment suppliers cannot simply bill Medicare millions of dollars in a few months and get out of town scot free. HHS, CMS and their contractors have to do more to detect potentially fraudulent claims and use the tools that are available to make sure the claims are legitimate before they are paid.

And even with all that, we must remain vigilant in our oversight efforts, because tomorrow's criminals will find ways to get around the laws and regulations we put in place today. That's why I will be introducing a bill today that contains provisions of S. 2964 that did not get enacted last year.

The bill would create a national clearinghouse of information so we can better detect and prevent and thereby deter medical identity theft. This is about the federal government sharing information it already has in ways that protect the taxpayer and work against those defrauding the system and hopefully deter those who are thinking about stealing from the taxpayer.

It would change federal laws that require Medicare to pay providers quickly, regardless of the risk of fraud, waste, or abuse. Under current law, the government is required to make payment for a "clean" claim within 14 to 30 days before interest accrues on the claim. And that is not enough time for the limited number of Medicare auditors to determine if the claim is legitimate before the payment has to be made. The result is that this

"prompt payment rule" requires that Medicare pay bad actors first, and ask questions later.

This requirement doesn't make any sense. So this bill would extend the time that payments must be made if the Secretary of Health and Human Services determines there's a likelihood of fraud, waste and abuse.

In addition, the bill would expand the HHS Inspector General's authority to exclude an individual from participating in federal health care programs if, for example, at the time an entity engaged in misconduct—such as health care fraud—the individual had ownership or control interests in that entity.

Last week, the *Los Angeles Times* reported that the Food and Drug Administration (FDA) is struggling to keep unapproved drugs off the market. It reported that "In many cases, the agency doesn't even know what the drugs are, or where they are." This is another example of flaws in the federal reimbursement system – how Medicaid pays for drugs creates an incentive for unapproved drug makers to sell their drugs without meeting FDA requirements. Medicaid pays until FDA identifies a drug or class of drugs as not approved for marketing and takes formal action. Under such circumstances, the federal government doesn't even have the option to chase after these payments. My bill would stop such payments unless the state first verifies with FDA that the drug is being legally marketed.

The changes I'm proposing would go a long way to deter those who would defraud our health care programs. It also would provide greater protections to the taxpayer.

I look forward to hearing from the witnesses today on what more can be done to deter and detect health care fraud, waste and abuse. And I look forward to working with all my colleagues on the Committee to build on reforms to enhance the government's ability to fight fraud. Thank you.

**STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER
U.S. SENATE COMMITTEE ON FINANCE HEARING OF MARCH 2, 2011
PREVENTING HEALTH CARE FRAUD: NEW TOOLS AND APPROACHES
TO COMBAT OLD CHALLENGES**

WASHINGTON - U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Committee on Finance, today delivered opening remarks at a committee hearing exploring current efforts to curb fraud and abuse within the federal health care system and ensure the transparency and accountability of taxpayer dollars.

A full copy of Hatch's remarks, as prepared for delivery, follows:

There is no doubt that this is a challenging time. We are in the midst of one of the greatest fiscal crises to ever confront our country and this week Congress is making tough choices regarding spending to keep the federal government's doors open. It is fitting that we are here today to talk about risk to our health care dollars: specifically, the amount of fraud, waste and abuse in the federal health care programs. As the number of Medicare and Medicaid beneficiaries escalates, and funds to pay for those services become preciously stretched, it is imperative that we take a critical look at how tax dollars are being spent to reduce the amount of fraud, waste and abuse. I am pleased to welcome Inspector General Daniel Levinson of the Department of Health and Human Services Office of Inspector General (HHS-OIG) and Dr. Peter Budetti of the Centers for Medicare & Medicaid Service's (CMS) Center for Program Integrity today to speak on this important topic and share with us what efforts are being made to ensure the dollars entrusted to HHS are being spent wisely.

Medicare and Medicaid make up the bulk of the federal health care programs with nearly 100 million participants and more than \$800 billion in outlays in 2010. When the States' Medicaid matching amounts are added in, these federal programs spend over \$1 trillion per year. Estimates of the amount of fraud, waste and abuse in the these programs vary greatly, but CMS has reported that improper payments for Medicare alone in 2010 may have been nearly \$48 billion and some estimates have said that the amount of fraud, waste and abuse could be nearly ten percent of our total federal entitlement program outlays.

While there is much to be explored today in how HHS-OIG and CMS are spending the money entrusted to them to curb fraud, waste and abuse, I also wish to point out that the path to recovering these monies is a path fraught with peril. If the methods used to ferret out fraud, abuse and waste are not just, respectful of due process, and recognize distinctions between the truly "bad actors" and errors that are the result of confusing rules and ambiguous regulations, then the agencies will lose their credibility with the health care organizations they monitor and the taxpayers who expect vigorous but fair vigilance.

Figuring out how much fraud exists is the first step to better being able to determine how to address it. Determining how to effectively fight it is the next step. In the past year, Congress has given additional tools and appropriated significant new resources to the agencies testifying here today, but it remains to be seen how effective those tools and resources ultimately will be in curbing improper payments. Recent reports seem to indicate that there are reasons to be optimistic about success such as the over \$4 billion in recoveries cited by HHS and the Department of Justice in their 2010 Health Care Fraud and Abuse Control Fund (HCFAC) report. Moreover, the recovery reports and figures do not address what portion is the result of intentional fraud or is attributed to mistakes due to regulations that are tripping up health care organizations by the sheer size and complexity.

I am sincerely concerned about the helter-skelter approach being taken to implement the new health care law's tools to address improper payments. For example, the recent stop and start and then reverse guidance by CMS to States and health care organizations on Medicaid RACs is mind-boggling. PPACA required CMS to establish a Medicaid RAC program by December 31, 2010. Last month CMS sent a letter to States which effectively says "don't worry about it" and promised to take up Medicaid RACs at an unspecified time "later this year." The examples abound in which CMS has issued guidances, only to retract, amend or postpone them indefinitely. Is it a wonder that health care organizations think that trying to comply with agency rules can seem like stacking papers in the middle of a tornado?

Lastly, I must address the way the President's budget for fiscal year 2012 uses health care fraud recoveries to suppress the real cost of health care reform and seeks a substantial increase in "fraud fighting funds" when this Administration has not yet shown sustained progress in reducing improper payments. I see that there is a request for a nearly \$581 million increase in discretionary spending for health care fraud efforts, a significant increase over the \$311 million contained in the FY 2011 continuing resolution and more than doubling the \$259 million spent in FY 2010. This is a sizeable increase at a time when there are scant extra dollars to be spared in the federal budget. Just two weeks ago at the Senate Appropriations Committee Labor/HHS Subcommittee, Dr. Budetti stated that any spending reduction would be a "major impediment" for CMS' program integrity efforts. While I appreciate the need for more resources, I wonder why that money cannot come from the \$1 billion dollar implementation fund set up under health care reform rather than from additional appropriations. I think it is essential we look at the real return on investment of dollars specifically targeted toward implementation of the fraud fighting provisions of PPACA and determine their effectiveness before committing to additional spending.

Ensuring the integrity and fiscal longevity of our Federal health care programs is an essential priority for all of us and I look forward to working with you to find ways to achieve that goal. You both have difficult jobs and I thank you both for all the work you and your staff do on behalf of the taxpayers

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Testimony of:
Daniel R. Levinson
Inspector General
U.S. Department of Health & Human Services

Good morning, Chairman Baucus, Ranking Member Hatch, and other distinguished Members of the Committee. I am Daniel Levinson, Inspector General of the U.S. Department of Health & Human Services (HHS or the Department). Thank you for the opportunity to testify about the efforts of the Office of Inspector General (OIG) and our partners to combat waste, fraud, and abuse in Medicare and Medicaid. I also thank you for your continued commitment to furthering our shared goal of safeguarding the fiscal integrity of these programs.

Medicare and Medicaid fraud, waste, and abuse cost taxpayers billions of dollars each year and put beneficiaries' health and welfare at risk. The impact of these losses and risks is magnified by the growing number of people served by these programs and the increased strain on Federal and State budgets. Moreover, new and expanded programs under the Patient Protection and Affordable Care Act (Affordable Care Act or ACA) further heighten the need for robust oversight.

My testimony today describes the nature and scope of health care fraud, waste, and abuse; OIG's ongoing initiatives to fight these problems, including our highly productive collaboration with our colleagues in HHS and the Department of Justice (DOJ); and new tools and initiatives to prevent and detect fraud, waste and abuse and hold accountable those who engage in it. OIG is committed to building on our successes, employing all oversight and enforcement tools available to us, and maximizing our impact on protecting the integrity of government health care programs and the health and welfare of the people they serve.

OIG Work Highlighting the Nature and Scope of Health Care Fraud, Waste, and Abuse

Fraud is a serious problem requiring a serious response.

Although there is no precise measure of the magnitude of health care fraud, we know that it is a serious problem that demands an aggressive response. OIG has been leading the fight against health care fraud, waste and abuse for more than 30 years. Although the majority of health care providers are honest and well-intentioned, a minority of providers who are intent on abusing the system cost taxpayers billions of dollars. Over the past fiscal year, OIG has opened more than 1,700 health care fraud investigations. Additionally, our enforcement efforts have resulted in more than 900 criminal and civil actions and more than \$3 billion in expected investigative recoveries in fiscal year (FY) 2010. OIG's total expected recoveries for FY 2010 also include more than \$1 billion in audit receivables.

OIG investigations uncover a range of fraudulent activity. Health care fraud schemes commonly include purposely billing for services that were not provided or were not medically necessary, billing for a higher level of service than what was provided, misreporting costs or other data to increase payments, paying or receiving kickbacks, illegally marketing products, and/or stealing

providers' or beneficiaries' identities. The perpetrators of these schemes range from street criminals, who believe it is safer and more profitable to steal from Medicare than to traffic in illegal drugs, to Fortune 500 companies that pay kickbacks to physicians in return for referrals.

Many OIG investigations target fraud committed by criminals who masquerade as Medicare providers and suppliers but who do not provide legitimate services or products. The rampant fraud among durable medical equipment (DME) suppliers in south Florida is a prime example. In these cases, our investigations have found that criminals set up sham DME storefronts to create the appearance that they are bona fide providers; fraudulently bill Medicare for millions of dollars; and then close up shop, only to reopen in a new location under a new name and continue the fraud. The criminals often pay kickbacks to physicians, nurses, and even patients to recruit them as participants in the fraud schemes. When their schemes are detected, some of these perpetrators flee with the stolen Medicare funds and become fugitives.

The Medicare program is increasingly infiltrated by violent and organized criminal networks. For example, the Government recently charged 73 defendants with various health-care-fraud-related crimes involving more than \$163 million in fraudulent billings. According to the indictments, the Armenian-American organized crime ring behind the scheme was the Mirzoyan-Terdjanian Organization, which has allegedly used violence and threats of violence to ensure payments to its leadership.

The scheme perpetrated by this crime ring involved subjects allegedly stealing the identities of thousands of Medicare beneficiaries from around the country, as well as the identities of doctors who were usually licensed to practice in more than one State. Other subjects leased office space and opened fraudulent clinics and bank accounts to receive Medicare funds—often in the name of the doctor whose identity they had stolen. Upon becoming approved Medicare providers, the subjects allegedly billed Medicare for services never provided, using the stolen beneficiary information. The funds they received from Medicare were quickly withdrawn and laundered, and sometimes sent overseas. Although Medicare identified and shut down some of the phony clinics, members of the criminal enterprise simply opened up more fraudulent clinics, usually in another State. The investigation uncovered at least 118 phony clinics in 25 States.

Health care fraud is not limited to blatant fraud by career criminals and sham providers. Major corporations, such as pharmaceutical and medical device manufacturers, and institutions, such as hospitals and nursing facilities, have also committed fraud, sometimes on a grand scale. For example, in August 2010, Allergan, Inc., agreed to plead guilty to misdemeanor misbranding and paid \$600 million (including a \$375 million criminal fine and forfeiture and a \$225 million civil settlement) to resolve criminal and civil liability arising from the company's promotion of Botox®. Our investigations found that the company illegally marketed the drug for indications that, during the relevant time periods, had not been approved as safe and effective by the Food and Drug Administration (FDA). These unapproved indications included headache, pain, spasticity and juvenile cerebral palsy. In addition, the settlement resolved allegations that Allergan misled doctors about the safety and efficacy of Botox®, instructed doctors to miscode claims to ensure payment by Government health care programs, and paid kickbacks to doctors.

Despite our successes, there is more to be done. Those intent on breaking the law are becoming more sophisticated, and the schemes are more difficult to detect. Some fraud schemes are viral,

i.e., schemes are replicated rapidly within communities. Health care fraud also migrates—as law enforcement cracks down on a particular scheme, the criminals may redesign the scheme (e.g., suppliers fraudulently billing for DME have shifted to fraudulent billing for home health services) or relocate to a new geographic area. To combat this fraud, the Government’s response must be swift, agile, and well organized.

Waste and abuse cost taxpayers billions of dollars and must be addressed.

Waste of funds and abuse of the health care programs also cost taxpayers billions of dollars. In FY 2010, the Centers for Medicare & Medicaid Services (CMS) estimated that overall, 10.5 percent of the Medicare fee-for-service claims it paid (\$34.3 billion) did not meet program requirements. Although these improper payments do not necessarily involve fraud, the claims should not have been paid. OIG’s analysis of the Medicare error rate found that insufficient documentation, miscoded claims, and medically unnecessary services accounted for almost all of these errors.

For our part, OIG reviews specific services, based on our assessments of risk, to identify improper payments. For example, OIG reviewed high-utilization claims for blood-glucose test strips and lancet supplies. Our audits identified an estimated \$270 million in improper Medicare payments for these supplies. OIG has also conducted a series of audits over the past decade identifying improper Federal Medicaid payments for school-based health services. Most recently, we found that Arizona was improperly reimbursed an estimated \$21.3 million in Federal Medicaid funds for school-based services.

OIG’s work has also demonstrated that Medicare and Medicaid pay too much for certain services and products and that better aligning payments with costs could produce substantial savings. For example, OIG reported that Medicare reimbursed suppliers for pumps used to treat pressure ulcers and wounds based on a purchase price of more than \$17,000, but that suppliers paid, on average, approximately \$3,600 for new models of these pumps.

OIG and its Partners Are Leading the Fight Against Health Care Fraud, Waste, and Abuse

Collaboration and innovation are essential in the fight against health care fraud. The collaborative antifraud efforts of HHS and DOJ are rooted in the Health Insurance Portability and Accountability Act of 1996, P. L. No. 104-191 (HIPAA), which established the Health Care Fraud and Abuse Control (HCFAC) Program. The HCFAC return-on-investment is at an all-time high. Over the past 3 years (FY 2008- FY 2010), for every \$1 spent on the HCFAC Program, the Government has returned an average of \$6.80. OIG’s, HHS’s and DOJ’s HCFAC activities returned \$4 billion in fraudulent and misspent funds to the Government in FY 2010 and have returned more than \$18 billion to the Medicare Trust Fund since 1997.

On May 20, 2009, the HHS Secretary and the Attorney General announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). This initiative marshals significant resources across the Government to prevent health care waste, fraud, and abuse; crack down on those who commit fraud; and enhance existing partnerships between HHS and DOJ.

Medicare Fraud Strike Forces are a proven success in fighting fraud.

Medicare Fraud Strike Forces are an essential component of HEAT and have achieved impressive enforcement results. Strike Forces are designed to identify and investigate fraud, and prosecute the perpetrators quickly. Strike Force teams are composed of dedicated prosecutors from DOJ and U.S. Attorneys Offices and Special Agents from OIG; the Federal Bureau of Investigation (FBI); and, in some cases, State and local law enforcement agencies. These “on the ground” enforcement teams are supported by data analysts and program experts. This coordination and collaboration have accelerated the Government’s response to criminal fraud, decreasing by roughly half the average time from the start of an investigation to its prosecution.

OIG and DOJ launched their Strike Force efforts in 2007 in south Florida to identify, investigate, and prosecute DME suppliers and infusion clinics suspected of Medicare fraud. Building on the success in Miami, Strike Force teams have been established in eight more locations—Los Angeles; Detroit; Houston; Brooklyn; Baton Rouge; Tampa; and, most recently, Dallas and Chicago.

The Strike Force uses data analysis and a collaborative approach to focus enforcement resources in geographic areas at high risk for fraud. Strike Force cases are data driven to pinpoint fraud hot spots through the identification of suspicious billing patterns as they occur. To support this approach, OIG created a team of data experts composed of OIG special agents, statisticians, programmers, and auditors. Together, the team brings a wealth of experience in using sophisticated data analysis tools combined with criminal intelligence gathered directly from special agents in the field to identify more quickly ongoing health care fraud schemes and trends. To expand the coalition of data experts focused on this effort, OIG has garnered the support and participation of our law enforcement partners at DOJ and FBI. This model is particularly effective in detecting sham providers and suppliers who masquerade as bona fide providers and suppliers.

The Strike Force model has proven highly successful. Since their inception in 2007, Strike Force operations in nine cities have charged almost 1,000 individuals for fraud schemes involving more than \$2.3 billion in claims.

Just last month, Strike Forces engaged in the largest Federal health care fraud takedown in history. Teams across the country arrested more than 100 defendants in 9 cities, including doctors, nurses, health care company owners and executives, and others, for their alleged participation in Medicare fraud schemes involving more than \$225 million in false billing. The defendants are accused of various health-care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft. More than 300 special agents from OIG participated in partnership with other Federal and State agencies, including fellow Offices of Inspector General. With the approval of the Attorney General, the Council of the Inspectors General on Integrity and Efficiency (CIGIE) has established procedures to permit special agents from within the Inspector General community to work together on operations like the HEAT Strike Forces, thereby maximizing efficiency and reducing operational costs.

The effectiveness of the Strike Force model is enhanced by our use of important tools. We refer to CMS credible allegations of fraud so that CMS can suspend payments to the perpetrators of these schemes. For example, during a July 2010 Strike Force operation, OIG worked with CMS to initiate payment suspensions and pre-pay edits on 18 providers and suppliers targeted in the investigation. The prompt action taken by OIG and CMS stopped the potential loss of more than \$1.3 million in claims submitted by the defendants. During the February Strike Force operations discussed above, OIG and CMS worked to impose payment suspensions that immediately prevented a loss of more than a quarter million dollars in claims submitted by Strike Force targets.

OIG's work with CMS during these recent Strike Force operations reflects the multi-pronged, collaborative approach that is critical to success. OIG and our law enforcement partners investigate and prosecute those who steal from Medicare. Relying on our work, CMS "turns off the spigot" to prevent dollars from being paid for fraudulent claims.

OIG recommendations prevent fraud, waste, and abuse.

OIG has also recommended actions to remedy program integrity vulnerabilities and prevent fraud, waste, and abuse. We found, for example, that Medicare's average spending per beneficiary for inhalation drugs was five times higher in south Florida, an area rife with Medicare fraud, than in the rest of the country, and that a disproportionately high rate of these claims in south Florida exceeded the maximum dosage guidelines. OIG's recommendations included adding new claims edits to prevent fraudulent or excessive payments, including edits to detect dosages exceeding coverage guidelines. In another example, to prevent future improper payments for blood-glucose test strips and lancet supplies, we recommended that CMS contractors implement various payment edits, such as edits to identify claims with overlapping dates of service. We have also found that Medicare has paid for prescription drug and DME claims that did not include valid prescriber identifiers, and we have recommended that CMS verify the prescriber identifier on claims before they are paid. Many other recommendations to prevent fraud, waste, and abuse are described in our annual *Compendium of Unimplemented OIG Recommendations*; our latest edition will be published later this month.

Enhanced Tools and New Initiatives Further Support Our Mission

The Affordable Care Act enhances program integrity in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

The ACA, as amended by the Reconciliation Act, promotes program integrity by addressing program vulnerabilities, strengthening law enforcement resources and authorities, and encouraging greater coordination among Federal agencies. Consistent with OIG's recommended program integrity strategy, the ACA:

- strengthens provider enrollment standards;
- addresses payment vulnerabilities;
- promotes compliance with program requirements;
- enhances program oversight; and
- fortifies the Government's arsenal of fraud-fighting tools and penalties.

The ACA includes numerous provisions that address vulnerabilities in CMS program operations and payment methodologies. To address the need for more upfront oversight, the ACA authorizes more robust provider and supplier screening procedures, temporary enrollment moratoria when the Secretary identifies fraud “hot spots,” provisional periods of enhanced payment oversight for newly enrolled providers and suppliers, heightened disclosure and transparency requirements, and mandatory compliance programs.

The ACA also addresses particular fraud, waste, and abuse risks by altering program requirements. The following examples are illustrative. The law requires physicians to document that the physician (or a designated health professional) has had a face-to-face encounter with a patient for whom the physician is certifying the need for DME or home health services. The law requires community mental health centers that provide partial hospitalization services to provide at least 40 percent of their services to non-Medicare beneficiaries, which should help reduce fraud by centers that set up shop to prey on Medicare. The ACA addresses misaligned payments by, for example, rebasing home health payments, and the law will produce cost savings by increasing the Federal Medicaid rebate for generic drugs. The ACA addresses quality-of-care vulnerabilities through provisions that create incentives for hospitals to reduce readmissions and prevent hospital-acquired conditions.

The ACA strengthens the Government’s ability to respond rapidly to health care fraud and hold perpetrators accountable. Increased HCFAC funding will support important fraud-fighting resources, including new technology for detecting suspected fraud more effectively and “boots on the ground” for our vital oversight and enforcement efforts. The ACA provisions that strengthen cross-agency collaborations and information sharing will aid our program integrity efforts. Enhanced authority to suspend payments pending the investigation of credible allegations of fraud will help ensure that the Government can effectively stop perpetrators from absconding with ill-gotten program funds. Important changes to the False Claims Act, the Federal anti-kickback statute, OIG’s administrative authorities, and the Federal Sentencing Guidelines, among others, will help the Government more effectively prosecute those who defraud or abuse Federal health care programs.

OIG promotes program integrity by removing untrustworthy individuals from Federal health care programs.

Once we determine that an individual or entity has engaged in fraud or abuse or provided substandard care, OIG can use one of the most powerful tools in our arsenal: the authority to exclude that provider from participating in Federal health care programs. Program exclusions bolster our fraud-fighting efforts by removing from Federal health care programs those who pose the greatest risk to our programs and their beneficiaries.

No program payment may be made for any item or service that an excluded person or entity furnishes, orders, or prescribes. This prohibition applies regardless of whether the excluded person is paid directly by the programs (such as a physician) or whether the payment is made from the program to another person (such as payments to a hospital for services by its employed

nurses and other staff or payments to a pharmacy for drugs manufactured by a pharmaceutical company). Those who employ the services of an excluded individual or entity for the provision of items or services reimbursable by Medicare or Medicaid may be subject to monetary penalties and program exclusion. Because of its scope and effect, the risk of exclusion creates a strong incentive to comply with the programs' rules and requirements.

In imposing discretionary exclusions, OIG must weigh the fraud and abuse risks to the programs and beneficiaries against the impact on patient access to care if the provider or entity is excluded from Federal health care programs. Some hospital systems, pharmaceutical manufacturers and other providers play such a critical role in the care-delivery system that they may believe that OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries. We are concerned that these providers may consider engaging in fraud schemes, and paying civil penalties and criminal fines if caught, as a cost of doing business. As long as the profit from the fraud outweighs those costs, abusive corporate behavior is likely to continue. For example, some major pharmaceutical corporations have been convicted of crimes and paid hundreds of millions of dollars in False Claims Act settlements and continue to participate in Federal health care programs.

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk. To that end, in 2008, we excluded three executive officers of the pharmaceutical company Purdue Frederick based on their convictions for misbranding the painkiller OxyContin. Each of the executives was convicted based on his status as a responsible corporate officer.

OIG also has the discretionary authority to exclude certain owners and the officers and managing employees of a sanctioned entity (i.e., an entity that has been convicted of certain offenses or excluded from participation in Federal health care programs) even if the executive has not been convicted of a crime. This authority, section 1128(b)(15) of the Social Security Act, allows OIG to hold responsible those individuals who are accountable for corporate misconduct. OIG has used this exclusion authority in more than 30 cases since it was added to the statute in 1996. But until recently, we had typically applied this exclusion authority to individuals who controlled smaller companies, such as pharmacies, billing services, and DME companies and not to executives of large complex organizations such as a drug or device manufacturer.

Moving forward, we intend to use this essential fraud-fighting tool in a broader range of circumstances. For example, in addition to excluding the Purdue Frederick executives, we recently excluded an owner (and former executive) of Ethex Corporation Company under our section (b)(15) exclusion authority. Ethex operated manufacturing facilities in St. Louis. In March of last year, Ethex pled guilty to felony criminal charges after it failed to inform the FDA about manufacturing problems that led to the production of oversized tablets of two prescription drugs. The owner was excluded for a period of 20 years.

We are mindful of our obligation to exercise this authority judiciously, and we do not propose to exclude all officers and managing employees of a company that is convicted of a health care-

related offense. However, when there is evidence that an executive knew or should have known of the organization's underlying criminal misconduct, OIG will operate with a presumption in favor of exclusion of that executive. We have published on our Web site guidance that sets out factors that we consider when evaluating whether a section (b)(15) exclusion should be imposed. This guidance alerts health care providers and executives to the standards of ethical conduct and responsibility to which they will be held accountable by OIG. Even if we decide exclusion of a major health care entity is not in the best interest of Federal health care programs and their beneficiaries, we may decide that executives in positions of responsibility at the time of the fraud should no longer hold such positions with entities that do business with the programs.

OIG is engaging health care providers and the public in the fight against fraud.

We recognize that the vast majority of health care providers and suppliers are honest and well-intentioned. Health care providers and suppliers are valuable partners in ensuring the integrity of Federal health care programs and preventing fraud and abuse. OIG seeks to collaborate with health care industry stakeholders to foster voluntary compliance.

OIG is using the Internet to enlist the health care industry and the public in the fight against fraud. Our Web site, <http://oig.hhs.gov>, offers extensive information to health care providers and patients about ways to reduce the risk of fraud and abuse. These extensive resources include OIG's voluntary compliance program guidance, fraud alerts, and advisory opinions on the fraud and abuse laws. OIG also offers a guide for patients to avoid becoming the victim of medical identity theft, a growing problem that can disrupt lives, damage credit ratings, and waste taxpayer dollars. We offer tips to Medicare beneficiaries and their caregivers on how to avoid medical identity theft and where to report misuse of personal information.

The Web site also includes information about the OIG's self-disclosure protocol, which offers a way for providers that uncover fraudulent billings or other misconduct within their organizations to self-disclose the problem and to work with OIG to resolve the issue, including return of any inappropriate payments.

Another example of OIG's commitment to promoting compliance is the HEAT Provider Compliance Training Initiative. The initiative brings together representatives from a variety of Government agencies to provide free compliance training to local provider, legal, and compliance communities. The first of these seminars took place in Houston in February, and we have scheduled additional seminars in Tampa, Kansas City, Baton Rouge, Denver, and Washington, DC throughout the Spring of 2011. In May, OIG will provide a Webcast of the seminar for those unable to attend in-person training. Our aim is to educate providers about fraud risks uncovered by OIG and to share compliance best practices so that providers can strengthen their compliance efforts. We believe these efforts to educate provider communities will help foster a culture of compliance and protect Federal health care programs and beneficiaries.

In response to requests from physicians just beginning their practices, OIG recently published *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*. The *Roadmap* summarizes the five main Federal fraud and abuse laws and provides guidance on how

physicians should comply with these laws in their relationships with payers, vendors, and fellow providers.

Finally, we also have posted OIG's list of the 10 most-wanted health care fraud fugitives, including photographs and details about the fugitives and their schemes. Our current most-wanted list includes 10 individuals who have allegedly defrauded taxpayers of approximately \$136 million. We are asking the public to help us bring these fugitives to justice by reporting any information about their whereabouts to our Web site or fugitive hotline (1-888-476-4453).

Conclusion

Health care fraud, waste, and abuse cost taxpayers billions of dollars every year and require focused attention and commitment to solutions. Through the dedicated efforts of OIG professionals and our collaboration with HHS and DOJ partners, we have achieved substantial results in the form of recoveries of stolen and misspent funds, enforcement actions taken against fraud perpetrators, improved methods of detecting fraud and abuse, and recommendations to remedy program vulnerabilities. Finally, we have enhanced tools and authorities and have engaged in new initiatives aimed at achieving our mission. Thank you for your support of this mission. I would be happy to answer any questions that you may have.

United States Senate Committee on Finance
Public Hearing
“Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges”
March 2, 2011

Questions Submitted for the Record for Daniel R. Levinson

Questions From Senator Max Baucus

HCFAC Successes

The Health Care Fraud and Abuse Control (HCFAC) program funds the major health fraud prevention activities conducted by HHS, OIG, DOJ, and the FBI. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established the HCFAC Program under the joint direction of the Attorney General and the Secretary of HHS, designed to coordinate Federal, state and local law enforcement activities to combat health care fraud and abuse. Since 2009, HCFAC's return on investment has been \$6.80 per every \$1. In total, HCFAC has returned more than \$18 billion to the Medicare Trust Fund. In January of this year, HHS announced that the Health Care Fraud and Abuse Control Program (HCFAC) recovered over \$4 billion in fraudulent payments in 2010—the largest annual recovery ever.

I was impressed to see that last year, the combined efforts by HHS and DOJ, through the HCFAC program, recovered over \$4 billion. I understand this is the highest annual recovery under this program.

1. Please describe what was done differently to allow such a high recovery.

OIG's work is guided by its core values, which are integrity, credibility, and impact, in all facets of its work. To maximize our impact, we conduct risk assessments and use data analysis and field intelligence to strategically deploy our resources. We also continually innovate and refine our techniques to maximize our efficiency and effectiveness. However, it is difficult to determine whether any particular change caused the increased recovery this fiscal year. The \$4 billion in recovered funds primarily include: criminal fines and civil monetary penalty cases involving Federal health care offenses, penalties and damages obtained from False Claims Act cases involving the provision of health care items or services, and recovered audit disallowances.

Recoveries are a function of several variables, including, for example, the magnitude of the fraud scheme that is uncovered (which may not be known at the start of an investigation), the findings produced by data analytics, the quantity and quality of fraud complaints and referrals, and the course of litigation and settlement negotiations. In particular, the timing and scope of qui tam settlements, which are among some of the largest settlements, cannot be predicted from year to year.

As HCFAC funding has increased and we have gained valuable knowledge and experience in working with others to combat health care fraud, these recoveries have also

increased. OIG will continue to use its resources strategically to ensure maximum impact.

2. With the new tools provided in the health reform law becoming effective this year, should we expect a higher number next year?

OIG will use its share of the increased HCFAC funding in ACA to support important fraud-fighting efforts, including enhanced data analysis and collaborative approaches for detecting suspected fraud more effectively and “boots on the ground” for our vital oversight and enforcement efforts. Furthermore, expanded law enforcement authorities, opportunities for greater coordination among Federal agencies, and increased penalties provided in the ACA have the potential to strengthen OIG’s efforts to combat fraud, waste, and abuse. However, it is difficult to predict actual recoveries in any given year. We note that today’s recoveries often reflect investments from past years. Similarly, increased investments today may yield returns several years in the future.

Additionally, it is important to note that many of the tools created in ACA are ultimately aimed at preventing fraud, promoting earlier fraud detection, and stopping potentially fraudulent payments more quickly. The tools could result in averting fraudulent payments on the front-end rather than increased recoveries of misspent and stolen funds on the back-end.

3. What else can we do to improve the effectiveness of HCFAC?

As you note, the HCFAC program has returned significant resources to the Government since 1997 and the program’s return on investment continues to be high. We believe that the program’s history of impressive results underscores the value of continued investment and the effectiveness of the HCFAC program. We are confident that support of the HCFAC program as outlined in the recent President’s Budget requests will result in additional savings and strengthened program integrity. The President’s Budget also includes program integrity proposals, aimed at bolstering the Department’s fraud-fighting efforts.

The legislative recommendation that would most directly strengthen OIG’s tools to fight fraud and abuse is to enhance OIG’s permissive exclusion authority under the Social Security Act sec. 1128(b)(15). We recommend enhancing this authority in two ways:

- Authorize OIG to exclude executives who were in positions of authority at the time of bad conduct but have left those positions before OIG could exclude them.
- Strengthen OIG’s ability to use our discretion to exclude entities affiliated with convicted or excluded entities.

4. Does HCFAC have the resources necessary?

The HCFAC program continues to be a sound investment. The FYs 2011 and 2012 President’s Budget requests included \$561 million and \$581 million, respectively, in HCFAC discretionary funding for the combined efforts of OIG, CMS, and DOJ to provide oversight of Medicare and Medicaid. The increased funding would support

important fraud-fighting efforts, including enhanced data analysis and collaborative approaches for detecting suspected fraud more effectively and “boots on the ground” for our vital oversight and enforcement efforts. OIG will use its resources to continue oversight activities previously funded through mandatory appropriations; expand program integrity efforts, including the HEAT Medicare Fraud Strike Forces; and focus investigative efforts on civil fraud, including off-label marketing and pharmaceutical fraud. Again, we are confident that support of the HCFAC program through the FYs 2011 and 2012 President’s Budget requests will result in additional savings to the Government.

State Fraud Enforcement Actions

States are under enormous financial stress as a result of the economy. Because revenues have fallen and Medicaid expenditures have grown, states are under pressure to find ways to save money. Many of the tools included in the Affordable Care Act (ACA) apply to both Medicare and Medicaid, including increased screening requirements and an expansion of the recovery audit contractors. In addition, the ACA requires a state Medicaid program to terminate any provider that has been terminated due to fraudulent activity by Medicare or a different state’s Medicaid program. This prevents criminals from simply moving from state to state perpetrating similar schemes. Finally, the President’s budget proposed additional policies aimed at reducing fraud in Medicaid.

The great recession has put states under enormous pressure to balance their budgets. As a result, they are looking for a variety of ways to reduce spending. As you well know, one way to reduce spending is to root out fraud.

5. Can you talk about ways the Affordable Care Act allows states to prevent fraud and in turn reduce spending on Medicaid?

Title VI of ACA includes many program integrity provisions applicable to the Medicaid program. In addition to the provider screening and recovery audit contractor provisions you note above, Title VI mandates that providers and suppliers return overpayments to the States generally within 60 days, extends the period of time States have to collect overpayments due to fraud, mandates that States use the national correct coding initiative to reduce improper payments, requires that Medicaid providers and suppliers have mandatory compliance programs, and permits the States to suspend payments while investigating credible allegations of fraud. ACA also includes payment methodology changes that could reduce Medicaid spending, such as increases to the rebates that pharmaceutical manufacturers are required to pay for Medicaid-covered drugs.

6. Have you identified certain states that have excelled in preventing and fighting fraud and what lessons can be learned from those states?

OIG evaluates State Medicaid Fraud Control Unit (MFCU) performance on an annual basis under a set of performance standards that are published in the Federal Register. As part of OIG’s review, management practices are identified for improvement or as a best practice. Each year, OIG selects one MFCU to recognize for its efficient and effective management practices in combating fraud and abuse in the Medicaid program.

Questions From Senator Orrin Hatch

Health Care Reform Implementation

In the OIG's top management challenges, the first challenge discussed is health care reform implementation and the challenge HHS faces with respect to successfully implementing health care reform.

1. Can you please elaborate on some of these challenges and how well prepared you think HHS is to meet these challenges?

ACA expanded or modified existing HHS programs and added new programs to the HHS portfolio. Based on our work experience overseeing the more than 300 HHS programs, including our experience monitoring the implementation of the Part D program and our oversight role under the American Recovery and Reinvestment Act, we identified several areas of focus for successful implementation of ACA, including: meeting tight implementation timeframes; ensuring compliance with program rules; ensuring accuracy of claims data and payments; providing effective oversight of grants, contracts, and other obligations; promoting quality of care; implementing changes to Part D and other Medicare and Medicaid programs; and responding to fraud schemes that put HHS and its beneficiaries at risk.

As noted in the FY 2010 Top Management and Performance Challenges Identified By Office of Inspector General (Top Management Challenges), the Department has taken steps to address the challenges posed by implementation of the Act, including establishing a structure of working groups to promote effective collaboration, engaging dedicated staff to maintain a database with a dashboard feature to track implementation milestones and deliverables, and conferring regularly to monitor progress in meeting the implementation goals. The Department is also building infrastructure to support implementation of the Act. For example, CMS has created the Center for Medicare and Medicaid Innovation to focus on new delivery models and has established the Center for Program Integrity to strengthen CMS's oversight of the Medicare and Medicaid programs. In addition, the Center for Consumer Information and Insurance Oversight (CCIIO) has been structured to include an enforcement division responsible for ensuring compliance with insurance reforms. The Department is also devoting additional resources and effort to enhance the use of information technology to foster effective implementation of the Act.

OIG has provided and is continuing to provide grants oversight training to grants management officers within the Department who are or will be responsible for many of the ACA grant programs. We are currently planning a variety of work to examine the Department's early implementation of ACA provisions.

HEAT

In your testimony and in the latest HCFAC report, there has been a great focus on the results generated from the work of the HEAT teams. Recently it was announced that the HEAT initiative was expanding to two additional cities bringing the total number of cities to nine and my understanding is that the plan is to continue that expansion to more cities in the coming

months. However, in areas like Miami, Florida, while there has been a marked increase in enforcement, there still appear to be large amounts of fraud that have remained undiscovered.

2. Can you explain to me why from the OIG's perspective, you believe it is more effective to expand to more cities rather than putting additional resources into areas like Miami where fraud has been proven to be particularly pervasive?

OIG is constantly analyzing fraud trends to determine which areas represent the greatest fraud risks, and we deploy our resources accordingly. OIG uses data analysis and field intelligence to ensure that our use of resources is effective when determining whether to increase our activity in any particular area.

Medicare Advantage and Medicare Part D

One of the areas which has been the focus of several recent OIG reports and which was mentioned in your top management challenges was oversight of the Medicare Advantage and Part D programs.

3. With the additional resources allotted to CMS and the new focus on program integrity, do you think CMS is adequately addressing oversight of these two important programs?

OIG has identified oversight vulnerabilities and made several recommendations to CMS to improve its oversight of Medicare Advantage and Part D and promote program integrity. For example, in Medicare Advantage, OIG has recommended that CMS take appropriate actions to protect beneficiaries who remained vulnerable to sales agents' marketing practices. In a separate review of investment income earned by Medicare Advantage organizations, we identified a missed opportunity for program savings and recommended that CMS either (1) pursue legislation to adjust the timing of payments to the organizations to account for the time that Medicare funds are invested before providers are paid for medical services or (2) develop and implement regulations that require organizations to reduce their revenue requirements in their bid proposals to account for anticipated investment income.

In Part D, OIG has recommended that CMS take steps to address a number of oversight vulnerabilities including: payments for Part D drug claims with invalid prescriber identifiers and for drugs that FDA has found to be less than effective; limitations in Medicare Drug Integrity Contractors' identification of potential Part D fraud and abuse, and limitations and lack of sponsor accountability in CMS's Part D bid audit process.

CMS has taken steps to address some of our recommendations. For example, CMS recently issued a notice regarding invalid prescriber identifiers in Part D. As indicated in our response to the following question, OIG has also made a number of recommendations to CMS that it has not implemented. These recommendations would help CMS to better oversee Medicare Advantage and Part D and would promote program integrity.

4. What additional types of program integrity oversight efforts from CMS do you think is needed in these areas?

OIG's *Compendium of Unimplemented Recommendations* includes several recommendations that, if implemented, would improve CMS's oversight of Medicare Advantage and Part D.¹ Examples include recommendations to ensure the accuracy of sponsors' bids and prospective payments, the adequacy of sponsors' compliance plans, and that sponsors' have effective programs to detect and deter fraud and abuse. Please see Part II of the *Compendium* for a comprehensive list and description of these recommendations.

We note that ACA includes a number of provisions that will impact Medicare Advantage and Part D. As CMS promulgates regulations and begins to implement these changes, we will assess risks and monitor CMS's oversight activities.

Self-disclosure Protocols

Both of your agencies have self-disclosure protocols. The OIG has a general self-disclosure process for providers and CMS recently adopted a self-disclosure protocol for non-compliance with the physician self-referral law (also known as the Stark Law).

5. Could both of you tell me how long it takes for an organization to resolve a matter which uses your respective self-disclosure protocols?

At the end of fiscal year 2010, the average age of a self-disclosure matter pending with OIG was 13.18 months. As of March 31, 2011, the average age of pending self-disclosure matters is 11.43 months. This represents a 13% reduction in age of pending matters. There are many factors that can determine the length of time it takes a self-disclosure matter to be resolved, including: the type of conduct at issue, provider cooperation, and length of negotiations.

6. Are there any estimates in how much it costs health care organizations to go through the self-disclosure process?

The OIG has not estimated the cost of going through the self-disclosure process. Providers have reported that they find the self-disclosure process to be cost effective based on the OIG's April 15, 2008 open letter. The open letter states that OIG will presumptively not require a Corporate Integrity Agreement (CIA) in cases where a provider has self-disclosed. Providers have reported that the cost savings associated with not having a CIA are an incentive to self-disclose.

7. That is, how many personnel hours are needed, or what types of costs do organizations incur to work through the process?

In order to be accepted into OIG's self-disclosure protocol, a provider must provide (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the Federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and (4) a statement of the laws potentially violated by the conduct. The cost to

¹ Available online at: <http://www.oig.hhs.gov/publications/docs/compendium/2011/CMP-March2011-Final.pdf>.

the provider depends on the complexity of the matter being disclosed, the provider's knowledge of the matter, and the provider's ability to organize the information requested.

Questions From Senator Chuck Grassley

H.R. 675

Last year the House passed H.R. 6130, Strengthening Medicare Anti-Fraud Measures Act of 2010, by voice vote to expand the permissive authority the Inspector General for the Department of Health and Human Services has to exclude individuals or entities from participation in Medicare or Medicaid. Unfortunately, the Senate did not get it passed before the session ended. This bill has been reintroduced in the House as H.R. 675. I included the same provision in the bill I introduced on March 2, 2011—S. 454, Strengthening Program Integrity and Accountability in Health Care Act of 2011.

Inspector General Levinson, I understand that you believe H.R. 675 would provide valuable tools for combating fraud and abuse. I appreciate your comments on the bill at the hearing.

- 1. I am reiterating that question for the record. Can you discuss the types of fraud and abuse you could address if H.R. 675 were passed? Please feel free to expand on your response from the hearing and include any additional information you did not have a chance to provide last week.**

The bill would help OIG protect Federal health care programs and beneficiaries from individuals and entities that pose a risk to the programs' integrity or beneficiaries' health.

The bill would also authorize OIG to pursue permissive exclusion against entities affiliated with a convicted or excluded entity. This discretionary authority would allow OIG to exclude (or require compliance measures as an alternative to exclusion) entities that would otherwise avoid remedies despite their link to a sanctioned entity.

The following are several examples that illustrate how the authorization to pursue permissive exclusion would help protect the programs and beneficiaries:

- **Substandard Care by a Pediatric Dental Chain:** OIG recently investigated a national pediatric dental chain that allegedly provided medically unnecessary pulpotomies, otherwise known as "baby root canals," on children. Although we developed substantial evidence of such unnecessary procedures at many of the chain's clinics, the corporate structure made it difficult for OIG to pursue exclusion of the parent company. Under the amended 1128(b)(15), if OIG could exclude clinics for providing unnecessary and substandard care, we could also exclude the parent and other affiliated entities.
- **Poor Quality of Care in Nursing Homes:** Complex ownership structures in the long term care industry have shielded responsible individuals and entities from government oversight. The Affordable Care Act requires transparency in ownership for the long term care industry; however, this additional information is

only useful if we have the ability to act on it. Under current law, if an individual facility is convicted of fraud for grossly failing to provide sufficient care to its residents, we do not have the authority to pursue the corporate parent based on such a conviction. Criminally substandard care at a long term care facility is often related to poor resources, support, and policies from its corporate parent and affiliates. The proposed amendment to section 1128(b)(15) would enable OIG to better protect the health and well-being of patients by either excluding entities, or requiring corporate integrity agreements with independent quality monitors across all the long term care facilities owned or operated by chains in which poor care has led to criminal convictions.

- **DME Crime Rings in South Florida:** In fraud hot spots like south Florida, we have uncovered sophisticated crime rings and virulent fraud spreading through communities. For example, individuals involved in a crime ring may open numerous fraudulent DME storefronts. Once one such entity was convicted, we could use the amended section 1128(b)(15) to exclude all the similar entities under common control.

Other provisions in the bill would effectively close the loophole available to individuals who leave a company to avoid accountability. Because the current law is phrased in the present tense, we can only exclude those individuals who are owners, officers, and managing employees at the time we take action. For the most part, the executives of major corporations that have engaged in criminal fraud are no longer with the company by the time it is convicted. Right now, these individuals are free to hold positions of responsibility at any kind of health care entity.

In sum, the proposed amendments to section 1128(b)(15) would greatly enhance OIG's ability to protect the integrity of federal health care programs and the health and safety of our beneficiaries.

Suspicion of Fraud

Under the Patient Protection and Affordable Care Act, the Secretary may suspend payments pending an investigation of credible allegations of fraud in Part A and B. In Medicare Part D, a prescription drug plan must pay a clean claim within 14 days. However, I have been told that the plans are not able to suspend payments even when they have evidence of potential fraud, such as claims being filed from empty storefronts.

2. What is your position on statutory changes to allow prescription drug plans to suspend payments when there is suspicion of fraud?

We defer to the Department's Office of General Counsel to address whether plans are able to suspend payments when they have evidence of potential fraud. If statutory changes are required, we are happy to review proposed language and provide technical assistance.

Questions From Senator John Ensign**Electronic Health Records**

- 1. Will the use of electronic health records and e-prescribing systems reduce fraud, waste, and abuse in our federal healthcare programs?**

Electronic health records and e-prescribing systems are changing the way that health care services are delivered. These systems are also changing the way we approach our work. OIG is considering ways in which the design and function of electronic health records and health IT systems can help prevent and detect fraud, waste, and abuse as well as ways in which these tools can be misused to facilitate fraud, waste, and abuse and impede their detection.

- 2. What kinds of controls need to be built into these systems to prevent fraud and abuse?**

In general, OIG supports electronic health records and e-prescribing systems that include features which help ensure that health records accurately reflect the actual care provided—as opposed to the care that should have been provided or the care that billing and coding experts suggest would command a higher payment. These systems should include audit features that cannot be disabled or circumvented and that accurately track who accessed and edited records and when.

Pay and Chase

It appears that HHS spends most of its time chasing after providers for dollars after payments have already been made.

- 3. What kinds of structural and systematic changes can be made on the front end to help prevent fraud and abuse from ever happening and to also achieve cost-savings?**

It is not possible to stop all fraud and abuse, but it can be reduced. OIG has long recommended that CMS devote more resources and effort to front end fraud prevention, such as provider enrollment screening and prepayment reviews. ACA provides for enhanced provider enrollment and re-enrollment screening procedures, provisional periods of enhanced oversight and prepayment review, and the ability of the Secretary to impose temporary moratoria on enrollment. ACA also requires providers and suppliers to have compliance plans as a condition of enrollment. CMS has implemented or is in the process of implementing these ACA program integrity provisions.

- 4. Has CMS established goals and benchmarks in this area?**

We defer to our colleagues at CMS to describe its goals and benchmarks for preventing fraud and abuse on the front end.

HIPAA Eligibility Transition System

It is my understanding that there is an electronic program, known as the HIPAA Eligibility Transition System. Many providers use this system to verify Medicare eligibility for specific services. I have heard rumors that the system has been experiencing timing out issues. It is also my understanding that the HETS system will be transitioning to a new program called the 5010 system. If these types of glitches remain, there could be an increase in fraud; providers could experience more bad debt; and Medicare beneficiaries could be forced to pay for services up-front.

5. Can you please explain how HHS is responding to these technical issues and how it intends to manage the change to the new 5010 system?

We defer to the Department to address how it is responding to technical issues associated with the HIPAA Eligibility Transition System and how it plans to manage the transition to the 5010 system.

Questions From Senator Tom CoburnUnimplemented Recommendations

Your office publishes a compendium of unimplemented recommendations each year.

1. In your professional estimation, should CMS look at implementing these program integrity provisions to increase savings for taxpayers and enhance Medicare's program integrity?

Yes. The compendium includes significant monetary and nonmonetary recommendations that, when implemented, will result in cost savings and/or improvements in program efficiency and effectiveness.

Medicare Contractors

Last year's Departmental audit found some Medicare contractors still use financial processes that are "subject to an increased risk of inconsistent, incomplete, or inaccurate information" and have not implemented [Healthcare Integrated General Ledger Accounting System]. According to the audit, the accuracy of these contractors' reports "remains heavily dependent on inefficient, labor-intensive, manual processes that are also subject to an increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS."

2. Do you believe this kind of contractor problem could put taxpayer dollars at risk?

The independent auditor of the Department's financial statements identified the Department's lack of an integrated financial management system as a material weakness that impaired the Department's ability to report accurate and timely financial information. The auditor stated that HIGLAS is not fully implemented and that the Department continues to rely on a combination of claims processing systems, personal computer-

based software applications, and other ad hoc system to tabulate, summarize, and prepare financial reports. As a result, the accuracy of these reports “remains dependent on inefficient, labor-intensive, manual processes that are also subject to an increased risk of inconsistent, incomplete, or inaccurate information. . . .” The auditor did not consider the amounts associated with these weaknesses to be material to the financial statements taken as a whole, but noted that “these matters are indicative of serious systemic issues that must continue to be resolved.”

Medicare Payment System

Your office has stated that the manner in which Medicare pays providers effectively encourages the system to be defrauded.

3. Do you believe any of the immediate changes to payments under the health care overhaul represent game-changing Medicare *payment reform*?

To clarify, Medicare pays providers and suppliers in a variety of ways, and our office has stated that the manner in which Medicare pays providers influences the manner in which Medicare is defrauded. For example, a cost-based payment system is susceptible to the artificial inflation of costs, a fee-for-service payment method is susceptible to overutilization by dishonest providers, and capitated or prospective payment systems are susceptible to underutilization and stinting on necessary care. Thus, it is important that payers, such as Medicare, tailor integrity measures to address the fraud risks inherent in specific payment systems. With respect to the risk of fraud and abuse, the ACA includes a number of promising payment reforms. For example, ACA gives Medicare the ability to suspend payment in cases where there is credible evidence of fraud. This tool has already been used to stop the payments to the targets of OIG criminal investigations. ACA payment reforms also allow the Department to create incentives that encourage the quality of care rather than the volume of services. CMS is in the process of issuing regulations for the new Medicare Shared Savings Program and is at work on other demonstrations for new payment models. OIG will continue its oversight of the implementation of ACA payment reforms to help ensure they accomplish their intended objectives.

Senior Medicare Patrol Project

The Senior Medicare Patrol Project recruits retired professionals to serve as educators and resources in helping beneficiaries to detect and report fraud, waste, and abuse in the Medicare program. According to one of your office’s report from 2008, the program has resulted in recoveries averaging about \$10 million each year, but has cost taxpayers slightly more than the \$10 million each year. This means that, according to your office’s report, the program has shown no significant *financial* return on investment over the course of the past decade.

4. Do you still believe the program is important to maintain for *qualitative* reasons? If so, why?

Evaluating the success of the Senior Medicare Patrol Project is not just a matter of comparing recoveries to the cost of the program. The number of beneficiaries who have learned from the Senior Medicare Patrol Projects to detect fraud, waste, and abuse and

who subsequently call the OIG fraud hotline or other contacts cannot be tracked. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track substantial savings derived from a sentinel effect whereby fraud and errors are reduced in light of Medicare beneficiaries' scrutiny of their bills.

We defer to Congress and to program officials to determine whether a program is important to maintain.

5. How could we improve it to get better return-on-investment for taxpayer dollars?

OIG has not made specific recommendations on this issue. We are aware that AoA has initiatives underway to increase the program's impact, as well as plans to conduct a program evaluation that will assess performance measures to determine how to best measure the program's value, including return on investment.

Medicaid Statistical Information System

In 2009, your office said that the Medicaid Statistical Information System does not provide "timely, accurate, or comprehensive information for fraud, waste, and abuse detection." Your office said CMS could "improve the documentation and disclosure of error tolerance adjustments and expand current State Medicaid data collection and reporting to further assist in fraud, waste, and abuse detection. . . ."

6. Do you believe that if this claims database were updated regularly with accurate information, it would help increase program integrity?

Program integrity relies heavily on the timeliness and accuracy of data available to CMS in administering its programs and to OIG in meeting its mission. Thus, regular claims database updates with accurate information would help to improve program integrity.

The MSIS system of records notice indicates that CMS collects MSIS data from States "to establish an accurate, current, and comprehensive database containing standardized enrollment, eligibility, and paid claims of Medicaid beneficiaries to be used for the administration of Medicaid at the Federal level." The system of records also notes that MSIS data is used to "assist in the detection of fraud and abuse in the Medicare and Medicaid programs." According to CMS, MSIS is used in a number of ways including to analyze policy alternatives. OIG relies on MSIS to meet Health Care Fraud Prevention and Enforcement Action Team objectives and to perform a variety of audits and evaluations.

7. Can this be accomplished through administrative or legislative action?

Section 6504 of ACA amended Section 1903(r)(1)(F) of the Social Security Act (42 U.S.C. 1396b(r)(1)(F)) by allowing the Secretary of HHS to add data elements to MSIS "necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine." We will monitor the implementation of this provision and provide feedback to the Department as necessary.

Common Access Card

The Department of Defense has a “common access card” that is used for identification purposes, that meets or exceeds requirements of privacy laws, and uses integrated chips, a magnetic stripe, and a bar code to enable a secure to log-on to networks.

8. Do you think it could be beneficial for the Medicare program to explore the utility of this kind of technology or other smart cards for beneficiaries or providers that existing commercial financial networks?

Making both provider and beneficiary IDs more secure would be valuable in curbing fraud, waste, and abuse, but OIG would need to review the specifics of any proposal to make any further comment.

Duplicative and Ineffective Programs

On March 1, 2011 the Government Accountability Office published a large report of duplicative and ineffective programs. Included in this report was a series of recommended changes to the Medicare and Medicaid programs to enhance program integrity and achieve savings.

9. Which of these GAO recommendations would you most strongly suggest Congress to consider?

Many of GAO’s recommendations are consistent with recommendations that OIG has made to improve program integrity. OIG highlights the following priority areas.

Improved Targeting of Claims for CMS Contractor Review

GAO made several recommendations that improved targeting of claims for CMS contractor review could reduce Medicare improper payments. We agree with those recommendations, and have made similar recommendations to CMS. For example, we recently completed an analysis of errors identified in CMS’s FY 2009 Comprehensive Error Rate Testing (CERT) Program. In this review, we identified the most frequent types of payment errors (i.e., medically unnecessary, insufficient documentation, etc.) associated with the provider types that accounted for the vast majority of errors identified in CERT (i.e., inpatient hospitals, DME suppliers, physicians, etc.). We recommended that CMS use the results of our analysis to identify the types of payment errors indicative of programmatic weaknesses and any additional corrective actions needed to strengthen the CERT program.

Future Cost Savings to the Medicare Program

GAO’s report also included recommendations that would result in potential future savings to the Medicare program. For example, GAO recommended that Congress consider reducing Medicare home oxygen payment rates to align them more closely with the costs of supplying home oxygen. OIG concurs with that recommendation, and would encourage a broader look at payment rates for other types of durable medical equipment. In 2006, OIG found that Medicare allowed more than \$7,000 for 36 months of rental payments for oxygen concentrators that cost \$587, on average, to purchase. OIG also

found that Medicare allowed an average of \$4,018 to purchase standard power wheelchairs and \$11,507 for complex rehabilitation power wheelchair packages, compared with supplier acquisition costs of \$1,048 and \$5,880, respectively. OIG has recommended that CMS determine whether these amounts should be adjusted using its inherent reasonableness authority, using information from the Competitive Bidding Acquisition Program, or seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. OIG's 2009 findings that more than half of power wheelchair claims submitted by suppliers do not meet the requirements for payments underscores the need to closely align the amount Medicare pays for power wheelchairs with the costs to suppliers.

Reduction of Improper Medicaid Payments

Finally, GAO's report includes many recommendations that would reduce improper payments in the Medicaid program by implementing new processes and improving oversight. One specific area addressed by GAO that is of ongoing concern to OIG is CMS's oversight of projects developed by consultants on a contingency-fee basis. GAO recommended that CMS's oversight be improved by routinely requesting information on these projects and associated claims. We agree that increased oversight would be useful and our work has identified vulnerabilities related to these payments.²

Enhance Program Integrity

Similarly, the Government Accountability Office has a list of more than 30 significant recommendations, based on reports they have done, that would enhance program integrity in Medicare or Medicaid. These recommendations, updated as of January 2011, and have not been implemented.

10. Which of these GAO recommendations would you most strongly suggest Congress to consider?

Please see our response to the previous question as some of the recommendations on GAO's list overlap the recommendations referenced in its March 1 report. In addition, based on similar OIG studies of CMS's Part D bid audits, we note our concurrence with the recommendations included in GAO's report entitled *Medicare Advantage: Required Audits of Limited Value*. Finally, we share GAO's concern about improper home health payments. For example, OIG's *Compendium of Unimplemented Recommendations* includes our recommendation that CMS should review home health providers that exhibit aberrant outlier payment patterns and respond appropriately based on the findings.

HEAT

HHS and the Justice Department sent Sen. Grassley a letter in late January (2011) explaining the results from the Administration's much-publicized HEAT initiative, Health Care Fraud

² OIG issued a Special Advisory Bulletin on consultant liability in June 2001 (www.oig.hhs.gov/fraud/docs/alertsandbulletins/consultants.pdf). The bulletin highlights several questionable consultant practices including making illegal or misleading representations, making promises or guarantees, encouraging abusive practices, and discouraging compliance efforts.

Prevention and Enforcement Action Teams. We all support the goal of reducing fraud, but if I read the data correctly, in 2010, convictions in all but one city (Miami) decreased.

11. Can you please explain this? How much did DOJ and HHS spend per conviction?

The statistics on page three of the letter sent on January 24, 2011, indicate that convictions (measured as guilty pleas and guilty verdicts) increased from FY 2009 to FY 2010 in each Strike Force City that has been operational for those two years. Regarding the second question, OIG does not calculate an average cost per conviction. The investigative process does not necessarily lend itself such a calculation.

Questions From Senator John Thune

The CLASS Act and the Potential for Fraud

In December 2010, the bipartisan National Commission on Fiscal Responsibility and Reform released its report containing a set of recommendations to address the fiscal situation, which included a recommendation to reform or repeal the new Affordable Care Act entitlement program known as the Community Living Assistance Services and Supports (CLASS) Act. The Commission noted the CLASS Act is financially unsound because beneficiaries will pay modest premiums yet receive significantly higher benefits at payout. I would appreciate if you could provide insight regarding the following questions:

1. It stands to reason that any government program that has significant payout in relation to modest premiums is highly vulnerable to fraud. Dr. Budetti and Mr. Levinson, do you feel the CLASS Act is susceptible to fraud?

a. If so, can you elaborate on why you believe it is?

In our experience, all health benefits programs are susceptible to potential fraud, waste, or abuse. Under the CLASS Act, OIG is mandated to issue annual reports examining the CLASS Act implementation and operations. Our work will attempt to evaluate the potential and actual vulnerabilities, both as the regulatory rules for the program are drafted, and as the benefit is implemented. Our ongoing evaluation of the development of the program and our reports should be helpful to the Department and Congress as they continue to assess the planned program.

Fraud at Aberdeen Area Indian Health Services

A recent Senate Indian Affairs Committee investigation of Indian Health Service's (IHS) Aberdeen Area found three service units in particular have a history of missing or stolen narcotics and that nearly all facilities in the Area have failed to perform consistent monthly pharmaceutical audits of narcotics and other controlled substances. The report also found that between 2006 and 2008, there was a 27 percent increase in prescription volume in that Area. Not only does this raise issues about waste and fraud, but prolonged deficiencies in this area can lead to CMS and other third party reimbursement decertification, a funding source IHS facilities

cannot afford to lose. I would appreciate if you could provide insight regarding the following questions:

1. Mr. Levinson and Dr. Budetti, is there any evidence that this type of criminal activity is occurring in other IHS areas?

OIG has identified and investigated multiple allegations of controlled substance diversion and loss in IHS Areas outside of the IHS Aberdeen Area.

OIG recognizes controlled substance abuse to be one of the most serious threats to the health and safety of American Indians and Alaska Native people. The security of controlled substances at IHS and tribal facilities is a key to maintaining the safety and integrity of these facilities, their programs, and the people they serve.

OIG has identified that IHS and tribally operated pharmacies under the direction of nearly all IHS Area Offices are potentially vulnerable to controlled substance abuse including: diversion and trafficking from IHS employees, contract providers, patients, and non-tribal members. The rural isolation of many of these facilities and the black market value of controlled substances exacerbates the dangers and motivations for these crimes.

2. Mr. Levinson, what if anything has HHS done to investigate and/or remedy this situation?

OIG has led multiple investigations into drug diversion at IHS facilities that have resulted in numerous criminal convictions of IHS employees and contractors involved in schemes to obtain controlled substances by fraud, theft, and conspiracy including:

- In Montana, OIG investigated allegations that an IHS employed nurse practitioner wrote medically unnecessary prescriptions for controlled substances. The patients, some of whom were also IHS employees, then filled the prescriptions at an IHS pharmacy and returned the drugs to the nurse practitioner in exchange for cash. Seven defendants were sentenced to various terms of incarceration and probation as a result of the investigation.
- In Oklahoma, OIG investigated allegations that a nurse at an IHS Hospital diverted controlled substance for her own use. The nurse signed out narcotics and documented records indicating that she administered narcotics to patients although the patients had already been discharged from the hospital. She was sentenced after pleading guilty to obtaining controlled substances by fraud.

Our oversight activities are also directed at identifying systemic weaknesses and vulnerabilities in IHS pharmacies that can be mitigated through corrective management actions, policy changes, regulations, or legislation. OIG's Office of Audit Services issued five audit reports in 2006 and 2007 on safeguards over controlled substances at IHS hospitals and clinical centers. These audits examined five IHS hospitals and health centers regarding their handling of Schedule II substances. The audits found that some of the hospitals and health centers did not always comply with requirements to secure and account for their Schedule II substances. The audits also detected faulty internal controls

that rendered the Schedule II substances vulnerable to theft and mismanagement. OIG recommended improvements to internal controls, such as (1) adequately separating the key duties of ordering controlled substances and recording their receipt, (2) monitoring an after-hours alarm system, and (3) fully accounting for substances at other pharmacy locations or automated dispensing units.³

Additionally, OIG's 2011 Work Plan includes plans to review inventory controls for other medications that, not categorized as controlled substances.

3. Mr. Levinson, is HHS OIG working jointly with Drug Enforcement Administration's Diversion Investigators to analyze and investigate this activity?

OIG frequently conducts joint investigations with Federal, State, tribal, and local law enforcement agencies in situations where there is concurrent jurisdiction and the sharing of expertise or authority will obtain the most positive and cost effective results. Our pursuit of joint investigations regarding allegations relating to IHS and Indian County matters are no exception. Joint investigations with our law enforcement partners in the DEA include work with DEA Special Agents and Diversion Investigators. These joint investigations have proved productive in the past resulting in multiple criminal convictions.

a. If so, can you elaborate on the work?

Examples of joint investigations with DEA Diversion Investigators include:

- In Minnesota, OIG and DEA Diversion investigators initiated a joint investigation after an IHS Hospital's chief pharmacist identified over 14,000 missing Hydrocodone (in the form of Vicodin) tablets over a six month period. Two IHS employees were sentenced in this case based on their guilty pleas to Unlawful Possession of Hydrocodone. Investigators learned that the former IHS employees responsible stole an average of 100 tablets per day during the relevant time period.
- In South Dakota, OIG and DEA worked together to investigate allegations that a Supervisory Operating Room Nurse, employed by IHS, unlawfully acquired pain medications from multiple pharmacies within and outside the IHS system of care. As a result of the joint investigation, the IHS employee pled guilty and was sentenced on one felony count of Obtaining Controlled Substances by Fraud.

OIG will continue to actively pursue and investigate allegations of waste, fraud and abuse in IHS and Indian County matters in order to safeguard the Department's programs, operations and beneficiaries. OIG will also continue to identify systemic weaknesses and vulnerabilities that can be mitigated through corrective management actions, regulation or legislation.

³ These reports can be accessed at: http://oig.hhs.gov/oas/ihs_archive.asp.

COMMUNICATIONS



March 15, 2011

The Honorable Max Baucus
Chairman
Finance Committee
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Baucus:

Thank you for the opportunity to provide written comments related to the March 2, 2011, hearing entitled "Prevent Health Care Fraud: New Tools and Approaches to Combat Old Challenges." The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to suggest additional approaches to stemming the growth of Medicare fraud.

The Academy is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. Various of the Academy's members work within managed care organizations to prevent Medicare fraud in the Medicare Part D drug benefit.

Federal and private-sector estimates of Medicare fraud range from three percent to 10 percent of total expenditures, amounting to between \$68 billion and \$226 billion annually. HHS Secretary Sebelius said "When criminals steal from Medicare, they are stealing from all of us."¹ The substantial size of the dollars lost annually in fraud, waste and abuse in Medicare Parts A, B, C and D have prompted Medicare fraud to be one of the federal government's top priorities. Fraudulent activity within pharmacy benefits can take many forms, including patients acquiring prescriptions under false pretenses, providers writing illegitimate prescriptions and the trafficking of counterfeit drugs.

First, the Academy strongly supports the premise of stopping the cycle of "paying and chasing" fraudulent activity. The Academy appreciates the inclusion of Section 6402 in the Patient Protection and Affordable Care Act, P.L. 111-148, (the Affordable Care Act) that permits the Secretary to suspend payments to a provider of services or supplier under Medicare Parts A and B, pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless there is good cause not to suspend the payment. Pursuant to this provision, the Secretary is required to consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud.

¹ Gebhart, F., "CMS Launches Anti-fraud Program," *Drug Topics*. December 2009.

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The Academy strongly recommends that the Committee consider legislation that would extend the authority in the Affordable Care Act to suspend payment of claims wherein there is a credible allegation of fraud in Medicare Part D. Such legislation should provide for an expansion of time in which managed care organizations pay claims believed to be fraudulent. Further, AMCP recommends that Medicare Part D be included in the law by extending to the Secretary and/or Office of Inspector General the authority to suspend payments through the existing managed care organizations in instances of fraud.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) adopted a reduced period in which prescription drug plans (PDP) are required to pay pharmacies. As a result, Part D plans are limited to a retrospective analysis of pharmacy claims and provider payment trends which are primarily directed at administration errors, e.g., coding errors, etc.

Generally, a seven to 10-day payment cycle is required to meet MIPPA's 14 day "prompt payment" standard. For instance, a two-day time period between the end of a payment cycle (run on day 11) and the production of payment (run on day 13) obviates any significant prospective opportunity to conduct analysis of claims and reimbursement data prior to payment being sent to the pharmacy provider. As a result, Part D plans must rely on a "pay and chase" approach to recovering suspected fraud once proven. One plan's experience is that since 2006, approximately 9% to 12% of retrospectively reviewed claims have been deemed outliers and warranted additional scrutiny and investigation. Some of the metrics used by managed care organizations in a retrospective analysis include the following:

- Pharmacy provider reimbursement spikes relative to peers per payment cycle
- Increased brand drug dispensing, relative to generic drug dispensing (compared to peers)
- Increased dispensing/reimbursement of targeted high cost therapeutic classes or therapeutic classes with street value on the black market, i.e.:
 - Controlled substances
 - HIV drugs
 - Injectable specialty drugs
- Geographic prescription claim volume per capita, as compared to peers

Second, the Academy appreciates the expanded data matching provisions provided for in Section 6402(a) of the Affordable Care Act. Section 6402(a) expands the "Integrated Data Repository" (IDR) at CMS that will incorporate data from all federal health care programs, including Medicare Parts A, B, C and D; Medicaid; CHIP; health-related programs administered by the Secretary of Veterans Affairs; health-related programs administered by the Department of Defense; Federal old-age survivors, and disability insurance benefits established under Title II of the Social Security Act; and the Indian Health Service and the Contract Health Service program. This provision establishes the ability to create a comprehensive database that reflects all claims involving federal government programs.

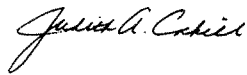
The Academy submits that it may be useful to link the claims data compiled in the IDR with the data compiled by the Medicare Drug Integrity Contractor (MEDIC) reporting infrastructure. The MEDIC database contains reports of fraud from private sector managed care organizations. To end the cycle of "paying and chasing" fraudulent activity, it will be important to ensure that there is a two-way communication of information between the public and private sectors with regard to fraudulent activity.

Fraud, waste and abuse are unacceptable within any health care program, especially within health care programs that are financed through taxpayer dollars. In a time of diminishing financial resources, it is

more important than ever that Medicare providers, including Part D plan sponsors, are effectively able to combat suspected fraud. AMCP recognizes the seriousness of this problem and is supportive of efforts that would reduce the instance of fraudulent activity.

The Academy would be pleased to work with you to develop legislative language that addresses fraudulent activity in the Medicare Part D drug benefit. Thank you again for the opportunity to provide these written comments. Please do not hesitate to contact Lauren L. Fuller, Director of Legislative Affairs, at 703-683-8416 or lfuller@amcp.org if we may be of further assistance.

Sincerely,



Judy A. Cahill
Executive Director

cc: The Honorable Orrin Hatch
Ranking Member



APRIA HEALTHCARE

**Senate Committee on Finance Hearing
“Preventing Health Care Fraud: New Tools and Approaches to Combat Old
Challenges”
March 2, 2011**

Statement for the Record

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Introduction

We are writing to provide formal comments related to the Senate Finance hearing scheduled on Wednesday, March 2, entitled, “Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges.” Apria Healthcare is a national provider of home respiratory, specialty infusion therapy and medical equipment services with a long history of serving both Medicare/Medicaid and commercially insured patients across the United States. With over 11,500 employees and 500 locations, Apria serves over two million patients’ homecare needs annually throughout all 50 states. Accredited for all service lines for over 20 years, Apria Healthcare was the first provider of durable medical equipment and respiratory services to voluntarily seek and obtain accreditation.

With a comprehensive corporate compliance program in place for over a decade which incorporates the Health and Human Services Office of Inspector General’s (HHS/OIG) Guidelines for Healthcare Organizations, Apria has been a leader in strengthening the industry’s overall compliance and anti-fraud and abuse efforts. For example, Apria has used its longstanding experience to offer specific recommendations to both Congress and the Centers for Medicare and Medicaid Services (CMS) and to lead the development of new, comprehensive Codes of Ethics for the two primary trade associations dedicated to the DMEPOS and home infusion segments of homecare.

Anti-Fraud and Abuse Efforts Play Key Role But Current Investments Are Misdirected

Apria strongly agrees with the need to reduce the amount of fraud, waste and abuse in the healthcare system and to prevent such fraud from occurring in the first place. We also recognize that audits and fraud investigations are integral components of the government's efforts to ensure that claims are properly paid. Apria has therefore been extremely troubled by the recent auditing trend, which has unduly targeted legitimate providers, has been highly inefficient, inconsistent and administratively burdensome for both providers and the government, has impermissibly applied new auditing standards retroactively and has completely lacked transparency.

We refer specifically to auditing efforts through what is known as Medicare Zone Program Integrity Contractors (ZPICs). Over the last eight months, Apria has received over 5000 individual line-item audit requests, which represents triple the volume compared to the eight months prior. In the case of two of Apria's Florida facilities, the ZPIC in question sent out individual requests (an envelope containing three pages) for each of 1,500 dates of service – totaling over 4,500 pages or nine reams of paper just for two moderately-sized branch locations. While multiple dates of service in question were for the same patient, the ZPIC did not request one set of paperwork pertaining to all dates of service for that particular patient. Instead, the ZPIC required Apria to submit individual responses for each date of service, resulting in our having to repeatedly submit all of the paperwork necessary to substantiate the claim for each date of service.

Incorrect Data Calculations and Error Rates Submitted to Congress

Especially troubling are the incorrect conclusions and error rates being calculated by the ZPIC, which are ultimately reported to the CMS Durable Medical Equipment Medicare Administrative Contractor (DMEMAC), CMS and Congress, and the questionable data requests being made by ZPIC auditors. Regarding the first point, the ZPIC reported to one of our branches that it had a 100 percent error rate, based on only six dates of service out of hundreds that had been requested and to which we responded on a timely basis, five of which the ZPIC incorrectly alleged that the paperwork hadn't been submitted. Examples of the questionable data requests made to one of our Florida branches include on-site inspectors requesting photographs of all of the Medicare patients we serve and a list of our current and ex-employees' Social Security numbers. No auditor in the history of Medicare audits has ever requested photographs of patients and no regulation requiring providers to obtain photographs of home-based patients exists, not to mention the fact that such a practice would potentially violate the government's own federal regulations concerning patient privacy (Health Insurance Portability and Accountability Act (HIPAA)). The on-site auditor commented verbally that it was clear that we operated a legitimate location which was properly licensed by the State of Florida, included a real warehouse, company-owned vehicles, obvious inventory and busy staff, making the request for current and ex-employees' Social Security numbers more curious indeed.

It is also important to note that during the five months in which the ZPIC conducted a medical necessity review, Medicare held payment on the audited product lines – a practice which has already had severe consequences for smaller providers who cannot withstand the adverse impact on their cash flow. Finally, when Apria brought this matter to CMS' attention, CMS did not participate in a substantive review and discussion of the claims at issue with Apria and the ZPIC but instead advised Apria to appeal the ZPIC's determinations on more than 1,000 dates of service, at significant cost to the government as well as to Apria.

A very high percentage of these appeals will likely be overturned by higher level administrative law judges (ALJs), thus supporting our point that certain aspects of the new audits represent a misapplication of anti-fraud and abuse funds that could otherwise be put to better use either in the area of real-time monitoring of brand new or rapidly-growing Medicare providers or in pursuing truly criminal or potentially criminal providers. Also, by the time the ALJs rule on the appeals, an incorrect error rate will have already been reported to various government officials, thus resulting in potentially misleading and incorrect conclusions which are rarely, if ever, corrected.

Retroactive Application of Brand-New Auditing Standards is Contrary to Administrative Law Principles

In addition to the burdensome requirements being imposed by the ZPICs and erroneous audit results, Apria is disturbed that CMS' auditors are *retroactively* applying these new auditing standards, contrary to well-established principles of administrative law. The retroactive application includes claims for patients referred to service as long ago as a decade. By its very nature, a rule applies to *future* occurrences. CMS has clearly engaged in retroactive rulemaking with respect to many of its new medical necessity documentation policies and has imposed new documentation policies on claims upon pre- and post-payment review of which DMEPOS suppliers had no prior notice. This is exactly the type of retroactive rulemaking prohibited under *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208-209 (1988), and its progeny.

It also became clear during a series of conference calls we held with various CMS officials based in Florida and Baltimore that they were unaware of at least some of the ZPICs' practices, thus calling into question whether CMS is appropriately carrying out its oversight responsibilities with regard to its subcontractors' operating policies and procedures. This also leads to inconsistent practices among the various auditing bodies. CMS officials were surprised by some of the data requests being made by the ZPIC subcontractors and asked for more detail to be provided by us so that they could address the behaviors. Yet, most of these processes are not documented in writing anywhere in the Program Integrity Manual, Medicare Learning Matters, Medicare DMEPOS Quality Standards, Medicare DMEPOS Supplier Standards or any other guidance document.

Summary

We conclude by reiterating Apria's absolute support for proper use of Medicare resources to effectively combat fraud, waste and abuse. It is critical, however, that these efforts be rational, balanced and targeted on a "rifle shot vs. shotgun" basis so that legitimate suppliers with a long history of serving the Medicare program are not unduly burdened. As Dr. Peter Budetti said in an interview with Richard Shackelford, President of the American Health Lawyers Association, "Certainly one of our {CMS' Center for Program Integrity} biggest challenges is preventing fraud while not adversely affecting beneficiary access or our partnership with legitimate providers and suppliers" (p. 4, January 2011 issue of *AHLA Connections*). Moreover, in public testimony, the HHS OIG has stated on the record that "[inadvertent] errors do not equal fraud."

We urge Congress and the Centers for Medicare and Medicaid Services to provide needed oversight to the ZPIC process to ensure that real fraud, waste and abuse is targeted and ultimately eliminated.

Respectfully Submitted,

/s/

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PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

**Statement for the Record of the
Pharmaceutical Care Management Association
Submitted to the**

**UNITED STATES SENATE
COMMITTEE ON FINANCE**

*“Preventing Health Care Fraud:
New Tools and Approaches to Combat Old Challenges”*

March 2, 2011

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The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP). PCMA appreciates the opportunity to submit a statement for the record to the Finance Committee related to health care fraud, waste and abuse (FWA).

PBMs typically reduce drug benefit costs by 30 percent for public and private payers by encouraging the use of generic drug alternatives, negotiating discounts from manufacturers and drug stores, saving money with home delivery, and using health information technology like e-prescribing to reduce waste and improve patient safety. Prior to the advent of these tools, there was no system wide approach to fully address the real dangers and costs of misuse, overuse, or under-use of prescription drugs. In the Medicare Part D program, research cited by the Centers for Medicare & Medicaid Services (CMS) notes that strong Part D plan negotiations have been a key driver in the benefit, which is now expected to cost taxpayers \$373 billion over ten years, a 41 percent drop from the initial cost estimate of \$634 billion for 2004-2013.

Most estimates of Medicare fraud are at three to ten percent of all claims. With increasing spending along with the complexity of our health care system, the amount of total dollars lost due to fraud will only increase, barring systematic and successful detection and prevention. Although not a significant area for fraudulent activity, prescription drugs are not immune to this threat. Whether it is through doctor and pharmacy shopping to obtain prescription drugs illegally, or simply a pharmacy billing for more prescriptions than it actually dispenses—law enforcement, Part D plans, and pharmacy benefit managers (PBMs) must remain vigilant.

PBMs are dedicated to providing access to affordable prescription drugs while protecting tax payer resources from FWA. Pharmacy claims, unlike medical claims, are typically adjudicated in real-time as the patient stands at the pharmacy counter or upon dispensing the drug by a mail-service pharmacy. Most of these claims are adjudicated electronically, which not only provides a seamless process for the beneficiaries, but also provides the ability to stop the more obvious FWA from occurring. In addition, PBMs monitor overall claims and detect patterns of potential abuse or fraud. For example, an individual who fills multiple prescriptions at multiple pharmacies is a likely fraud candidate, as is a pharmacy whose claims sharply increase in a given period of time.

With nearly 5 billion prescription drug claims processed per year, detecting and preventing FWA before a claim is paid is far superior to paying a claim and then chasing down the fraudster to pay it back, known as "pay and chase." Unfortunately, one statutory provision in Part D makes it especially difficult for Part D plans to avoid "pay and chase" scenarios: a requirement that a Part D plan pay a pharmacy within fourteen days regardless of suspicion of fraud. Even if a PBM has evidence that a fraud is occurring, as long as the claims that have been submitted are "clean," it must pay them. This is not the case in any other part of Medicare.

As with any business, PBMs rely on auditing their contracted pharmacies periodically to ensure that they are not engaged in less detectable forms of fraud—small dollar transactions or others that may seem legitimate until studied more closely. In a business that transacts nearly 5 billion claims annually, there must be unfettered ability to audit randomly and with little notice, to provide greater opportunity to detect pharmacy fraud.

PCMA believes that the National Health Care Anti-Fraud Association's (NHCAA) analysis entitled "Seven Guiding Principles for Policymakers" in fighting health care fraud underscores the efforts PBMs are making to detect and prevent fraud. At the same time, the NHCAA's analysis raises questions about legislative efforts in the 111th, and potentially 112th, Congress to reduce accountability and oversight especially of independent pharmacies.

Some policy proposals meant to help independent pharmacies inadvertently open the door to fraud, abuse, and wasteful spending. The NHCAA's white paper suggests that the following types of policies, many of them contained in recent legislative proposals, would be problematic:

Policies that require payers to partner with pharmacies that are banned from federal programs ("Any Willing Pharmacy" policies). Legislation that would force plans to include in their networks even pharmacies that have been banned from federal programs "runs counter" to preventing fraud, according to NHCAA. This low bar would allow admission for pharmacists "even if they have records of harmful prescription errors or a high number of consumer complaints."

Policies that undermine payers' ability to audit independent pharmacies suspected of fraud ("Audit Reform" policies). CMS is required by law to audit Medicare Part D plans every three years. Similarly, many pharmacy benefit managers periodically audit pharmacies that are part of their networks. In addition to random audits, PBMs typically request audits upon suspicion of fraud. NHCAA supports measures that would "protect the integrity of health care audits by giving auditors more discretion and flexibility to perform their duties." Unfortunately, legislative proposals championed by the independent drugstore lobby would instead grant pharmacies (even those with wasteful or abusive practices) substantial advance notice before they were subject to audits. PCMA supports continuing to permit PBMs and health plans to audit as needed both randomly and upon suspicion of fraud, without notice.

Policies that reduce payers' time to verify pharmacy claims before payment ("Prompt Pay" policies). PCMA believes strongly that insufficient time to investigate potential fraud before paying a claim leads to so-called "pay and chase." It is much more difficult to recover payments after the fact than to spend adequate time identifying potentially fraudulent claims and avoiding paying them. In its report, NHCAA notes that "if claims are not rushed through the payment process, auditors and investigators will have more opportunities to detect attempts at fraud before they come to fruition." So-called "prompt pay" laws in Medicare Part D that mandate rapid payment reduce the time available to detect pharmacy fraud, waste, and abuse and should be repealed. At the very least, Part D plans should be able to suspend payments when they suspect fraud, reflecting the same authority already provided in Medicare Parts A and B. What is good for one part of the program should be good for the other part.

On behalf of PCMA and our members, we look forward to working with the Committee to develop ways in which to rid the system of fraud, waste and abuse to safeguard federal government resources, while ensuring that patients maintain high access to needed medications.