S. HRG. 112–393

FIGHTING FRAUD AND WASTE IN MEDICARE AND MEDICAID

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

SPECIAL HEARING

FEBRUARY 15, 2011—WASHINGTON, DC

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FIGHTING FRAUD AND WASTE IN MEDICARE AND MEDICAID

TUESDAY, FEBRUARY 15, 2011

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Shelby, and Kirk.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies (Labor-HHS) will now come to order.

Today we will discuss the critical challenge of combating waste, fraud, and abuse in Medicare and Medicaid.

But before we begin I want to welcome Senator Richard Shelby, the distinguished ranking member of this subcommittee.

Senator Shelby is no stranger to Labor-HHS. He has been on the subcommittee since 2003. But this is his first hearing as ranking member, so it's a special day for him and for this subcommittee.

Since 1989, when I took over the chairmanship from Senator Lawton Chiles, only three people have ever served as Chair or ranking member of this subcommittee—Senator Specter, Senator Cochran and me. During that time we established a strong tradition of bipartisanship. Senator Specter and I transferred the gavel several times over the course of 20 years, but no matter who was in charge, we respected each other's views, we never surprised each other, and we treated each other as partners.

I know Senator Shelby very well. I have tremendous respect for his abilities and his interest in the subject areas that we cover here. We served together in the House for a number of years, then I came to the Senate, and then Senator Shelby came to the Senate, so we've served here together for 24 years. I count Dick and his wife Annette as two of our friends. And so, I'm confident that the longstanding spirit of cooperation will continue with Senator Shelby as ranking member and, of course, I look forward to working with you, Dick, on all the issues that come before this subcommittee.

Speaking of things that this subcommittee's been doing for a long time, we turn to the subject of today's hearing—fighting fraud and waste in Medicare and Medicaid. This subcommittee has held four

hearings over the last 10 years on Medicare and Medicaid fraud and billing discrepancies. Today, as we look for ways to reduce the deficit, the challenge has never been more urgent. When taxpayer funding for Medicare and Medicaid is wasted or stolen by criminals, it means the cost of the program goes up, and so does the pressure to cut back on benefits for the rest. We in Congress have a responsibility to do whatever we can to prevent that from happening.

There are two reasons why today's hearing is so timely. First, we have compelling new evidence that spending Federal dollars to crack down on fraud and waste in these programs is a good deal for taxpayers. Two weeks ago, Secretary Sebelius announced that efforts to prevent and root out healthcare fraud recovered—recovered—a stunning $4 billion in taxpayer dollars last year—a record high. On average, every $1 that the Federal Government spent on these efforts returned $6.80 to the U.S. Treasury—also a record high. At a time when this country is struggling with record deficits, this is a success story we should be proud of.

The second reason for the timeliness of this hearing is yesterday's release of the President's fiscal year 2012 budget, which proposes $511 million in discretionary funding for rooting out healthcare fraud and abuse. This funding is critically needed. Eighteen years after Attorney General Janet Reno announced that healthcare fraud was "the number two crime problem in America," after violent crime, we still cannot say exactly how much fraud and waste there is in healthcare. One thing everyone agrees on is that anti-fraud efforts have not begun to keep pace with the scope of the problem. That's why in fiscal year 2009 this subcommittee began appropriating funds for this effort. Until then, only mandatory funding was used to pay for these efforts. But in fiscal year 2009 this subcommittee provided $198 million to crack down on healthcare fraud. The following year, $311 million. If Congress had passed the fiscal year 2011 omnibus in December, that level would have risen to $471 million. We hope to maintain that level in the final fiscal year 2011 bill, whenever that happens.

Unfortunately, the House of Representatives seems determined to undermine these efforts. The continuing resolution they proposed last week would cut $160 million from the omnibus level for combating healthcare fraud and abuse. Again, I think that's penny wise and pound foolish budgeting. Given the return on the investment of nearly $7 for every $1 spent, that's like throwing away more than $1 billion in savings to the taxpayers.

The President's budget is more encouraging. The discretionary funding provided by this subcommittee has been essential to the Nation's efforts to reduce healthcare fraud. It's allowed the Centers for Medicare and Medicaid Services (CMS) to expand fraud and abuse detection to Medicare Advantage plans and to the prescription drug benefit. It's created strike force teams that root out perpetrators in cities that have high rates of fraud. It's helped the Department of Justice (DOJ) prevail in complex multi-State cases against criminal enterprises with deep pockets and high-priced lawyers.

PREPARED STATEMENT

Today, we'll hear from several distinguished witnesses who are integral to our programs to combat waste, fraud, and abuse. We'll hear about the partnership between CMS and the DOJ. We'll hear from a company that has helped to develop the model for the Recovery Audit Contractor (RAC) program. And we'll hear about a program that engages seniors in the fight to preserve the integrity of Medicare.

I look forward to their testimony. But first, I yield to Senator Shelby for any opening remarks that he may wish to make.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies (Labor-HHS) will now come to order.

Good morning. Today we will discuss the critical challenge of combating waste, fraud and abuse in Medicare and Medicaid. But before we begin, I want to welcome Senator Richard Shelby, the distinguished Ranking Member of this subcommittee.

Senator Shelby is no stranger to Labor-HHS—he has served on this subcommittee since 2003. But this is his first hearing as Ranking Member, so this is a special day for him—and for this subcommittee.

Since 1989, when I took over the chairmanship from Senator Lawton Chiles, only three people have ever served as Chair or Ranking Member of this subcommittee—Senator Specter, Senator Cochran, and myself. During that time, we established a strong tradition of bipartisanship. Senator Specter and I transferred the gavel several times over the course of 20 years. But no matter who was in charge, we respected each other's views. We never surprised each other. And we treated each other as partners.

I know Senator Shelby very well, and have tremendous respect for his abilities. I am confident that the long-standing spirit of cooperation will continue with Senator Shelby as Ranking Member. Senator, I look forward to working with you.

Speaking of things this subcommittee has been doing for a long time, we turn now to the topic of the day: Fighting fraud and waste in Medicare and Medicaid. This subcommittee has held four hearings over the last 10 years on Medicare and Medicaid fraud and billing discrepancies. Today, as we look for ways to reduce the deficit, this challenge has never been more urgent. When taxpayer funding for Medicare and Medicaid is wasted or stolen by criminals, it means the cost of the program goes up and so does the pressure to cut back on benefits for the rest of us. We in Congress have a responsibility to do whatever we can to prevent that from happening.

There are two reasons why today's hearing is so timely. First, we have compelling new evidence that spending Federal dollars to crack down on fraud and waste in these programs is a great deal for taxpayers.

Two weeks ago, Secretary Sebelius announced that efforts to prevent and root out healthcare fraud recovered a stunning $4 billion in taxpayer dollars last year—a record high. On average, every $1 that the Federal Government spent on these efforts returned $6.80 to the U.S. Treasury—also a record high.

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The second reason for the timeliness of this hearing is yesterday's release of the President's fiscal year 2012 budget, which proposes $511 million in discretionary funding for rooting out healthcare fraud and waste.

This funding is critically needed. Eighteen years after Attorney General Janet Reno announced that healthcare fraud was "the number two crime problem in America" after violent crime, we still cannot say exactly how much fraud and waste there is in healthcare. The one thing everyone agrees on is that anti-fraud efforts have not begun to keep pace with the scope of the problem. Some have compared our fraud detection efforts to standing in a lake with a bucket—the bucket looks really full, until you look at the lake.

That's why, in fiscal year 2009, this subcommittee began appropriating funds for fraud prevention and enforcement. Until then, only mandatory funding was used to pay for these efforts. But in fiscal year 2009, this subcommittee provided $198 million to crack down on healthcare fraud, and the following year, $311 million. If Congress had passed the fiscal year 2011 omnibus in December, that level would have

risen to $471 million. We hope to maintain that level in the final fiscal year 2011 bill whenever it is completed.

Unfortunately, House Republicans seem determined to undermine these efforts. The continuing resolution they proposed last week would cut $160 million from the omnibus level for combating healthcare fraud and abuse. That is a classic case of penny wise pound-foolish budgeting. Given the return on investment of nearly $7 for every $1 spent, that's like throwing away more than $1 billion.

However, the President's proposed increase, to $511 million, is encouraging. The discretionary funding provided by this subcommittee has been essential to the Nation's efforts to reduce healthcare fraud. It has allowed Centers for Medicare & Medicaid Services to expand fraud and abuse detection to Medicare Advantage plans and to the prescription drug benefit. It has created strike force teams that root out perpetrators in cities that have high rates of fraud. It has helped the Department of Justice to prevail in complex, multi-State cases against criminal enterprises with deep pockets and high-priced lawyers.

Today we will hear from several distinguished witnesses who are integral to our programs to combat waste, fraud, and abuse. We will hear about the partnership between the Centers for Medicare and Medicaid Services and the Department of Justice. We will hear from a company that has helped to develop the model for the Recovery Audit Contractor program, which the Obama administration hopes to expand Government-wide. And we will hear about a program that engages seniors in the fight to preserve the integrity of Medicare.

I look forward to their testimony. But first, I yield to Senator Shelby for any opening remarks he may wish to make.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman. I'm glad to join you here as, you, the chairman of the subcommittee, and this is my first day as ranking member. I look forward to working with you. We know we have some difficult issues and difficult days ahead. But we've been together on a number of things. As you mentioned, we served in the House and the Senate, and we served on the Appropriations Committee together for a long time. So, we understand the impediments from time to time.

Mr. Chairman, I want to thank you especially for calling this hearing to discuss how the Department of Health and Human Services (HHS) and the DOJ fights fraud and waste in Medicare and Medicaid.

We have a distinguished panel, as you mentioned, and I look forward to hearing their testimony. But before, I have a few opening statements.

This is my first hearing, as I've said, as ranking member of the Labor-HHS Subcommittee, as the ranking member, and I'm honored to be here with you.

The total Medicare expenditures were $509 billion in 2009, and because of an aging population and overall increases in medical costs, expenditures are projected to increase in future years at a faster pace than our economy. The Medicare trust fund is estimated to be exhausted in 2029. The financial outlook for the Medicare program continues to raise serious concerns. And yet, fraud analysts and law enforcement officials estimate that between 3 percent and 10 percent of total healthcare expenditures are lost to fraud on an annual basis. That's a lot of money. We must do more to protect the program's scarce resources.

As Medicare and Medicaid have grown, they have increasingly become a target for fraudulent activity. As the inspector general of HHS testified before the House Energy and Commerce Health Subcommittee in 2009, healthcare fraud has become attractive to perpetrators of organized crime because the penalties are lower than

for other organized crime-related offenses. There are low barriers to entry. Fraud schemes are easily replicated. And a lack of data hampers detection efforts.

I believe we must preserve, Mr. Chairman, the integrity of the Medicare and Medicaid programs. Medicare fraud and abuse affects every person who struggles to pay for healthcare benefits, every person who worries about Medicare's ability to cover them, and every taxpayer who helps fund these programs.

Healthcare frauds in my State of Alabama recoveries in 2009 were $26 million and more than $1 million in 2010. The collaborative effort between the Attorney General's office of the DOJ and the Secretary of HHS has successfully identified and prosecuted egregious instances of healthcare fraud and put money back in the proper hands.

I look forward, Mr. Chairman, to working with you and the staff to prevent further fraud and abuse and to protect these important healthcare programs. And I thank you for calling this hearing.

Senator HARKIN. Thank you very much, Senator Shelby. I look forward to working with you, as you said we have for so many years together in both the House and the Senate.

We now turn to our panel. We welcome first Dr. Peter Budetti. He serves as the Deputy Administrator of the CMS and the Director of the CMS Center for Program Integrity.

A board-certified pediatrician, Dr. Budetti earned his medical degree from Columbia University, law degree from the University of California, and undergraduate degree from the University of Notre Dame.

Mr. Tony West was confirmed Assistant Attorney General for the Civil Division of the DOJ in April 2009, having previously served numerous posts in California for the DOJ and being a partner at Morrison & Foerster, LLP. He graduated with honors from Harvard College and received his law degree from Stanford Law School, where he was elected president of the Stanford Law Review.

So, we welcome you both here. Your statements will be made a part of the record in their entirety.

We'll start with you, Dr. Budetti, and then we'll go to Mr. West. If you could sum up your testimony in several minutes, we'd appreciate that. So, please proceed, Mr. Budetti. Thank you.

STATEMENT OF DR. PETER BUDETTI, CENTER FOR PROGRAM INTEGRITY CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, BALTIMORE, MARYLAND

Dr. BUDETTI. Good morning. And thank you, Chairman Harkin and Ranking Member Shelby, and welcome—your first day as ranking member. I appreciate being here at that point.

Thank you for this invitation to discuss CMS' efforts to reduce fraud, waste, and abuse in the Medicare, Medicaid and Children's Health Insurance Program, and the new tools provided and authorities provided under the Affordable Care Act. And I'm particularly glad to be here with my distinguished colleague and partner in fighting fraud, Assistant Attorney General Tony West.

I've had the privilege now of leading the Center for Program Integrity for a little more than 1 year, and from the first day that

I took my position, I've been asked two questions practically every day. Number 1, why do you let crooks into the programs? Number 2, why do you pay their claims when they're fraudulent?

Well, I'm pleased to be able to tell you that with the support that's provided by this subcommittee, and the new authorities and support that was provided under the Affordable Care Act, we're making progress on both fronts. We're in a position now to keep the bad guys out of the programs when they try to get in, to kick them out when they are in, and to stop payments when we believe that they present an allegation of fraud.

CMS now has the flexibility to tailor our resources to the actual risks that we're facing, and to target the most serious problems on the basis of the actual risk that we're seeing, and to do this in a transformative way that's really different than we have done in the past.

The program management and discretionary funds provided under the Health Care Fraud and Abuse Control (HCFAC) Program by this subcommittee are of vital importance in making it possible for us to implement the new initiatives necessary to get the full benefit of the Affordable Care Act provisions.

CMS has taken a number of administrative steps to better meet the emerging needs and challenges in fighting fraud and abuse. CMS consolidated the Medicare and Medicaid Integrity Programs under the unified Center for Program Integrity, which I now lead, precisely in order to pursue a more coordinated set of program integrity policies and activities across both Medicare and Medicaid. This change has also facilitated our collaboration on anti-fraud initiatives with our law enforcement partners both in the DOJ and the Department of HHS's Office of Inspector General. The Affordable Care Act enhances this organizational change by providing us with an opportunity to jointly develop Medicare, Medicaid, and CHIP policies on these new authorities.

A number of the Affordable Care Act provisions apply equally to both Medicare and Medicaid, and this ensures better consistency in our approach to fraud prevention across all of our programs.

One point bears stressing, which is that as we crack down on those who would commit fraud, we are mindful of the necessity to be fair to all of the legitimate providers and suppliers who are our partners in caring for beneficiaries, and to protect beneficiary access to necessary healthcare services. This requires striking the right balance between preventing fraud and other improper payments without impeding the delivery of critical services to beneficiaries. That's what our programs are all about—delivering healthcare to people in need of those services. And, as both of you remarked, any dollar that is wasted, deprives those people of those services. CMS is committed to providing the healthcare services while cracking down on fraud and abuse.

The implementation of the Affordable Care Act provisions, as well as other fraud efforts, will require ongoing resources to succeed. I'm particularly grateful for the continuing support this subcommittee has provided to the HCFAC Program, which provides the critical resources necessary to fight fraud. To continue the administration's focus on fraud prevention, the President's fiscal year budget released yesterday includes a program integrity legislative

package that will save $32.3 billion over 10 years, as well as the requested $270 million increase in HCFAC Program funding. The proposed increase would allow us to build on the recent successes, which just reported the highest return on investment in history in fiscal year 2010.

The discretionary HCFAC resources that this subcommittee has appropriated the last 2 years are essential to the success of our program integrity efforts. These funds pay for a variety of new, innovative fraud detection and prevention activities. Without these additional discretionary funds, CMS would be left with its mandatory base funding, forcing us to remain primarily in what we've always called a pay-and-chase mode, rather than moving toward the prevention of fraud in the first place.

Let me highlight a couple of the new and pioneering activities that will be funded with the additional discretionary funds. This will allow for the expansion of the Health Care Fraud Prevention and Enforcement Action Team initiative, the joint Cabinet-level effort established by the President and led by Secretary Sebelius and Attorney General Holder, and will allow the expansion of the Strike Forces to as many as 20 areas.

The funding that you have provided has helped fund a number of successful program integrity activities, including the development of prepay automatic, automated edits that deny claims on the front end—and that's an integral part of our new initiative to prevent fraud in the first place. Additionally, the funds have supported the National and Regional Fraud Prevention Summits that have raised awareness of the risks of fraud, waste, and abuse in the Medicare and Medicaid programs.

A major new initiative, which is what this poster is all about, is our work to implement an innovative risk-scoring technology that applies effective predictive models to identify complex patterns of fraud and improper claims and billing schemes, and trigger effective, timely administrative actions by CMS, and timely referral to law enforcement. Given the changing landscape of healthcare fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as they appear.

This just diagrams the fact that we will be developing these systems and implementing them, on the basis of the actual risk presented by a particular problem that we're seeing, into our payment system, in order to avoid making those payments in the first place.

One other point I would mention is that I'm particularly pleased that we continue to work with, and rely on, our beneficiaries through the Senior Medicare Patrol (SMP) program led by the Administration on Aging. And I know you will be hearing from the SMP program a little later on. We have partnered with the SMP program to expand their activities and to get more Medicare beneficiaries involved in, and aware of, the problems of fraud and the need to participate in fighting fraud and preventing it.

In conclusion, healthcare fraud and improper payments undermine the integrity of Federal healthcare programs. Taxpayer dollars lost to fraud, waste, and abuse harm some of our most vulnerable seniors and other people in this country, not just the Federal Government. Eliminating the problem requires the long-term, sustained commitment that brings together beneficiaries, healthcare

providers, the private sector, Federal, State and local governments and law enforcement agencies in a collaborative partnership to develop and implement long-term solutions. The administration's made a firm commitment to rein in fraud and wasteful spending. With the Affordable Care Act and the financial support from this subcommittee, we have more tools than ever before to implement important and strategic changes.

PREPARED STATEMENT

We thank the Congress for providing us with these new authorities and resources, and we look forward to working with you in the future as we continue to make improvements in protecting the integrity of Federal healthcare programs and safeguarding taxpayer resources.

Thank you very much for this opportunity to speak to you.

Senator HARKIN. Dr. Budetti, thank you very much, Dr. Budetti.

[The statement follows:]

PREPARED STATEMENT OF PETER BUDETTI

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, 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 healthcare 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 Medicare, Medicaid, or CHIP. 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 healthcare 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 healthcare programs, we are mindful of the necessity to be fair to healthcare providers and suppliers, who are our partners in caring for beneficiaries, and to protect beneficiary access to necessary healthcare services, supplies or medication. CMS is committed to improving care for our beneficiaries; engaging States and law-abiding providers and suppliers to ensure our activities reflect their interests is a foundation of our program integrity work. 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 healthcare services to beneficiaries. At their core, Federal healthcare programs are designed to provide affordable healthcare to families in need, people with disabilities, and aging Americans. Additionally, the vast majority of healthcare providers are honest people who abide by their legal and professional duties and provide critical healthcare services to millions of CMS beneficiaries every day. CMS is committed to providing healthcare 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 healthcare programs. While improper payments are not necessarily fraudulent, 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 re-examining our claims 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 involves many different activities, which we are carrying out with the powerful new antifraud 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 payment and provider and supplier 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 healthcare programs is to appropriately screen providers and suppliers who are enrolling or revalidating their enrollment in Medicare, Medicaid, and CHIP to verify that only legitimate providers and suppliers who meet our stringent enrollment standards are providing care to our 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 healthcare 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.—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 suppliers. CMS has also established certain triggers that would move a provider or supplier into the highest screening level, including exclusions by the OIG or other final adverse actions.

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 simi-

lar 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 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 withheld from providers or suppliers if there is a credible allegation of fraud pending an investigation or final action. The law also requires States to withhold 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 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, which will be used along with additional discretionary funding sought in the President's budget request to place more "feet on the street" by hiring more law enforcement agents and other efforts to reduce improper payments and fight fraud in the healthcare 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 healthcare 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 most Medicare-covered items and services for Medicare beneficiaries be enrolled in Medicare. In addition, it adds requirements for providers, physicians, and other suppliers participating in the Medicare program to provide and maintain documentation on referrals to for items or services at high risk of fraud, waste, and abuse. Specifically, it includes suppliers of 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 certain other providers of services and supplies. These surety bonds are a condition of enrollment and help ensure that DMEPOS suppliers and home health agencies, and 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 its items and services to non-Medicare beneficiaries.

Expanded Use of Recovery Audit Contractors

CMS is drawing from the lessons learned from the Fee-For-Service (FFS) Recovery Audit 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, managed care Medicare, the part D drug benefit and Medicaid, CMS has taken a multi-pronged approach to implement 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 strat-

egies 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 Recovery Audit Contractors (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 their recovery audits with other entities to minimize the likelihood of overlapping audits. CMS is working with States to implement this program and plans to disseminate information on how States are utilizing RACs in the Medicaid program.

Increased Flexibility in Medicaid Recovery Rules

Further, 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. Under this new authority, States now have up to 1 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 1 year of discovery, the State has until 30 days 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 Self-Referral Disclosure Protocol on its Web site to enable providers and suppliers to disclose actual or potential violations of the physician self-referral statute. Section 1877 of the Social Security Act 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 penalty otherwise owed for a violation of the physician self-referral statute. The protocol states the factors CMS may consider in reducing the amounts otherwise owed, which include: (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. This new process reflects CMS' goal to be transparent to the public about program requirements and compliance.

Fraud Detection and Reporting

CMS has improved the processes for fraud detection by our contractors and 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 Program Safeguard Contractors (PSCs) and 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 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 contracting and better identify potentially fraudulent behavior across all parts of the Medicare program.

Another of these improvements involves modifications to the 1–800–MEDICARE call center procedures. In the past, if a caller reported that they did not recognize a physician or provider or did not receive the service documented on their Medicare Summary Notice form, they were asked to followup with the provider prior to filing a fraud complaint. However, now 1–800–MEDICARE will review the patient's claims records with them and if the discrepancy is not resolved, it 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' com-

plaints in new ways. For instance, CMS is generating weekly "fraud complaint frequency analysis reports" that compile provider-specific complaints and flags providers who have been the subject of multiple fraud complaints for a closer review. This is just one example of using 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.

THE HEALTHCARE FRAUD AND ABUSE CONTROL (HCFAC) PROGRAM

HCFAC Funding

I appreciate this subcommittee's long-time support of the HCFAC program and CMS' administrative budget requests, which provide the critical resources CMS uses to pay claims accurately and fight fraud.

The fiscal year 2011 President's budget request includes a little more than $1.7 billion for the HCFAC program, including mandatory and discretionary sources, divided between CMS' Medicare and Medicaid programs and our law enforcement partners at the OIG and DOJ. The fiscal year 2011 discretionary HCFAC request is $561 million, a $250 million increase over the fiscal year 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 Strike Force to as many as 20 areas with ongoing and emerging fraud threats. Further, if provided by Congress, discretionary HCFAC funding would also support ongoing efforts to strengthen audit and oversight activity in Medicare parts C and D, expand data sharing and coordination between DOJ and CMS, increase data capabilities and targeted special demonstrations to identify fraudulent schemes and practices before they take root, and eliminate systemic vulnerabilities being exploited by fraudulent providers and suppliers.

To help implement the new prevention tools and legislative authorities in the Affordable Care Act, the legislation provided $350 million in mandatory funding over 10 years, plus an inflation adjustment, for the HCFAC account, the Medicare Integrity Program, and the Medicaid Integrity Program. This funding provides important financial resources for the HCFAC program over the next decade and, combined with our discretionary funding request, will enable us to pursue critical new prevention focused activities and address emerging healthcare fraud schemes. In fiscal year 2010, CMS was allocated approximately $16.5 million by HHS in HCFAC Wedge funds and $251.4 million in discretionary funds to support a variety of projects related to fraud, waste, and abuse in the Medicare and Medicaid programs. CMS invested $158 million of the discretionary funds in strengthening Medicare parts C and D oversight by aligning the functions of the Medicare Drug Integrity Contractors (MEDICs) with specific contracting functions of compliance and enforcement and benefit integrity, plan performance assessment, audits of programs and vulnerability analysis of policy and operational processes. HCFAC funds were also used to develop and validate prepay automated fraud edits that deny claims on the front end. Additionally, these funds have supported the National and Regional Fraud Summits (discussed below) and fraud prevention media campaign that have raised awareness of the risks of fraud, waste and abuse, as well as educated key stakeholders, including beneficiaries, how to prevent, identify and report fraud. In the Medicaid program, HCFAC resources have supported enhanced audits and payment error rate measurement efforts.

HCFAC Program Successes

HCFAC has been steadily growing since it began in 1997 and, as shown in the recently released fiscal year 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 fiscal year 2010, HCFAC has resulted in the return of $18 billion to the Medicare trust funds. In fiscal year 2010, $2.8 billion was returned to the Medicare Trust Funds and $683 million was returned to the Federal Treasury from Medicaid recoveries. The return-on-investment (ROI) from various HCFAC activities ranges from 6 to 1 for audit, investigative, and prosecu-

torial work performed by OIG and DOJ to 14 to 1 for the Medicare Integrity Program's activities. The HCFAC return-on-investment (ROI) is currently the highest it has ever been, according to the fiscal year 2010 HCFAC report. The 3-year average for ROI (2008–2010) 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 Strike Forces*.—This coordinated effort is needed in order to fight fraud on the ground, by supporting field offices in high risk regions of the country that will protect seniors and recover funds stolen from the Medicare Trust Fund.

—*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 healthcare fraud investigations and prosecutions, particularly related to emerging fraud schemes in areas such as pharmaceutical services, medical devices, and durable medical equipment. 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 Agency on Aging (AoA), empowers seniors to identify and fight fraud through increased awareness and understanding of Federal healthcare 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 more than 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 Web site, 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 healthcare 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. HEAT consolidated the anti-fraud efforts of DOJ's Civil Division and U.S. Attorneys' Offices, 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.

In the 3½ years since their inception, Strike Force prosecutors filed 465 cases charging 829 defendants who collectively billed the Medicare program more than $1.9 billion; 481 defendants pleaded guilty and 48 others were convicted in jury trials; and 358 defendants were sentenced to imprisonment for an average term of nearly 44 months.[1]

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 healthcare fraud prevention, bringing together Federal and State officials, law enforcement experts, private insurers, healthcare providers, and beneficiaries for a comprehensive discussion on the scope of fraud, weaknesses in the current healthcare system, and opportunities for collaborative solutions.

Building on the momentum generated by the National Health Care Fraud Summit in January 2010, regional healthcare 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 three additional cities, brought together Federal and State officials, law enforcement experts, private insurers, beneficiaries, caregivers, and healthcare providers to discuss innovative ways to eliminate fraud within the Nation's healthcare system. These summits also featured educational panels that discussed best practices for providers, beneficiaries and law enforcement in preventing healthcare 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 5 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 healthcare 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 combina-

[1] These statistics are for the period of May 7, 2007 through September 30, 2010.

tion 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. 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 healthcare 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.

The Small Business Jobs and Credit Act of 2010 provided $100 million, beginning in fiscal year 2011 to phase-in the implementation of predictive analytics in Medicare FFS, Medicaid, and CHIP over 4 years. The new predictive modeling technology will incorporate lessons learned through pilot projects. For example, 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 10 years. Outside of DMEPOS, CMS is working to redesign our Medicare payment systems and institute delivery system reforms that will realign Medicare payments in line with market prices and in turn, 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

Healthcare fraud and improper payments undermine the integrity of Federal healthcare 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, healthcare providers, the private sector, and Fed-

eral, 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 healthcare 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 healthcare programs and safeguarding taxpayer resources.

Senator HARKIN. And how we turn to Mr. West.

Mr. West, please proceed.

STATEMENT OF HON. TONY WEST, ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, DEPARTMENT OF JUSTICE

Mr. WEST. Thank you, Mr. Chairman.

And Ranking Member Shelby, it's a privilege to welcome you on your first day and to address you to talk about the work that we're doing at the DOJ and in the Civil Division and, in collaboration with HHS, to combat healthcare fraud and recover taxpayer dollars on behalf of the American people.

And let me say it is always a pleasure to be able to be with my good colleague Dr. Budetti from CMS.

As this subcommittee knows, the Civil Division represents the United States in a whole range of litigation. As the Department's largest litigating component, we defend Congress and the executive branch against challenges in court, and the cases that we handle touch upon nearly every aspect of Government operations, as well as this administration's national security, domestic, and foreign policy objectives. And central to our mission is the recovery of taxpayer dollars which are lost through fraud. Nowhere is this more evident than in the Civil Division's efforts to fight fraud perpetrated against our own public healthcare programs.

When I appeared before the Senate Judiciary Committee less than a month ago, I reiterated then something that I have said many times since assuming my role as head of the Civil Division, and that is, we in the DOJ have recognized the urgency posed by healthcare fraud—that it's not only something that costs taxpayers millions of dollars, but also undermines the quality, integrity, and safety of patient care. And our efforts to curb healthcare fraud have paid off.

DOJ has never been more aggressive nor more successful in the anti-fraud battle than it has been in the last 2 years. Indeed, since January 2009 the Civil Division has, working with our U.S. Attorney partners throughout the country, opened more healthcare fraud matters, secured larger fines and judgments, negotiated higher settlements, and recovered more than $8.5 billion for the taxpayers in healthcare fraud cases. This is a record, representing more healthcare fraud monies recovered in any 2-year period than in any other time in the history of the DOJ.

And the cases that we work on, that comprise that record-breaking amount, span the broad spectrum of healthcare fraud, from sophisticated illegal over-billing schemes, to individual doctors who

endanger the lives of those in their care just to bump up their Medicaid reimbursements.

Now, we know that most healthcare providers, most companies, most individuals who are doing business with the Government when it comes to providing healthcare services, we know that they are dealing fairly, that they are playing by the rules, and that they are careful with the taxpayer dollars that they receive. They are trying to do the right thing.

But we've also found that it is the case at times that there are those who attempt to cut corners, to take advantage and put profits over patient safety. And those companies and individuals, I submit to you, are those who attract our enforcement attention.

Now, the historic recoveries that we've been able to achieve in the fight against healthcare fraud have not happened by accident. It's what happens when we maximize the efficient use of resources and we combine that with the data sharing, enhanced collaboration, and cooperative strategizing that has occurred since we formed this collaboration between HHS and the DOJ—also known as HEAT—the Health Care Fraud Prevention and Enforcement Action Team. That commitment has resulted, Mr. Chairman, as you noted, in a record amount of civil, criminal and administrative recoveries of more than $4 billion in the last fiscal year, fiscal year 2010. That's $4 billion that has been returned to the Medicare Trust Fund, victim agencies, and others in that last fiscal year. And that success also demonstrates the impact that we can have when we invest in our anti-fraud law enforcement efforts, as the President proposes to do in his budget announced yesterday.

We've already seen what additional resources devoted to fighting healthcare fraud can produce. In fact, the 3-year rolling average return on investment, something else you noted, Mr. Chairman, is $6.80. That's nearly $7 for every $1 we spend on healthcare enforcement efforts. And given that these are complex, difficult cases that are often resource-intensive—they take years to investigate and pursue, requiring the interviews of countless witnesses, the review of millions of documents, and the hiring of scores of consultants and experts—the money that we spend on healthcare fraud enforcement is one of the best investments we make as taxpayers.

PREPARED STATEMENT

Mr. Chairman, my written testimony outlines in more detail some of the things that we are doing at the DOJ to fight healthcare fraud, and I look forward to working with you, with Ranking Member Shelby, and the members of this subcommittee, as we continue to tackle the challenges posed by fraud on the American taxpayers. I thank you so much for the opportunity to be here. And I'm happy to answer any questions you might have.

[The statement follows:]

PREPARED STATEMENT OF TONY WEST

Chairman Harkin, Senator Shelby, and members of the subcommittee: I am honored to appear before you today on behalf of the Department of Justice (DOJ) and I appreciate the opportunity to discuss the work of the Civil Division to combat fraud and secure the recovery of monies on behalf of American taxpayers. I also am pleased to be here today with our valued partner in these enforcement efforts, Dep-

uty Administrator Peter Budetti from the Centers for Medicare & Medicaid Services.

The Civil Division represents the United States, its agencies and instrumentalities, Members of Congress, Cabinet officers, and other Federal employees. The Division is made up of approximately 1,400 permanent employees, more than 1,000 of whom are attorneys. Each year, Division attorneys handle thousands of cases that collectively involve billions of dollars in claims and recoveries. In my capacity as Assistant Attorney General, I oversee much of the Federal Government's civil litigation across the country, including many of the DOJ's efforts to protect consumers and recapture billions of taxpayer dollars lost to fraud, such as healthcare fraud, procurement fraud, and mortgage fraud.

OVERVIEW OF COMBATING FRAUD AND SECURING

Recoveries on Behalf of American Taxpayers

The DOJ takes seriously its obligation to guard the United States Treasury. Over the last year, the DOJ has made significant strides in protecting taxpayer dollars—as well as the integrity of Government programs that depend on those dollars—through aggressive civil enforcement actions aimed at rooting out waste, fraud, and abuse. For fiscal year 2010, the Civil Division, working with our partners in United States Attorneys' offices throughout the country, secured $3 billion in civil settlements and judgments in cases involving fraud against the Government. Our primary tool in these fraud enforcement matters is the False Claims Act, which requires that wrongdoers repay the Government three times the amount of their false or fraudulent claims and also imposes significant penalties. Although the False Claims Act dates back to the Civil War, it has been significantly strengthened in recent years to enhance its whistleblower provisions and to strengthen the Government's ability to recover taxpayer dollars. I am glad to say that amounts recovered under the False Claims Act since January 2009 have eclipsed any previous 2-year period, with $7 billion in taxpayer dollars returned to the Medicare Trust Fund, the Treasury, and others since 1986, when Congress substantially strengthened the civil False Claims Act, now total nearly $29 billion. These matters have consisted of fraud against a variety of Federal agencies and programs. Our most significant recoveries, however, have been those alleging fraud and false claims schemes perpetrated against Government healthcare programs, most notably the Medicare and Medicaid programs. It is this area to which I will devote the remainder of my testimony today.

HEALTHCARE FRAUD RECOVERIES

Fighting fraud committed against public healthcare programs is a top priority for the administration. On May 20, 2009, Attorney General Eric Holder and Secretary of the Department of Health and Human Services (HHS) Kathleen Sebelius, announced the creation of a new interagency task force, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), to elevate coordination in these matters to the Cabinet level and to optimize criminal and civil enforcement. These efforts not only protect the Medicare Trust Fund for seniors and the Medicaid program for the country's neediest citizens, they also help to maintain the integrity of services and to prevent the costs of fraud from being passed on to patients and taxpayers. The evils of healthcare fraud are many: it undermines the judgment of healthcare professionals, deprives people of the treatment that they need, and, in some cases, can put patients' health and safety at risk.

The high-level, inter-agency collaboration made possible by HEAT has led to extraordinary results. Since January 2009, the Civil Division, working with HHS, our partners in U.S. Attorneys' offices around the country, and our State and Federal colleagues, has opened more healthcare fraud cases, secured larger fines and judgments, and recovered more than $8.5 billion for the taxpayers in healthcare fraud cases—more than in any other 2-year period. That total includes more than $5.54 billion in taxpayer funds recovered from healthcare providers and others in the industry under the False Claims Act—another 2-year record. In fiscal year 2010, the DOJ secured $2.5 billion in civil healthcare fraud recoveries—the largest single-year recovery in the DOJ's history.

Violations of the Food, Drug and Cosmetic Act (FDCA) are pursued by the Civil Division's Office of Consumer Protection Litigation (OCPL), which is authorized to bring both civil and criminal actions for violations of that statute. Together with our partners in the United States Attorneys' offices around the country, OCPL pursues the unlawful marketing of drugs and devices, fraud on the Food and Drug administration, and the distribution of adulterated products, among other violations. Since January 2009, the DOJ has secured more than $3.3 billion in fines, forfeitures, res-

titution, and disgorgement under the FDCA and we have convicted 28 defendants in criminal cases. In fiscal year 2010, our efforts yielded more than $1.8 billion in criminal fines, forfeitures, restitution, and disgorgement—the largest healthcare-related amount under the FDCA in a single year in the DOJ's history.

A significant component of the DOJ's healthcare fraud caseload consists of cases that allege misconduct by manufacturers of pharmaceutical and device products. For example, in December of last year, we announced settlements totaling more than $700 million with multiple pharmaceutical manufacturers resolving allegations that they had engaged in a scheme to report false and inflated prices for many of their pharmaceutical products, knowing that Federal healthcare programs such as Medicare and Medicaid relied on those reported prices to set payment rates. In April of last year, we obtained a $520 million settlement with AstraZeneca LP and AstraZeneca Pharmaceuticals LP to resolve allegations that the marketing of the anti-psychotic drug Seroquel for uses that were not "medically accepted indications" and therefore, not covered by Medicare and State Medicaid programs which caused false claims to be submitted to Federal healthcare programs. In 2009, the DOJ announced the largest healthcare fraud settlement in its history in a case that arose from Pfizer's illegal promotion of several pharmaceutical products. Pfizer pled guilty to misbranding the painkiller Bextra in violation of the FDCA and agreed to pay $2.3 billion in fines and civil recoveries. Last October, a subsidiary of GlaxoSmithKline pled guilty to violating the FDCA and the company paid fines and civil recoveries totaling $750 million to resolve allegations that it manufactured and distributed certain adulterated drugs made at its now-closed plant in Cidra, Puerto Rico.

Healthcare fraud that affects the health, safety, and well-being of Medicare and Medicaid beneficiaries is of paramount concern to the DOJ. In January 2010, the DOJ negotiated a $24 million settlement to resolve allegations that a national chain of Small Smiles dental clinics was providing unnecessary dental services to children on Medicaid in order to maximize the company's Medicaid reimbursements. The services included unnecessary tooth extractions that resulted in healthy teeth being pulled and needless crowns and excessive root canals for baby teeth.

The DOJ also leads an Elder Justice and Nursing Home Working Group, which focuses on healthcare fraud involving elderly patients, such as when a skilled nursing facility bills Medicare or Medicaid for grossly deficient services. Such conduct not only wastes taxpayer dollars, but also threatens the health of some of our most vulnerable citizens. Last year, the DOJ announced criminal pleas and civil recoveries arising from our investigation of five nursing homes operated by Cathedral Rock, a Texas corporation, and its chief executive officer. Our investigation found that these homes were staffed inadequately, that residents often did not receive their medications as prescribed, and that medical records were falsified to appear that the medications were given properly. The resolution of this case required that the homes institute a rigorous compliance program to ensure that this conduct is not repeated. Earlier this year, I personally launched a training program that involved more than 50 attorneys and investigators intended to hone their skills in this difficult enforcement area. This training is part of our emphasis in ensuring that our most vulnerable citizens receive the care for which Medicare and Medicaid pay.

Finally, I should note that most of the cases resulting in recoveries were brought to the Government by whistleblowers under the False Claims Act. In 1986, Congress amended the False Claims Act to revise the statute's qui tam (or whistleblower) provisions, which encourage whistleblowers to come forward with allegations of fraud. The changes enacted in 1986 made the record-setting recoveries of last year possible, and they also resulted in an increase of the number of qui tam complaints filed with the DOJ from a total of 30 in fiscal year 1987 to 574 in fiscal year 2010—an increase of more than 1,800 percent. Indeed, just last year there was an increase in qui tam filings from the previous year of more than 32 percent—from a total of 443 qui tam actions filed in fiscal year 2009 to 574 filed in fiscal year 2010. In the last 3 years, the number of these filings greatly contributed to our current caseload of pending matters. The False Claims Act requires the Attorney General to diligently investigate each one of these qui tam matters when they are filed and to obtain the court's consent to extensions of time to do so. We are now confronted with increasingly complex allegations that often implicate multiple defendants, and investigating these allegations in a limited timeframe is extremely challenging. This requires that we dedicate more resources to fully and effectively investigate our growing caseload.

In order to properly investigate these matters and prevail in any ensuing litigation, the Government is forced to expend considerable sums. A typical fraud case requires that we review massive amounts of documentation, interview countless witnesses, hire consultants to assist us in areas where we may lack in-house expertise,

and engage experts who can testify for the Government if the matter proceeds to trial. We must also develop databases to organize the documents and assist us in analyzing them. The Government's continuing obligation to preserve documents necessary for fraud litigation often requires agencies, most notably HHS in healthcare investigations, to incur additional expenses as they suspend routine document preservation policies. Agencies such as HHS incur costs to provide their personnel as witnesses for depositions or trial and to produce reams upon reams of material requested by the other side during discovery. Once we have completed our investigation and allege fraud in a lawsuit, well-funded defendants are often able to mount a costly defense that includes teams of lawyers far in excess of the number we are able to devote to any particular case. They also are able to engage sophisticated (and costly) expertise to bolster their defenses, including state-of-the-art technology to manage and present extensive evidence. While we cannot match those costs dollar-for-dollar, and indeed often spend only a fraction of the amount our defense counterparts spend, we nevertheless have an obligation to pursue these matters with sufficient resources that permit us to maximize the potential for a recovery on behalf of the taxpayer.

FISCAL YEAR 2010 HEALTHCARE FRAUD AND ABUSE

Control Program Report

Thus far, I have spoken of the efforts of the Civil Division and our partners in the United States Attorney community. However, HEAT has drawn together various other components of the DOJ, such as the Criminal Division, U.S. Attorneys' offices, the Federal Bureau of Investigation (FBI), and those of HHS to produce record-breaking results. The Medicare Fraud Strike Force (Strike Force)—launched in 2007 and part of HEAT—is a recent example of the collaborative efforts now used to further combat healthcare fraud. The Strike Force is now operating in seven locations across the country and has successfully indicted hundreds of individuals and obtained substantial prison terms. In fiscal year 2010 alone, the Strike Force filed 140 indictments involving charges against 284 defendants who collectively billed the Medicare program more than $590 million.

For example, in one of the largest Medicare Fraud Strike force cases ever brought, Assistant Attorney General Lanny Breuer and I announced the unsealing of parallel criminal and civil enforcement actions against two Miami healthcare companies, American Therapeutic Corporation (ATC) and Medlink Professional Management Group, Inc., as well as ATC's owner and other senior executives in October 2010. The ATC prosecution, which alleges a $200 million fraud scheme against Medicare for purported mental health services, is the first Strike Force case that indicted a corporation and reflects the important coordination that is occurring between the DOJ's Criminal and Civil Divisions to hold fraudsters accountable who are stealing taxpayer dollars.

Last month, the DOJ and HHS issued their annual Health Care Fraud and Abuse Control Program Report—the HCFAC Report—for fiscal year 2010. The report reflected historic accomplishments in fiscal year 2010, including the fact that our collective efforts returned more than $4 billion in healthcare fraud resources to the Medicare Trust Fund, victim programs, and others. This amount, consisting not only of our civil recoveries under the False Claims Act, but also criminal fines, civil monetary penalties and administrative recoveries, was the largest in the history of our collective efforts and was made possible in large part by funding provided by Congress through the HCFAC program. In addition to the monetary results mentioned above, the report also noted that the DOJ opened 1,116 new criminal healthcare fraud cases involving 2,095 potential defendants. The DOJ filed criminal charges in 488 cases involving 931 defendants, and a total of 726 defendants were convicted for healthcare fraud-related crimes during the year. This represents the highest number of defendants charged and convicted in a single year in the history of the HCFAC program.

In 1996, Congress required the establishment of the HCFAC program under the joint direction of the Attorney General and HHS, acting through HHS's Inspector General, to coordinate Federal, State, and local law enforcement activities with respect to healthcare fraud and abuse. Since its inception, the funds expended by HCFAC to provide oversight of the Nation's healthcare expenditures have been dwarfed by the amounts returned to the Medicare Trust Fund as a result of those oversight efforts—more than $18 billion from 1997 through the end of fiscal year 2010. Historically, the average return on investment (ROI) for the HCFAC program has been 4.90:1. That is, for every $1 spent by HCFAC to fund enforcement efforts, $4.90 is collected. In fiscal year 2010, the 3-year average ROI was $6.80 collected for every $1 expended—an increase of almost $2 more than the historical average.

Results such as these show the cost effectiveness of the HCFAC program and highlight the importance of additional investigative and prosecutorial resources. Of course, we also cannot lose sight of the fact that these efforts not only return money to the various healthcare programs, they also provide an effective and incalculable deterrence to those who would otherwise cheat the Nation's most vulnerable citizens, such as our elders and our disabled, who rely on these programs for their vital healthcare. HCFAC has been a resounding success in both regards and it is crucial to our continued success that we not only maintain our HCFAC resources, but that they grow to keep pace with increased Government health expenditures and the growing caseload of qui tam matters.

As we move forward with the tough choices necessary to rein in our deficit and put the country on a sustainable fiscal path, we must balance those efforts with the investments and actions necessary to provide adequate oversight of such investments to ensure they are properly used for their intended purposes. The HCFAC program is one such investment that pays for itself many times over. With the discretionary resources sought in the President's fiscal year 2012 budget request, we can hire additional criminal prosecutors, civil attorneys, agents and professional support personnel who will help identify and seek redress for future fraud schemes. These funds also enable us to adequately support our investigations and litigation with the expertise and automated litigation support necessary to bring these actions to a resolution most beneficial to the taxpayers.

HEALTHCARE FRAUD RESOURCES

In fiscal year 2012, the DOJ is requesting a total of $283.4 million in reimbursable funding to combat healthcare fraud. These funds are provided directly to both the DOJ and the FBI, and represent an increase of $63.4 million more than the fiscal year 2011 continuing resolution level. Historically, the DOJ and the FBI received only mandatory reimbursable funding from the HHS. However, beginning in fiscal year 2009, the DOJ began receiving discretionary reimbursable resources, and it is these funds which have allowed the DOJ to expand its workforce of attorneys, agents, and professional support staff to address healthcare fraud. As I have indicated, these funds are used to address the myriad of healthcare fraud schemes that afflict the Medicare and Medicaid programs, the Federal Employees Health Benefits Programs and other federally funded healthcare plans and programs.

STRONGER TOOLS FACILITATED RECORD RECOVERIES

The enactment of the Fraud Enforcement and Recovery Act of 2009 (FERA) made additional improvements to the False Claims Act and other fraud statutes. Among other important changes, FERA authorized the delegation of the Attorney General's authority to issue civil investigative demands, which has substantially increased the use of this critical investigative tool in healthcare and other fraud matters.

FERA also has clarified and added important liability provisions to the False Claims Act. The statute now makes clear that it is a violation for a defendant knowingly to retain an overpayment, which is particularly important in the healthcare context. The Affordable Care Act adds a new section to the Social Security Act that addresses what constitutes such an overpayment under the FCA in the context of Federal healthcare program and requires the reporting and returning of overpayments to Federal and State governments. Combined, these provisions enable the Government to more effectively pursue those who obtained money from Medicare and other Federal healthcare programs to which they are not entitled.

I already have mentioned the qui tam provisions of the False Claims Act. Of the $3 billion in total False Claims Act settlements and judgments obtained in fiscal year 2010, more than $2.4 billion was recovered in lawsuits filed under the Act's qui tam provisions. Under these provisions, whistleblowers (known as "relators")—many of whom face considerable personal risk in coming forward with allegations of fraud—are entitled to recover between 15 and 30 percent of the proceeds of a successful suit. In fiscal year 2010, relators were awarded $386 million. Since 1986, when the qui tam provisions were strengthened by Congress, recoveries in qui tam cases have exceeded $19.7 billion, and relators have obtained more than $3.2 billion in awards.

The enactment of the Affordable Care Act, which included the additional HCFAC resources to which I previously referred, also provided the Civil Division with additional tools to combat fraud. Among many other changes, the Affordable Care Act amended the False Claims Act's public disclosure provision and strengthened the provisions of the Federal healthcare Anti Kickback Statute. On a much broader scope, and as Dr. Budetti will testify in greater detail, the Affordable Care Act also provided for enhanced provider screening and enrollment requirements, increased

data sharing across Government, expanded overpayment recovery efforts, and greater oversight of private insurance abuses. All of these tools are now in use in our efforts to combat healthcare fraud, and they will go a long way in facilitating our continued success.

On behalf of the DOJ, let me again express my thanks for allowing me to highlight the DOJ's efforts in this important area. On behalf of the Attorney General, we welcome the opportunity to continue to work with you and your staffs as we find ways to more effectively safeguard Government healthcare resources and, in so doing, protect taxpayers and consumers.

Senator HARKIN. Thank you both very much for excellent testimonies, and thank you for the work that you do.

We'll start rounds of 5-minute questions now.

Dr. Budetti, first, we're about halfway through the fifth month of a continuing resolution. I don't see any compromise in sight right now. What's the impact of the continuing resolution on your program, where we are right now?

Dr. BUDETTI. Senator, as you know, when we're under a continuing resolution there are several things that happen. One is, we're not in a position to start new initiatives, and many of the things that I've mentioned, and that are very important for our fighting fraud, are new initiatives. And those are constrained.

We're also not able to plan very well in terms of putting things into place that we know will require a longer-term investment, so that's a problem. So, things like the enhancements to our data systems and data sharing with law enforcement, things like the work that we're doing with respect to the improvements in the information that go out to Medicare beneficiaries, our field office support, to work with the prosecutors and other law enforcement personnel around the country, our ability to expand some of our innovative approaches such as the compromised number database, which lists the beneficiaries and providers whose identities have been compromised.

There are a lot of initiatives that will have to be either pared back or not implemented. And most important, we don't have a sense as to the longer-term structure and stability of the programs. And so, that's a major impediment.

Senator HARKIN. Thank you.

Now, I'm going to ask both of you this question. We hear a lot of varying estimates about how much fraud is out there. I've heard 20 percent of claims, I've heard $60 billion, and even the HHS actuary says that the return on investment will soon go down—presumably because we're finding the majority of fraud—so it will become harder to find, a point of diminishing returns. You're the experts. How much fraud is out there? Are we close to a saturation point? Are we close to where we're not going to get $7 for every $1?

Dr. BUDETTI. Senator, I'd love to see the day when we don't have to fight fraud at all because we've eliminated all of it. I don't think we're anywhere near the saturation point. It's already clear that the more we spend, the more we invest, the more we look for fraud, the more we find. I think that's very unfortunate. I think that the return on investment is particularly striking. But I would love to see the return on investment be eliminated as we prevent fraud in the first place, because that's much more efficient, and much more protective of our beneficiaries and our programs. I don't think we're anywhere near the flat of the curve, though, unfortunately.

Senator HARKIN. Yes, thank you.

Mr. West.

Mr. WEST. Mr. Chairman, as I think you know, we use a 3-year rolling average when we talk about that return on investment number, so that we can get a pretty accurate picture of where it is. And the one thing we know is that that return on investment number continues to increase.

There is no question that the more we invest in law enforcement efforts aimed at curbing healthcare fraud, it has an impact in rooting out more fraud and increasing that return on investment. But that said, whatever that saturation point is, we are not there yet. I agree with Dr. Budetti. We're certainly not there yet. And all of the evidence seems to suggest the more we invest here, the better we do.

Senator HARKIN. And, shouldn't we keep in mind, I was startled to find this figure out, that we add 19,000 providers to the Medicare system every month. Nineteen thousand new providers. And with the baby-boom generation coming on, that's going to accelerate. So it seemed to me, is that the potential for more fraud and abuse. And 2.8 million baby boomers are eligible to enroll this year. That's just this year. So the potential for fraud seems to be growing. Is that why we're not near the saturation point?

Mr. WEST. Well, I think there's no question that, as you pointed out, an aging population program that continues to grow, that spends billions of dollars—and I think many of the reasons that Dr. Budetti pointed out, namely that these schemes are constantly changing, evolving. People become very sophisticated. When you look at the cases that the Civil Division handles, they really do span the full spectrum. And some of them take years to investigate and pursue because they are so sophisticated. We don't see that changing anytime soon.

Senator HARKIN. Thank you very much.

Senator Shelby.

Senator SHELBY. Thank you, Mr. Chairman.

Dr. Budetti, could you take the first, I believe it was the first chart you had, and lead us through that, if you would? Because I think it's very interesting predictive modeling.

Dr. BUDETTI. Thank you for the question, Senator. Yes.

What we need to do is to take into account a wide range of different kinds of data and information in order to figure out what's going on with the fraudsters and where they're headed, and be able to spot things before the claims get paid. So, the left-hand box, where it's kind of gray, talks about the different kinds of data that we're looking at. Claims data? Yes, of course, claims data. But also, the information that we get when providers, when the 19,000 providers and suppliers apply every month to get into the programs, information from our law enforcement partners that, from investigations, complaints—we're taking a lot of complaints now from the 1–800–MEDICARE system, and we're putting them into a new analytical system so that we can learn more about the fraud that's being reported by our beneficiaries, and stolen identities—a very serious problem for both providers and beneficiaries around the country.

So, we're taking all of that data and using sophisticated new technologies to analyze all of it simultaneously, so that when a claim comes in, we know, we can apply a risk score based upon all of those factors, and we can alert our contractors who, as you know, pay the bills in Medicare. We can put this into our case management system so that we know what our law enforcement colleagues are doing and, based upon our interactions, it's a cycle, so that it feeds on itself, and we get more information, and it improves over time.

This is new for us. This is something that we are currently in the process of implementing, and we believe that it will be very useful in terms of advancing our ability to both prevent and detect fraud, Senator Shelby.

Senator SHELBY. Compare this, where you are today with this, as to where you were, say, 10 years ago. It's night and day?

Dr. BUDETTI. It's night and day, Senator. I think there are things that could have been done 10 years ago with the technologies. I think there are things that could have been done 10 years ago with index cards, frankly. But now I think we're in a new position with the sophistication and the computer systems that are available to make a much greater impact, Senator.

Senator SHELBY. I have a number of questions for the record, Doctor.

In your testimony you stated that HCFAC funds would be used to expand existing criminal and civil healthcare fraud investigations and prosecution, particularly related to, and I'll quote your words, "emerging fraud schemes in areas such as pharmaceutical services, medical devices, and durable medical equipment." Would you expand on some of these emerging fraud schemes and how fraud and abuse has evolved, and why criminals are getting more creative? Because these, put together in the aggregate, are big tickets, aren't they? A lot of money?

Dr. BUDETTI. Thank you for that question, Senator. Yes. I think one of the challenges that we face is that the fraud schemes are getting more sophisticated, and we need to stay ahead of them.

In the durable medical equipment area, in the other areas that you mentioned, what we see is, people who have the sophistication to submit claims and get them rejected over and over again, but to keep learning from the rejections so that they get them right eventually, and they look like real claims—they're able to set up phony enterprises and make them look like real enterprises until we really go and visit them and make sure whether or not they're operating. They can have beneficiary IDs and provider IDs that look real, because they are real. They're just not part of that actual enterprise. They belong to somebody else somewhere else in the country.

So, all of that lends to the increased sophistication, and it's something that we need to be equally or even more sophisticated about, Senator.

Senator SHELBY. Of course, predictive analytics, the credit card, the banking system uses that——

Dr. BUDETTI. Absolutely.

Senator SHELBY [continuing]. Now to predict fraud and so forth.

Could you tell us how the return on investment is coming? That's important from the standpoint of appropriations.

Dr. BUDETTI. Thank you for that question, because we've learned from our private sector partners and from other industries that their return on investment in this kind of analytics has been tremendous. We've had conversations with people in the banking industry. We've had conversations with people in a number of other industries about their use of advanced technologies and how dramatically it's lowered their fraud rates. So, we believe that their investment, what they've learned, can be readily applied to us in the Federal healthcare programs, and that's the direction we're moving in.

Senator SHELBY. A lot of it's basic—not basic for yesterday, but for tomorrow—information technology, the——

Dr. BUDETTI. Absolutely.

Senator SHELBY [continuing]. Explosion is, and you're using those tools, are you not?

Dr. BUDETTI. Yes, sir. That's exactly where we're going. We have a solicitation that's open right now. We're looking at some of the best ideas from around the country, from private sector companies that are offering these new solutions. And I think we're going to be very well poised to put those into place very soon.

Thank you, Senator.

Senator HARKIN. Thank you, Senator Shelby.

And now we welcome not only a new member to the Senate but to this subcommittee, my neighbor to the East, as I say, in Illinois. Senator Kirk was also on the House Appropriations Committee. And so we welcome him not only to the full committee, but to the best subcommittee of the full Appropriations Committee.

Senator Kirk.

Senator KIRK. I thank the chairman, and recall Chairman Natcher, who always called the bill that was produced by this subcommittee the people's bill. And we share the admiration of a former staffer for Chairman Harkin, Jim Sweeney, who I worked with very much until his tragic death, and remember Jim very much in the foreign policy work he did for the chairman.

I am new and old—new to the Senate 60 days, old in the sense that I am, first attended a Labor-HHS meeting for, with Congressman Porter back in 1984, and remember the subcommittee and its work, and what it's done. And I apologize for making a typical freshman mistake of actually showing up at a hearing in which he's not the ranking member. But I care very much about this bill and where we're going, and this topic.

I'm wondering, we're talking about predictive models, and we're talking about a high degree of bureaucratic involvement in finding waste, fraud, and abuse. I'm wondering if we can look to any thoughts you have or academic peer review data on empowering patients to help in this process.

First question is, the Medicare card itself, very much like the Social Security card, is highly outdated, compared to the cards regularly available elsewhere. This, for example, is a military ID card, called a common access card (CAC). The Department of Defense (DOD) has now put out about 20 million of these at a cost of roughly $8 each. It not only has the picture, the signature, the computer

chip, the bar code, and the magnetic strip picture on the back and another bar code. To my knowledge, DOD has yet to find a counterfeit version of this since the CAC card rolled out. My question is, would this card pay for itself, as Medicare beneficiaries had this technology available? Any thought of upgrading the card itself to help enforcement in where we go?

Dr. BUDETTI. Senator, and welcome to the hearing as well. I appreciate the honor of being here for your first hearing, as well.

Senator KIRK. Thank you.

Dr. BUDETTI. The Medicare card does pose, I think, many of the questions that you've raised. We are in the process of looking into exactly what you just mentioned. Over the years this has been looked at, and the emphasis, in my opinion, has been largely on the costs of switching over. I think it is time, as you mentioned, that we also look at what the payoff would be of doing exactly that, and decide whether that is a good investment.

I can tell you that in my Center for Program Integrity we have initiated a pilot program to use card reading technologies in a limited way, precisely to get experience with that. And we'll be issuing special cards in certain, in a limited pilot study. And when we get the results of that study, we'll be able to—you mentioned peer-reviewed research. We're not going to publish this. But we do want to know exactly what we're doing and try to follow through on a step-wise fashion. And so, we are conducting this technology in the DME area to verify the identities and the locations at which the durable medical equipment is being provided. And we view that as a first step toward understanding what the payoff would be of a major shift, as you mentioned.

Senator KIRK. Thank you.

I would just think, Mr. Chairman and Senator Shelby, it might be something for us to explore in the bill, to fund, or to give direction to the administration to look into. And I would hope that we not reinvent the wheel. Since DOD has already worked out this technology and has $20 million on the street, moving from $20 million to $40 million for Medicare could help the internal integrity of the system and would assist investigators. And so, I think it's productive for us to look into.

One last question. Our Federal employees can smell fraud faster than anyone else, especially at a local level. But, is there a way to further incentivize them—for example, a 1 percent reward for what they find in the system? Any sort of studies or review that have been done to look at what an actual cash percentage for the recovery would be to the Federal employee that you have determined has actually found the misdoings?

Dr. BUDETTI. Senator, I think you're very well aware of the major impact that the Federal False Claims Act and the State false claims acts have had in terms of creating incentives for people to report fraud, and they get a recovery of, a share of the recovery.

Interestingly enough, there actually is a program on the books, a Medicare incentive program that would allow us to pay a proportion of the recoveries to Medicare beneficiaries who report information that leads to fraud. We're in the process right now of looking very carefully at ways to reinvigorate that program. It has not been a major tool in our approach to this in the past. And we're right

now redesigning the program, and believe that it could be of major importance in terms of further creating incentives for Medicare beneficiaries and others to report fraud in the program.

Mr. WEST. Senator, welcome to the subcommittee.

Senator KIRK. Thank you.

Mr. WEST. Welcome to the Senate.

As you know, the False Claims Act, as Dr. Budetti has mentioned, has been a very important tool for the Civil Division and for the Department of Justice when it comes to getting at waste, fraud, and abuse in any of our public programs, but particularly in our healthcare fraud programs. I would say about two-thirds of our cases that we pursue are cases that come under the qui tam provisions that come from whistleblowers. And I think that is due not only to the publicity that those efforts that we've been making has generated, but also Congress' good judgment that there is an incentive for individuals who are on the inside and who are willing to oftentimes risk their careers, risk an awful lot, to come forward and uncover or disclose fraud, that there is an incentive to do that.

I will say that the Department has had quite a few conversations—and we are always happy to engage in many, many more—on this topic of whether or not public government employees, Federal Government employees ought to have the type of incentive that you describe. And I think it's fair to say that at this time we're not convinced that it will actually increase our efforts to get at waste, fraud, and abuse. I think, you know, we do have some concerns about whether or not that conflicts with the duties of a public employee, particularly a public employee whose job as a public servant is to, as part of their role, identify these types of waste, this type of fraud, and to report it, to then have personal gain from doing that person's job. We do have some concerns about whether or not that's inconsistent with what a public servant's role is.

But, as I said before, you know, there are ongoing conversations about this, and we're happy to engage in those.

Senator KIRK. Mr. Chairman, just, our Federal employees generally are overwhelmingly patriots. I was a Federal employee in the State Department where a rewards program was provided and available—it was not a common practice, but—to enable and incentivize the workforce to do the right thing, or even more exciting, we all have had beneficiaries tell us about fraud that they've seen. And allowing a 1 percent recovery for confirmed fraud I think empowers every senior in America to police their own care and program. And woe be unto the provider that now faces beneficiaries like this. And so, it's an area for us to explore.

But, thank you Mr. Chairman.

Senator HARKIN. Well, Senator, thank you very much. I want to explore that with you about that card. As I understand it, what you're saying is that if they had this card, that before a provider puts in for reimbursement using their number and the supposed patient's number, the patient would have to somehow swipe that card for every procedure. You'd have two inputs coming in.

Senator KIRK. Right. It depends, you know, for DOD, in very rough environments they'll just Xerox it. And then, for normal DOD applications, they'll have what's called a common access card reader, which is about $2 per computer.

Senator HARKIN. I'd like to see how that would work. In other words, right now when a provider puts in for reimbursement they put in their number and the patient number, and whatever code for whatever they provided. So, the card's not even used.

What you're saying, I think, is that maybe we should have a card where, if that provider puts in for reimbursement, there has to be a parallel input from that card.

Senator KIRK. Where the secretary at the doctor's office then sees if, you know, if the photo even matches.

Senator SHELBY. Just common sense.

Senator HARKIN. I'd like to take a look at that.

You say you're looking at things like that? Do you have a pilot program on that?

Dr. BUDETTI. As I mentioned, Senator, we do have a pilot program. The reason we started with a pilot program is that this would be a major change. This would not be a simple overnight change, or an inexpensive one, and——

Senator SHELBY. How long has the pilot program been going?

Dr. BUDETTI. The pilot program just started within the last few months, Senator, on our watch. But it's definitely worth thinking about. But I just, the caution, of course, has been that because there's so many people involved, and because it involves the coordination between the Social Security system and the Medicare system both—not that that can't be done, but that it needs to be looked at very carefully and implemented properly, and thought about over time, as well.

Senator HARKIN. Yes. I'd like to also know, what is the proportion? In other words, of all the different things that you go after in terms of fraud, how much of the total is undocumented claims that are made by providers, as opposed to, say, pharmaceutical companies using off-brand, off——

Mr. WEST. Off-label?

Senator HARKIN [continuing]. Off-label uses. I don't know what the proportion of that is.

Mr. WEST. Well, certainly, a large, large proportion—and I can get the exact number here—but a large proportion of our cases do involve the large pharmaceutical companies. When you talk about the recoveries and the numbers that we were just talking about, off-label marketing, as you point out, and other types of fraud related to marketing drugs that have not been approved as safe and effective by the Food and Drug Administration (FDA), there is, of course—and then, you know, a smaller proportion of our cases would involve other types of healthcare fraud. But there's no question that the big pharmaceutical company cases that you've just mentioned are a very large share.

[The information follows:]

LITIGATION TRACKING SYSTEM

The litigation tracking system used by the Civil Division does not allow for the tracking of cases by case type. As such, the Civil Division is unable to state what percentage of all healthcare fraud cases are cases which involve pharmaceutical companies and off-label marketing.

Dr. BUDETTI. The only thing that I would add to that, Senator, is that—I mentioned the compromised number database that we are putting together and that we're expanding—we now have about a quarter of a million Medicare beneficiary identities that we believe, or that we know, have been compromised and used to nefarious purposes. And I think that's an indicator of the scope of the problem. This is something that we're beginning to use in a more extensive and creative way to track who is submitting claims using those Medicare beneficiary identities.

Of course, there are still real people who need real care from real providers, and so we want to be cautious that we don't cut them off from care just because somebody stole their ID. But, this is clearly a growing problem, and it is something that we're taking very seriously as we put into place our advanced analytics. And——

Senator HARKIN. When I was going through your testimonies last night, reading them and then thinking about our past hearings on this, it came to my mind that, why is no one going to jail?

Senator SHELBY. That's a good question.

Senator HARKIN. Why is no one going to jail? Let me just pursue that just a little bit further. So, you've got $2.3 billion from Pfizer. Well, CEOs, the managers, whoever did all this, there's no money out of their pockets. It comes from the shareholders. And if they don't go to jail, then it's just, so what? They tried it. They got caught. The shareholders paid it off. And they don't have anything to worry about. Maybe they'll try it again and next time they'll get by with it. And it seems like every time we go down this path, someone gets fined, but no one ever goes to jail. Am I wrong?

Mr. WEST. Well, I would take issue with the premise a little bit. I think now——

Senator HARKIN. Well, give me some idea of who goes to jail. I've never seen any yet.

Mr. WEST. Well, here's maybe three examples. I think the first comes from our Strike Forces, which have been very, very successful in identifying individuals who are perpetrating fraud, and not just identifying them, but prosecuting them, convicting them, and sentencing them. So, you've had a number of convictions which have come out of our Strike Force efforts, which are in seven cities now. The plan with the President's budget is to move that to 20 cities, because it has been such a successful effort. So, that would be the first one.

The second one is, in the *Pfizer* case you mentioned, there were two individuals who were criminally charged. And we do look at individuals that, I think it's fair to say that we are equally aggressive whether it is against an individual or a corporate defendant. If the evidence and facts allow us to pursue individuals, we will do so. And I've been very, very clear about that in the last 21 months in this role, that we will look very closely at individual culpability.

Two examples of cases that we brought just last year. One case, or, actually, two cases involved two individual doctors who were performing heart surgeries when they were not qualified to do so, and were billing the taxpayers for the work that they did. Those cases actually resulted in significant, we believe significant, patient harm. And last year we charged the in-house counsel of a major

company because we believe she was engaged in obstruction of justice when it came to an FDA investigation.

And so, we try to be very, very clear that, whether it's the biggest of companies or the smallest of individuals, if you are perpetrating fraud on the American people in our public healthcare programs, then we will pursue you.

Senator HARKIN. Well, I'd like to know how many of these cases you've brought. When you got fines, how many people actually were charged criminally and how many actually were prosecuted to the extent that they actually served some time?

Mr. WEST. I'll be happy to get you that data, Mr. Chairman.

[The information follows:]

CRIMINAL PROSECUTIONS IN CIVIL PHARMACEUTICAL CASES

Together with its partners in the U.S. Attorney's Offices, since January 2009, the Office of Consumer Protection Litigation has brought charges against 11 individuals relating to Food, Drug, and Cosmetic Act healthcare offenses. Seventeen individuals have been convicted.[1] Ten individuals have been sentenced, and four of those were sentenced to a term of imprisonment. Seven others await sentencing.

The Department of Justice has charged and obtained convictions of individuals, including corporate executives and other individuals engaged in illegal activity in connection with the sale and marketing of pharmaceuticals and medical devices. Consistent with Department policy, upon conviction, we advocate for sentences of imprisonment within the advisory Sentencing Guidelines range in all but extraordinary cases. This policy reflects the Department's belief that the Sentencing Guidelines help us to achieve tough, fair, and consistent sentences in the Federal criminal justice system.

Mr. WEST. You know, it actually brings up something that you brought up earlier in the hearing. And that is, the impact of the CR, the continuing resolution, on our efforts. As I alluded in the opening statement, you know, these cases, particularly the kinds of cases involving the larger companies where you're looking for officers of the company, CEOs, you know, CFOs, people who are in charge with individual culpability, those are extremely, extremely intense, resource-intensive cases. Not only do they take time to investigate, but they take experts, they take lawyers, they take people who are willing to sit down and do multiple interviews. And, as you well know, these are well-funded adversaries on the other side, with lots and lots of lawyers in the room.

Senator HARKIN. That's true.

Mr. WEST. And that, of course, means that we have to, if we want to be able to match that type of firepower, then we're going to have to invest in our efforts to combat healthcare fraud. And so, to the extent we have the CR, and we're unable to expand our efforts, I think that has an impact. To the extent that we have a CR, and we can't expand to 20 cities with our Strike Force efforts, which have been amazingly successful, we have to stay in seven cities, which has an impact as well.

Senator HARKIN. Okay. Thank you.

Have you got anything else?

Senator SHELBY. Yeah.

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[1] The number of charges during a given time period and the number of convictions do not necessarily represent the same defendants, due to the fact that proceedings often span beyond that time period. This response reports the number of charges that were brought after January 2009, and the number of convictions that were entered since that time, regardless of when the cases were filed.

Senator HARKIN. Senator Shelby.

Senator SHELBY. I want to pick up on what Senator Harkin said.

You're in the DOJ, and you're in the law enforcement. One of the strongest emotions that we have is fear. And if it's individual fraud, they ought to be prosecuted. If it's corporate fraud, they ought to be prosecuted, not just pay the fine. Because you know it will send a message to everybody. And what Senator Harkin was, I think, getting at is very important. What kind of message is it if you can pay a little fine or a big fine, and you can go home, and the culprits are never called to account? Isn't that basically what he's talking about?

So, I think you can do both. Are you in complex litigation? Are you on this absolutely? Are they—people are going to fight you, the bigger they are and the resources they have. Absolutely. But I think you've got to do it both ways, with the little person who commits fraud, and the big person. Because justice should be across the board, should it not?

Mr. WEST. I could not agree with you more, Senator Shelby. I'm a former prosecutor. And I always say, nothing focuses the mind like jail time. So, I couldn't agree with you more on that.

But I will say, when you look at our record over the last 2 years——

Senator SHELBY. Well, I'm not getting on your record. I'm just——

Mr. WEST. Right, right, right. No. I appreciate it. But I think when you look at the sort of cases that we've brought, they include both cases against individuals as well as companies.

And I would also say, you know, the fines in these cases, the judgments and settlements in these cases are record-breaking. And that's for a reason. Because I could not agree with you more. It cannot be that a company sees healthcare fraud enforcement, law enforcement, imposing a fine as a cost of doing business.

Senator SHELBY. That's right.

Mr. WEST. That cannot be the case. And I think——

Senator SHELBY. Just a cost of doing business.

Mr. WEST. Right. It cannot be that. And so, I couldn't agree with you more. We need to deploy the full range of our criminal and civil law enforcement tools to bring to bear on healthcare fraud.

Senator SHELBY. I know we want to move on, but I want to pick up on the theme of what Senator Kirk was onto. And that's preventing fraud as much as you can. Of course, a good card won't prevent all fraud because there's a lot of fraud in the people who provide the services, and some fraud in the people who use the services. But if you can prevent fraud before it happens as a national healthcare integrity strategy, it will pay dividends big-time, would it not?

Mr. WEST. No question. No question. I've often said we can't prosecute our way out of this problem. And that's why I think the reforms that Dr. Budetti has just described here are so critical to our law enforcement efforts.

Senator SHELBY. And when people cheat, they're cheating everybody else, aren't they?

Mr. WEST. Absolutely.

Senator SHELBY. I mean, they're cheating some beneficiary that might be in need——

Mr. WEST. That's right.

Senator SHELBY [continuing]. Because the money won't be there. Especially in the future.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Shelby.

Well, I thank our panel. Thank you very much.

Our first panel will be excused. We'll call our second panel.

Rebecca Nurick has served as the Project Manager of the Pennsylvania SMP program since June 2005. She has previously worked as Assistant Coordinator of the Philadelphia Elder Abuse Task Force, Assistant Coordinator of the Guardianship Advisory Project, and a caregiver assistant service counselor. She's a graduate of Penn State University.

Robert Rolf serves as Vice President of Consulting Services for CGI Federal and manages the Health Care Business Process Services Business Unit. In his 15-year tenure with CGI, Mr. Rolf has presented at national conferences, including the National Health Care Anti-fraud Association and the National Association for Medicaid Program Integrity. A graduate of Ohio State University.

Welcome. Your statements will be made a part of the record in their entirety. I'll ask you to sum them up in about 5 minutes, if you could.

And, Ms. Nurick, welcome. Please proceed.

STATEMENT OF REBECCA NURICK, PROJECT MANAGER, PENNSYLVANIA SENIOR MEDICARE PATROL PROGRAM, PHILADELPHIA, PENNSYLVANIA

Ms. NURICK. Thank you very much.

My name is Rebecca Nurick, and I am the Program Manager of the Pennsylvania SMP at the Center for Advocacy for the Rights and Interests of the Elderly (CARIE).

Established in 1977, CARIE is a private nonprofit organization dedicated to improving the quality of life for frail older adults.

Good morning, Chairman Harkin, members of the subcommittee and staff. Thank you very much for convening these hearings and for the opportunity to present testimony today.

The national SMP, has been very busy since its inception in the mid-90s. The Pennsylvania SMP began as 1 of 12 local demonstration projects across the country through an initiative called Operation Restore Trust, begun by Senator Harkin. Senator Harkin had the foresight to see the need for a grassroots approach to curbing fraud and abuse in Medicare. Today there are 45 SMP programs—1 in every State, as well as the District of Columbia, Guam, U.S. Virgin Islands, and Puerto Rico.

Healthcare fraud is a serious problem. In 2009, more than 48 billion was lost to fraud, waste, and abuse. SMP staff and volunteers have spoken to beneficiaries in communities throughout the country about a myriad of issues, such as durable medical equipment fraud, providers charging for more costly procedures than those that were actually rendered, home health agencies billing for services provided by unauthorized and/or unqualified personnel, and marketing abuses by health insurance companies, just to name a few.

To address these issues, our project and other SMPs utilize a peer education model envisioned by Senator Harkin. SMPs recruit and train senior volunteers, Medicare beneficiaries, to conduct outreach and education to their peers, caregivers and professionals about Medicare and Medicaid fraud prevention.

The primary message here is that there is something that beneficiaries can do about this problem.

The project's goals are twofold. First, to educate and motivate consumers on how to prevent, detect and report healthcare fraud, errors, and abuse, and second, to receive, investigate and refer, as appropriate, complaints of potential healthcare fraud.

So, why is this important? Indeed, fraud costs Medicare more than $48 billion each year of massive financial loss to the Government and beneficiaries. Fraud can also cause people to lose access to care, suffer inappropriate or low-quality care, lose benefits, receive bad equipment, the wrong drugs, or other things they do not need, all affecting their health and well-being.

What does healthcare fraud look like? I will tell you about a couple of the scams and fraud that our SMP has encountered.

We were contacted by a beneficiary, a retired medical office worker, about a company that was coming around in a van dropping off scooters to people and collecting personal information such as Medicare numbers and birth dates and so on. When the company came to her home, she told them that she would not divulge any information and demanded that the van driver and his counterpart leave her property immediately. After 2 days of harassing her, she threatened to call the police, and they left her alone. The company ultimately did have some information about her and managed to bill her Medicare number for a $5,000 scooter that she never received. Company employees are currently under indictment because SMPs, in addition to other organizations, reported this problem to CMS.

Another beneficiary called our SMP with a concern about charges on her Medicare summary notice, or her MSN. The beneficiary went to her primary doctor with a sore throat and a fever. The doctor used a tongue depressor to look down her throat. He wrote a prescription for her and she went home. She later checked her summary notice and saw that the doctor had billed for an expensive procedure called a laryngoscopy. The office corrected the mistake after our office called it to their attention.

The success of the SMP program is a direct result of its volunteers. Volunteers have extensive training and show extreme dedication to the fight against fraud.

Terri Ivers, a retired Government worker from Langhorne, Pennsylvania, became a SMP volunteer because she has strong feelings about justice and law. She has been a volunteer for 14 years and was recognized for her work by the U.S. Administration on Aging.

I am attaching a flier that was recently created for outreach purposes. It features a few of our SMP volunteers here, and the photo really does reflect what a serious matter the volunteers consider fraud to be.

Nationwide, the SMP program has trained 60,000 volunteers, handled more than 104,000 complaints, and educated 2.3 million people. Millions more have been made aware of the problems

through television, radio and newspaper interviews, as well as distribution of consumer education materials.

The numbers are significant, but what is more important here is why those numbers matter. Beneficiaries are the first line of defense in the fight against fraud and abuse. They are on the front lines. When more people become aware of the issues that confront Medicare, the better able they will be to protect themselves, as well as the essential healthcare on which they depend. SMP volunteers teach their peers practical, simple and effective ways to protect themselves and their healthcare system. The essence of the message is to detect problems, protect personal information, and report suspicious activity or charges.

PREPARED STATEMENT

We hope that our testimony today will help to strengthen the message that Medicare and Medicaid fraud abuse prevention, through protecting information, detecting problems, and reporting concerns, is essential, and that beneficiaries across the Nation are ready and willing to protect themselves and this vital healthcare.

Thank you for the opportunity to speak with you today about this critical issue, and for championing the fight against Medicare and Medicaid fraud.

Senator HARKIN. Thank you, Ms. Nurick. Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF REBECCA NURICK

My name is Rebecca Nurick and I am the Program Manager of the Pennsylvania Senior Medicare Patrol (SMP) at the Center for Advocacy for the Rights and Interests of the Elderly (CARIE). Established in 1977, CARIE is a private nonprofit organization dedicated to improving the quality of life for frail older adults.

Good morning Chairman Harkin, members of the subcommittee and staff. Thank you for convening these hearings and for the opportunity to present testimony today.

SMP

The national SMP has been very busy since its inception in the mid-1990's. The Pennsylvania SMP began as 1 of 12 local demonstration projects across the country through an initiative called Operation Restore Trust begun by Senator Harkin. Senator Harkin had the foresight to see the need for a grass roots approach to curbing fraud and abuse in Medicare. Today there are 54 SMP programs, one in every State as well as the District of Columbia, Guam, U.S. Virgin Islands, and Puerto Rico. These programs are well supported by the national SMP Resource Center.[1] Healthcare fraud is a serious problem. In 2009, more than $48 billion was lost to fraud, waste, and abuse. SMP staff and volunteers have spoken to beneficiaries in communities throughout the country about a myriad of issues, such as durable medical equipment fraud, providers charging for more costly procedures than those actually rendered, home health agencies billing for services provided by unauthorized and/or unqualified personnel, and marketing abuses by health insurance companies, just to name a few.

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The project's goals are twofold: first, to educate and motivate consumers on how to prevent, detect and report healthcare fraud, errors, and abuse; and second, to receive, investigate and refer, as appropriate, complaints of potential healthcare fraud. So why is this important? Indeed, fraud costs Medicare more than $48 billion each

[1] The National Consumer Protection Technical Resource Center at www.smpresource.org.

year—a massive financial loss to the Government and beneficiaries. Fraud also can cause people to lose access to care, suffer inappropriate or low-quality care, lose benefits, and receive unnecessary or faulty equipment, the wrong drugs or other things they do not need—all affecting their health and well-being.

HEALTHCARE FRAUD

What does healthcare fraud look like? I will tell you about some of the scams and fraud that our SMP has encountered.

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Another beneficiary called our SMP with a concern about charges on her Medicare Summary Notice (MSN). The beneficiary went to her primary doctor with a sore throat and fever. The doctor used a tongue depressor to look at her throat, wrote a prescription for her and then she went home. Her total visit time was about 10 minutes. She later checked her MSN and saw that the doctor had billed for an expensive laryngoscopy. The office corrected the "mistake" after we called it to their attention.

The last example concerned a healthcare provider going to senior housing buildings in Philadelphia and buying Medicare numbers for $10, then providing a cursory diagnostic exam. The exams consisted merely of checking blood pressure and taking a temperature, but Medicare was billed for multiple, costly tests. Since no one should offer money or free items for Medicare numbers, we tell people to guard their Medicare number as if it were a credit card number.

VOLUNTEER IMPACT

The success of the SMP program is a direct result of its volunteers. Volunteers have extensive training and show extreme dedication to the fight against fraud. Terri Ivers, a retired Government worker from Langhorne, Pennsylvania became a SMP volunteer because she had strong feelings about justice and law. She has been a volunteer for 14 years and was recognized for her work by the U.S. Administration on Aging. I am attaching a flyer recently created for outreach purposes. It features a few of our Pennsylvania SMP volunteers. The photo reflects what a serious matter the volunteers consider fraud to be.

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The numbers are significant, but what is more important here is why those numbers matter: beneficiaries are the first line of defense in the fight against fraud and abuse. They are on the front lines. When more people become of aware of the issues that confront Medicare, the better able they will be to protect themselves as well as the essential healthcare on which they depend.

DETECT, PROTECT, AND REPORT

So what can beneficiaries do to protect themselves? SMP volunteers teach their peers practical, simple, and effective ways to protect themselves and their healthcare system. The essence of the message is to "Detect, Protect, and Report."

SMP volunteers suggest that beneficiaries:

—Keep a calendar of all healthcare visits and services (tests, equipment, etc.) Compare these records to Explanations of Benefits or Medicare Summary Notices to detect any inaccuracies.

—Protect Medicare or Medicaid numbers as if it were a credit card number.

—*Trust Their Instincts*.—If something sounds too good to be true, it probably is. Beneficiaries should report suspicious callers or charges.

—Never give any personal information (such as Medicare or bank account numbers, birth date) to callers or people who show up at your door.

—Always rely on their personal doctor to recommend all medical services and equipment.

—Know that Medicare and Social Security will never try to sell a service or product.

CONCLUSION

We hope that our testimony today will help to strengthen the message that Medicare and Medicaid fraud and abuse prevention, through protecting information, detecting problems, and reporting concerns, is essential, and that beneficiaries across the Nation are ready and willing to protect themselves and their vital healthcare.

Thank you for the opportunity to speak with you today about this critical issue and for championing the fight against Medicare and Medicaid fraud.

Senator HARKIN. And, Mr. Rolf, please proceed.

STATEMENT OF ROBERT ROLF, VICE PRESIDENT, CGI FEDERAL, INC., FAIRFAX, VIRGINIA

Mr. ROLF. Good morning, Chairman Harkin, Senator Shelby, members of the subcommittee.

My name is Rob Rolf. I'm vice president for CGI Federal, an information technology and business process services company that has been partnering with Government for nearly 35 years.

In my role, I'm responsible for CGI's efforts to implement the RAC program in region B, a seven State region in the Midwest, as well as similar audit and recovery efforts that CGI performs for its State government and commercial clients.

It is my pleasure to appear before you today at this hearing to examine the use of RAC in the Medicare program.

Originally authorized by the Tax Relief and Health Care Act of 2006, the Medicare Recovery Audit Contractor program is a nationwide program focused on the identification of improper payments made to hospitals, physicians, clinics, durable medical equipment suppliers, and other providers of services under Medicare parts A and B. The nationwide program follows a successful 3-year pilot that resulted in the identification of $1 billion in improper payments from six States.

Under CGI's contract with CMS, CGI is tasked with the identification of improper payments utilizing both automated and manual claim review processes intended to identify provider overpayments and underpayments.

Although most of this work involves catching improper payments on the back end, CGI fully supports all efforts to prevent such payments from happening in the first place. CGI currently assists CMS in the development of an improper payment prevention plan, a mission that CGI takes very seriously.

As a result of CGI's experience with the RAC program, I'd like to share a few observations about this important CMS program and some lessons learned about recovery audit efforts with the subcommittee.

First, transparency and communication are critical to the success of the program. It is important that RACs provide transparent information to Medicare providers regarding the program and the issues under investigation, as well as information about the basis for an improper payment determination.

Second, the RAC program promotes continuous process improvement for claims processing and payment. CGI participates along with the other RACs in major finding discussions with CMS. This process informs CMS of areas representing the greatest

vulnerabilities to the program, along with recommendations for corrective action.

Third, the contingency payment approach works well in practice. Medicare Administrator Contractors have many significant duties under the Medicare program, including claim review prior to payment. The MACs simply aren't able to catch every error or omission on the front end. The RACs have one primary mission, and that's to catch improper payments on the back end and correct them. The contingency payment approach allows RACs to dedicate the necessary resources to this task.

Fourth, the potential for this contingency approach to expand to other areas across Government has been recognized by Congress. Several legislative provisions in the Affordable Care Act expand the RAC approach to Medicaid as well as Medicare parts C and D, and the Improper Payments Elimination and Recovery Act passed last year requires the RAC approach to improper payment recovery across Federal agencies.

As the Medicaid RAC program is being implemented in each State, CGI is pleased to have been selected by the Commonwealth of Pennsylvania as its RAC contractor and by the Commonwealth of Massachusetts for improper payment reviews. Our contract is a continuation of over a decade of work in identifying improper Medicaid payments in partnership with the Department of Public Welfare, while our work with Massachusetts represents a new partnership in providing recovery audit work.

The Medicare RAC program is an essential element in the broader effort of program integrity. A comprehensive approach that CGI has been advocating for nearly two decades involves clearly defined program policies, pre-edit payment edit rules and audits of claims, postpayment recovery audits, and investigation of fraudulent activities. Each element is essential to ensuring compliance with the program and the ultimate goal of protecting the trust funds.

CGI prides itself on combining cutting-edge technology with years of domain expertise in creating valuable solutions for our clients. We are especially proud of our ability to deliver successfully on the RAC program by featuring our healthcare expertise and broad experience in our programs.

PREPARED STATEMENT

More than that, CGI remains passionate about the opportunity to partner with CMS and other public agencies in one of the most critical good Government efforts underway today.

I appreciate the chance to appear before you all today. I would be pleased to answer any questions you may have.

Senator HARKIN. Thank you very much, Mr. Rolf.

[The statement follows:]

PREPARED STATEMENT OF ROBERT ROLF

Good morning, Chairman Harkin, Ranking Member Shelby, and members of the subcommittee: My name is Rob Rolf. I am Vice President for CGI Federal (CGI), an information technology and business process services company that has been partnering with Government for nearly 35 years. In my role, I am responsible for CGI's efforts to implement the Recovery Audit Contractor (RAC) program in region B, which is comprised of seven States in the Midwest, as well as similar audit and recovery efforts that CGI performs for its State government and commercial clients.

It is my pleasure to appear today before you at this hearing to discuss the role of RACs in the Medicare program.

Originally authorized by the Tax Relief and Healthcare Act of 2006, the Medicare Recovery Audit Contractor program is a nationwide program focused on the identification of improper payments made to hospitals, physicians, clinics, durable medical equipment suppliers, and other providers of services under Medicare parts A and B. The nationwide program follows a successful 3-year pilot that resulted in the identification of $1 billion in improper payments from six States.

Under CGI's contract with Centers for Medicare & Medicaid Services (CMS), CGI is tasked with the identification of improper payments utilizing both automated and manual claims review processes intended to identify provider overpayments and underpayments. Although most of this work involves catching improper payments on the back end, CGI fully supports all efforts to prevent such payments from happening in the first place. CGI currently assists CMS in the development of an improper payment prevention plan, a mission that CGI takes very seriously.

Since contract inception in February 2009, CGI, much like our fellow RACs, has worked diligently to implement the program in an open and transparent fashion. Our efforts to date involved extensive outreach to the provider community in each State served, through town hall style meetings, as well as Internet and audio conferences, providing education on the program and CGI's processes. To date, CGI has conducted more than 80 such meetings and taken more than 15,000 calls at our call center, which we established to field provider questions and concerns.

In February 2010, CGI began sending notices of improper payments to the Medicare Claims Processors for recovery. As a result of CGI's experience with the RAC program, I'd like to share a few observations about this important CMS program and some lessons learned about recovery audit efforts with the subcommittee:

—*Transparency and Communication are Critical to the Success of the Program*.—It is important that RACs provide transparent information to Medicare providers regarding the program and the issues under investigation, as well as information about the basis for an improper payment determination. In this way, providers are kept informed during each step of the audit process. CGI also has established monthly conference calls with provider associations and continues to conduct provider outreach sessions to facilitate two-way communication. These activities will continue to enhance the program as it matures.

—*The Contingency Payment Approach Works Well in Practice*.—Medicare Administrative Contractors (MACs) have many significant duties under the Medicare program, including claim review prior to payment. The MACs simply aren't able to catch every error or omission on the front end. The RACs have one primary mission—to catch improper payments on the back end and correct them. The contingency payment approach allows RACs to dedicate the necessary resources to this task. Contrary to some assertions, the contingency approach does not incentivize the pursuit of questionable recoveries or disincentivize the pursuit of underpayments for three important reasons. First, RACs do not get paid unless and until a recovery is received by the Government. Second, fees earned on recoveries that end up reversed on provider appeals must be returned to the Government. Third, RAC contractors receive an equal fee for finding provider underpayments.

—*The RAC Program Promotes Continuous Process Improvement for Claims Processing and Payment*.—CGI participates along with the other RAC companies in major finding discussions with CMS. This process informs CMS of areas representing the greatest vulnerability to the program along with recommendations for corrective action. Additionally, CGI has identified situations where providers were paid in a manner that seemed incorrect, but was not addressed by an existing CMS rule forbidding payment. CGI informed CMS of the potential need for rule changes to close loopholes and front end coding edits to avoid future under/overpayments. In other cases, CGI has reviewed provider billing and reimbursement situations that seemed to warrant investigation only to conclude that the arrangements were entirely appropriate. This review process provides an important check and balance function for and promotes continuous improvement of the claims payment system.

—*The Potential for This Contingency Approach To Expand to Other Areas Across Government has Been Recognized by Congress*.—Several legislative provisions in the Affordable Care Act expand the RAC approach to Medicaid as well as Medicare parts C and D and the Improper Payments Elimination and Recovery Act passed last year requires a RAC approach to improper payment recovery across Federal agencies.

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and by the Commonwealth of Massachusetts for improper payment reviews. Our contract in Pennsylvania is a continuation of over a decade of work in identifying improper Medicaid payments in partnership with the Department of Public Welfare while our contract in Massachusetts represents a new partnership in providing recovery audit work.

While Medicare parts C and D are significantly different programs than the work being performed in parts A and B, CGI believes that the expansion of the RAC approach to these programs creates the potential for greater synergies to be found in contracting with single entities to perform both scopes of work. The lessons learned from current audits being conducted can be applied directly to the work of part C plans. Similarly, having access to the part D pharmacy data would allow a RAC to conduct audits that would not otherwise be possible if the medical and pharmacy data were audited separately. Matching this data together allows for a deeper level of analysis that identifies improper payments across claims.

The Medicare RAC program is an essential element in the broader effort of program integrity. A comprehensive approach that CGI has been advocating for nearly two decades involves clearly defined program policies; pre-payment edit rules and audits of claims; postpayment recovery audits; and investigation of fraudulent activity. Each element is essential to ensuring compliance with the program and the ultimate goal of protecting the trust funds.

CGI prides itself on combining cutting-edge technology with years of domain expertise in creating valuable solutions for our clients. We are especially proud of our ability to deliver successfully on the RAC program by featuring our healthcare expertise and broad experience in audit recovery programs. More than that, CGI remains passionate about the opportunity to partner with CMS, and other public agencies, in one of the most critical "good government" efforts underway today.

I appreciate the chance to appear before you all today and would be pleased to answer any questions you may have.

Senator HARKIN. Ms. Nurick, I was just telling Senator Shelby how this came about.

One time back in the mid-90s I was, you know, we all have different meetings in our States, and I was having a senior meeting with seniors. And a person came up to me. She came up to me and said, "I just got this bill, and look at this bill. I got charged for this." And she said, "I didn't get those." Someone else was standing there and said, "Well, you don't have to pay it." She said, "Well, I know I don't have to pay it, but it's not right." And then another man says, "Senator, I'm a retired CPA. Let me take a look at that."

Then I had another meeting where a similar kind of thing happened. A guy—he was a retired doctor—he said, "Maybe I could take a look at that." All of a sudden a light went on in my head—we've got a lot of retired people out there that are pretty expert in a lot of different things—they're accountants, they're doctors, they're lawyers, they're nurses, they're health professionals. They've been involved in this. So I thought, maybe we ought to get them involved in some kind of voluntary system to do this. And that's what's grown into this Operation to Restore Trust, or the SMPs now.

And I did not know until today the figures that you had, they've trained 60,000 volunteers, 104,000 complaints. Do you have any idea how much money's been recovered by this group?

Ms. NURICK. A recent figure that I saw through the Administration on Aging was more than $103 million, I believe. I can double-check that for you.

Senator HARKIN. And these, if I'm not mistaken, these are usually the small amounts. A couple thousand there, a thousand——

Ms. NURICK. This is true. A number of cases that come in to us are not very, very large sums.

Senator HARKIN. Right.

Ms. NURICK. They are smaller amounts. But these smaller amounts do add up.

Senator HARKIN. Is there anything that we need to do to help expand this? I mean, obviously it seems to be working well. Seniors are volunteering for this. There's a lot of expertise, a lot of retired people out there that know how to look at these things. Is there anything we need to do to expand this?

Ms. NURICK. I think that the continued funding of the program is essential. We——

Senator HARKIN. Well it doesn't cost—how much do we put into that? Thirteen million dollars?

Senator SHELBY. And gotten a lot back.

Senator HARKIN. We get a lot back from that.

Ms. NURICK. Right. There are a lot of very dedicated, very caring people out there, volunteers, who really want to see this system be well. Our volunteers come from many different backgrounds—homemakers, retired pharmacists, physicians, school teachers, all who very much understand the mission of why protecting Medicare and protecting themselves is very important.

The more people that we can reach—I can speak for my State, for Pennsylvania, it's a large State. We've got 67 counties, we've got a lot of older adults, a lot of Medicare beneficiaries throughout the State, rural areas as well as urban areas. And it's a lot of work to get the word out to all of these people. So, the more beneficiaries that we can train on this subject matter, the more beneficiaries we can reach.

Senator HARKIN. Well, thank you for what you're doing. I'm pleased to see this is working. And it seems to me this is, nationwide, a small amount of money, we get a big bang for the buck on that one.

Ms. NURICK. We really do. We really do.

Senator HARKIN. Mr. Rolf, let me ask you a provocative question.

First of all, I like what you're doing. I think your company has provided an excellent service in this regard. But one thing that I have heard is that the RACs, as they're called, that paying RACs only for an improper payment leads to a "bounty hunter" approach. How would you respond to that? And as we look to other areas of Government, what do you think is the right balance here? I've heard that complaint, "Well, the RACs are just bounty hunters" and so, you, I don't know. How do you respond to something like that?

Mr. ROLF. Well, thank you, Mr. Chairman, for the question.

Let's start with the premise that I don't think anybody enjoys being audited. But I think that there are a number of things that CMS has done in the permanent program that have put the correct incentives in place for proper action on behalf of both providers and the recovery audit contractors.

First and foremost, the transparency and outreach efforts that have been, set this program aside, in the 20 years that I've been involved in these types of efforts I have not seen a program on a commercial, State, or Federal level that has the level of transparency this program does. Providers are educated on every single audit initiative that is underway. They know before the audits even

begin what specific rules and what specific audits are going to be implemented in their region.

And I leave this subcommittee today to fly to Indiana for a provider outreach session with several hundred hospital employees to educate them about the RAC program and the nature of the work that we're doing. And that represents 1 of more than 70 outreach efforts that we've done across our seven State region. And we also hold monthly conference calls with the associations to understand what their concerns are about the program, give them updates on our activities and, again, create the sense of fairness and openness as part of that program.

I think also that you need to understand that in the contingency audit approach, with the rules that are in place with the RAC program, the Government only receives its benefits if we find an actual improper payment. And if the improper payment is eventually overturned on any level of appeal, CGI and the other RAC contractors owe that fee back to the Government. So we have every incentive to make the right determination the first time. We take a look at it and make sure that we're only looking at black and white issues.

And I think it's also important to note that there's an equal incentive—CMS defines improper payment as both an overpayment and an underpayment, and so we have equal incentive to find both instances.

Senator HARKIN. That's important.

Senator SHELBY. It is.

Senator HARKIN. I think that answers that question on the bounty hunter thing because it's equal on both sides.

Senator Shelby.

Senator SHELBY. Thank you, Mr. Chairman.

Ms. Nurick, how do you reach out to Medicare beneficiaries and educate them about the importance of keeping this program of Medicare and Medicaid honest, and it's to everybody's benefit, and they have the obligation and responsibility? We're taught that in school and home. I know this. But sometimes you have to re-emphasize it, that when people are cheating they're cheating us all. When there's fraud, they're milking the system, and it hurts a program that most people benefit from, and most people are honest. Do you agree?

Ms. NURICK. Yes. Thank you for the question, Senator Shelby. I do agree.

And we teach our volunteers that most people are honest, and the purpose of this initiative is to weed out those who are using the system for personal profit.

Our volunteers go into a wide array of different venues to teach their peers, which we find to be a very effective model—having a Medicare beneficiary teaching another beneficiary what they need to know about fraud and abuse prevention. They will go into senior centers, into libraries, buildings, subsidized housing buildings where there are activities going on, retiree groups, all sorts of places where you're going to have beneficiaries there or—caregiver groups are also very important, because caregivers are maybe taking care of their loved ones' financial and healthcare issues. So,

we're, we go into as many places in the community as possible to reach beneficiaries directly.

Senator SHELBY. What do they do with, generally, with doctors or hospital administrators, or people that cheat and steal, so to speak? Senator Harkin brought up a question earlier—he didn't read about anybody going to jail, you know, from time to time and so forth. But wouldn't tough treatment of people who commit fraud, no matter who they are or how big they are, or how small they are, be a deterrent in a sense?

Ms. NURICK. I think that would make a strong statement. Yes. I do. I think that would go a long way.

Senator SHELBY. Okay.

Mr. Rolf, I know you do, your company does some good things. You have to work for an incentive and, otherwise, a whistleblower program probably wouldn't work as much. You know, we'd like some of that. And, you have facilities everywhere. You have opened a facility in my State, you know, 300 jobs. That means there's probably fraud there, you know, here and there, in any program.

What are your impressions of how providers perceive RACs? Are they generally receptive and view you as someone who's there to help? Or do they fear you? I think they have to fear you some. No, I, but continuing, if they've done nothing wrong, they have nothing to fear. If they've made a mistake and can explain that, you know, that's good. People make mistakes. But just pure, unadulterated fraud, and continuing fraud, they've got to fear you on an audit sometimes.

Mr. ROLF. Thank you for the question, Senator Shelby.

The RAC program, it's important to note, is focused on improper payments, the waste and abuse part of the equation. Not true fraud. If we identify true fraud in going through our reviews we refer it back——

Senator SHELBY. You give it to somebody?

Mr. ROLF. Correct.

Senator SHELBY. Do you do that, too, Ms. Nurick? If there's fraud there you give to the law enforcement people to look at it?

Ms. NURICK. We, the SMPs——

Senator SHELBY. Or, what you might believe is fraud.

Ms. NURICK. Right. We don't determine what is fraud.

Senator SHELBY. Sure.

Ms. NURICK. We will submit those cases to CMS or to contractors——

Senator SHELBY. Okay.

Ms. NURICK [continuing]. For investigation, yes.

Senator SHELBY. Go ahead.

Mr. ROLF. So, the, we've made, we do a lot of activities in order to ensure that we're reducing the administrative burden of our reviews on the provider community. And so, working in partnership with the associations—keep in mind that most of what we identify is a result of data entry errors, payment processing errors, errors understanding, misunderstanding of rules——

Senator SHELBY. Are you working basically to, in the improper payment prevention area?

Mr. ROLF. Correct.

Senator SHELBY. Okay. And, by improper, prevention area, give us some examples of that.

Mr. ROLF. Improper payment could be the miscoding of services——

Senator SHELBY. Okay.

Mr. ROLF [continuing]. Billing for services that would——

Senator SHELBY. As opposed to pure fraud?

Mr. ROLF. Correct.

Senator SHELBY. Okay.

Mr. ROLF. Right.

Senator SHELBY. And do you see a lot of that?

Mr. ROLF. We do. There's, again, it's a direct result of misunderstanding of CMS program rules in some cases, data entry errors, entering in the wrong number of units on a——

Senator SHELBY. That would come under waste?

Mr. ROLF. Correct.

Senator SHELBY. And that would get into, probably, in a program like this, millions of dollars, would it not?

Mr. ROLF. As I said, in the 3-year pilot it cost six States more than $1 billion was identified and ultimately corrected.

Senator SHELBY. How is, do you believe, are you always trying to innovate in this program to make it work better?

Mr. ROLF. It's an ongoing effort at——

Senator SHELBY. Evolution?

Mr. ROLF. It's an evolutionary effort. I think, as Dr. Budetti stated earlier, there's a lot of advances technology-wise with the types of data analysis and reviews that we do to help target——

Senator SHELBY. Okay.

Mr. ROLF [continuing]. And identify those issues that are the prime issues to go after.

Senator SHELBY. Well, both of you, keep up your work. Be diligent, and don't quit. And we appreciate it very much. Thank you very much.

Mr. ROLF. Thank you, Senator.

Senator HARKIN. Thank you, Senator Shelby.

Again, thank you both.

Do either one of you have anything to add before we close down our hearing?

Again, I thank both of you in your respective areas for what you're doing to help us cut down on Medicare fraud and abuse. The RACs, I believe, are providing an important service, and now we're expanding that under the Affordable Care Act. The SMP people are out there volunteering, and I think that's a good thing.

So, I'm sure that Senator Shelby and I are going to continue to use this subcommittee to make sure that we have as good a system as possible to go after fraud and abuse wherever it occurs. So, we're going to work together hand in glove on that one.

ADDITIONAL COMMITTEE QUESTIONS AND STATEMENTS

The record will remain open for 10 days for any further questions or statements from Senators who couldn't make it here today.

[The following questions were not asked at the hearing, but were submitted to the witnesses for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO DR. PETER BUDETTI

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

Question. I understand it takes 10 days for the current CMS data system to do automated fraud checks. That seems like a long time for modern technology. On top of that, you have a statutory requirement that you pay providers within 14 days of receipt of the claim. That doesn't leave a lot of time to do anything more than a cursory review of claims before you put the money out the door. Why does it take so long to conduct the automated fraud checks? Would the data initiative proposed in the President's fiscal year 2012 budget give you more time to prevent improper payments?

Answer. CMS leverages automated checks or edits at a variety of places throughout the claims processing lifecycle. Automated checks are conducted at the front end of the process, on day one, as the claim is submitted to the Medicare Administrative Contractor (MAC). Additional automated checks take place as the claim is moved to the claims processing systems hosted in the CMS Enterprise Data Center (EDC). Once again, a different set of automated checks are applied in the Common Working File as the claim moves through the adjudication process.

The President's fiscal year 2012 budget request includes funds to support CMS' enterprise IT investments that support all parts of Medicare. Moreover, CMS is aggressively implementing and utilizing the anti-fraud and abuse tools and new statutory authorities provided by the Affordable Care Act, including enhanced and risk-based provider enrollment screenings, payment suspension when a credible allegation of fraud exists, and a moratorium on new provider and supplier enrollments when necessary to combat fraud.

In addition, 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 in order to identify complex patterns of fraud and improper claims and billing schemes.

Question. Are RACs able to receive and process electronic medical records, electronic claim information, or other types of electronic data from providers? If not, does the department have a plan to give them that capacity?

Answer. Yes, the RACs are currently able to receive and process electronic claims and records. Under the Medicare Fee-For-Service national program, which began in January 2010, CMS requires Recovery Auditors to accept medical records from providers in an electronic format, instead of a paper-based system as was required in the demonstration.

Question. Please provide more detail on the legislative proposal to give the Secretary more flexibility implementing the predictive modeling provisions of the Small Business Jobs Act (Public Law 111–240).

What is the current status of predictive modeling implementation efforts?

Answer. CMS has been piloting information technology solutions including predictive analytics, refining the technology, and addressing systematic vulnerabilities that the analytics identify for several months. During 2010, CMS began one pilot in April and another in September. CMS also held an Industry Day in October to let experts know about CMS' strategic goals, priorities, and objectives in the use of information technology solutions for fraud prevention in our programs.

In keeping with the predictive modeling requirements of the Small Business Jobs Act, CMS issued a request for capabilities and a solicitation December 16, 2010. Responses to the solicitation were received from bidders on January 31, 2011 and are currently being reviewed. CMS intends to make an award during the spring of 2011 and is on track to meet the implementation deadline of July 1, 2011.

Question. How have predictive analytical capabilities already been integrated into CMS information systems?

Answer. CMS is in the early stages of implementing predictive modeling and working it into our information systems. Thus far, predictive analytic pilots have only been tested on claims that have already been paid, and continue to be refined based on the results of these tests. As the models are refined and have a low number of false-positives, we intend to expand their use and apply the models to claims before payment has been made. This will trigger additional review of high-risk claims before payment when appropriate. The first models will be implemented in July, per the statutory requirements in the Small Business Jobs Act.

Question. Please describe future plans for implementation of predictive modeling systems.

Answer. CMS is implementing a National Fraud Prevention Program that integrates all of its analytic models and innovative technologies into a cohesive anti-fraud strategy. It includes an analytics laboratory, which will develop effective algorithms that will incorporate data from many sources, including HHS Office of Inspector General findings, complaint trends, policy concerns, and identified vulnerabilities. Further, the National Fraud Prevention Program will analyze multiple databases at a national level, including claims, complaints, and enrollment data, in addition to targeted analysis. In addition, CMS is relying on its newly granted legislative authority in both the Affordable Care Act and the Small Business Jobs Act to support the expansion of predictive modeling systems in Medicare.

CMS was charged with implementing Section 4241 of the Small Business Jobs Act that mandated the award and implementation of Predictive Modeling technology in the CMS environments by July, 2011. 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 in order to 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 will trigger 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 healthcare fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as they appear.

Further, the Small Business Jobs Act of 2010 provided $100 million, beginning in fiscal year 2011, to phase-in the implementation of predictive analytics in Medicare FFS. The Small Business Jobs Act of 2010 additionally provides that the Secretary shall start to phase-in the use of predictive analytics technologies to Medicaid and CHIP beginning April 1, 2015. 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.

Question. Why is the legislative proposal described above necessary? What provisions of Public Law 111–240 need to be changed and why?

Answer. The predictive modeling provisions in Public Law 111–240 are very prescriptive and require CMS to deploy predictive modeling in certain programs at specific times. Allowing the flexibility we are seeking in the fiscal year 2012 legislative proposal does not mean that CMS will not continue to aggressively develop predictive analytics. Rather, it would allow CMS to expand predictive analytics in a way that targets our resources as efficiently as possible. Greater flexibility sought in the legislative proposal would allow CMS to target technology in areas with the greatest return on investment, and enable us to adjust the implementation timeline, scope of services subject to predictive analytics, and the time period under which models need to be evaluated as necessary. The proposal would also recognize that some States may require extra time to implement and perfect their predictive models. The legislative proposal is estimated to result in $100 million in savings over 10 years, due to increased efficiency.

Question. In her letter to the Nation's Governors, dated February 3, 2011, Secretary Sebelius outlined a number of solutions that could help reduce States' Medicaid expenditures. Specifically, the Secretary identified greater use of generic drugs as a possible way to decrease prescription drug costs. Secretary Sebelius noted that the department would "also share additional approaches that States have used to drive down costs, such as relying more on generic drugs . . .". Has CMS examined and quantified the potential savings that would accrue to States and the Federal Government by improving generic utilization in Medicaid? Has CMS identified which policies act as a barrier to or help facilitate greater access to safe, lower-cost

generic medicines? If so, what efforts has the agency taken to communicate its findings with State Medicaid officials?

Answer. As you noted, in addition to encouraging States to ensure that their pharmacy reimbursement costs more accurately reflect the actual acquisition costs of drugs, the Secretary encouraged States to consider relying more heavily on generic drugs in their Medicaid Drug Programs.

The President's fiscal year 2012 budget includes two proposals to encourage greater generic drug use. First, the Administration proposed shortening the length of the exclusivity period for generic biologics from 12 to 7 years. Second, the Administration proposes giving the Federal Trade Commission authority to prohibit "pay-for-delay" arrangements between brand-name and generic pharmaceutical companies to delay the entry of generic drugs into the market. These proposals are estimated to save the Medicaid program nearly $2.5 billion over the 10-year budget window.

In a recent paper by the National Health Policy Forum (NHPF), published in September 2010, NHPF found that the State of Minnesota saves $10 million annually on their program to substitute generic drugs when available. However, it is important to note, as the Office of the Inspector General found in a 2006 report, "that single source drug prescribing caps the level of generic drug utilization that a State Medicaid program can attain."

In order to achieve the available savings through generic drug prescribing, States may need to encourage the prescribing of multisource drugs which have generic equivalents, use preferred drug lists, impose prior authorization requirements, or pursue supplemental rebates with generic drug manufacturers in exchange for providing drugs more favorable status in utilization management.

CMS recently created the Medicaid State Technical Advisory Teams (M–STAT) that are responsible for working directly with States to address steps they can take to improve efficiency in their programs and develop effective cost containment strategies. As we work with States and identify areas where savings can be achieved, increasing the use of generic drugs is an important priority.

Question. As you may know, the practice of chiropractic care originated in my State of Iowa, and Palmer College of Chiropractic is still one of the leading schools in the Nation. There seems to be some confusion among my constituents about what kinds of chiropractic care are covered by Medicare. Can you outline for me the guidelines of what is and what is not covered? Are there any misconceptions about what Medicare covers in this area? What is the biggest billing error that you see in this practice area?

Answer. Medicare makes payment for covered chiropractic services under the Physician Fee Schedule. For chiropractors, coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation when such treatment is legal in the State where performed. This requirement is specified in section 1861(r)(5) of the Social Security Act (the Act).

Chiropractic maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. Under the Medicare program, chiropractic maintenance therapy is not a covered service because it is not "manual manipulation of the spine to correct a subluxation" as specified in section 1861(r)(5) of the Act.

Question. Can you explain the distinction between a covered service and a reimbursable service? I would think if a service is covered in the Medicare benefit, then a provider administering that service should be reimbursed by Medicare for providing it. For example, your guidance on chiropractic care says: "Acute, chronic, and maintenance adjustments are all 'covered' services, but only acute and chronic services are considered active care and may, therefore, be reimbursable." What does it mean for a service to be covered by Medicare but not reimbursable?

Answer. As noted in the answer to the prior question, Medicare makes payment for covered chiropractic services under the Physician Fee Schedule. For chiropractors, coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation when such treatment is legal in the State where performed. This requirement is specified in section 1861(r)(5) of the Social Security Act (the Act).

In some instances, Medicare payment for covered services may be bundled and no separate payment is made for a covered item or service. As such, a service may be covered, but not separately reimbursed. For example, some chiropractors use hand-held manual devices in the course of furnishing their services. While the manual manipulation service using the hand-held device may be covered, there is no separate payment for the cost or use of the device.

Chiropractic maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or

therapy that is performed to maintain or prevent deterioration of a chronic condition. Under the Medicare program, chiropractic maintenance therapy is not a covered service because it is not "manual manipulation of the spine to correct a subluxation" as specified in section 1861(r)(5) of the Act.

Question. I've heard that one of the triggers for an audit is providing service to a larger number of Medicare clients than is typical. Coming from a State that regularly ranks high for our proportion of residents over 65 years of age, I'm curious about this practice. What might it indicate that a provider serves a lot of Medicare patients? If the audit comes out clean, is the provider penalized for seeing a great number of Medicare patients?

Answer. Medicare contractors conduct data analysis and use comparative statistics to analyze claims. A high volume of billings does not in itself trigger an audit. However, if a provider appears to have aberrant billing patterns that suggest he/she is an outlier compared to his/her peer group, CMS may conduct medical review to determine if claims for services are medically reasonable and necessary, and as appropriate, collect overpayments that are identified. Depending on the nature of the errors found through medical review, contractors implement corrective actions which range from provider education to 100 percent pre-payment medical review.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

Question. Describe the interaction between CMS fraud and abuse efforts and private sector insurers. You mentioned National Health Care Fraud Summits in your testimony. Are there other examples of ways you can collaborate on the common goal of reducing healthcare costs by eliminating fraud in the Nation's healthcare system?

Answer. 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. 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, CMS 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 our strategy for integrated, automated, provider screening and data integration.

Question. As we face a tight fiscal environment, our Subcommittee will face tough decisions with regard to allocating funding. You identify the Health Care Fraud and Abuse program as one initiative that has led to increasing returns to the Medicare Trust Fund as a result of oversight efforts. Can you identify any programs that have not been as effective and may potentially be cut or eliminated to allow for increasing resources to be directed toward HCFAC?

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 fiscal year 2012 budget request. While CMS programs were not eliminated in 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 healthcare 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 3-year rolling average of 6.8 to 1 and the Medicare Integrity Program averages 14 to 1. Further, CMS' Actuaries have determined that the multi-year discretionary program integrity investment, starting with the request of $581 million for fiscal year 2012, is estimated to save $4.6 billion over 5 years and $10.3 billion over 10 years, which more than pays for itself.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

Question. Given the extensive fraud problem we have in the United States—and the fact that this endangers patients and drives premiums ever higher, why doesn't the medical loss ratio (MLR) interim final rule allow all fraud expenses to be included in the numerator of the MLR? Why would we want to penalize insurers for the investment they make in antifraud efforts? I understand that efforts to prevent fraud from occurring is not being considered as a quality expenditure.

Answer. Quality Improvement (QI) expenses, for the purpose of the MLR, are all plan activities that are designed to improve healthcare quality and increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements. The expenses must be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees.

The Affordable Care Act required the National Association of Insurance Commissioners (NAIC) to develop uniform definitions of MLR activities, including activities that improve healthcare quality. The NAIC, in its model MLR regulation, determined that fraud prevention activities do not qualify as a quality improving activity. However, the NAIC also determined that, when factoring the MLR, an adjustment may be made to incurred claims to account for the amount of claims payments recovered through fraud reduction efforts not to exceed the amount of the fraud reduction expense. The MLR interim final regulation adopted and certified those recommendations in the model regulation of the NAIC.

Question. Given that the key rationale for the expensive transition of the coding system to ICD–10 is that ICD–10 will improve the quality of care, why doesn't the MLR include ICD–10 costs as part of quality?

Answer. As discussed above, the only expenses that are included in the Quality Improvement section of the MLR calculation are those that have the potential to have a positive impact on enrollee health outcomes through improvements in the quality of services.

The Secretary adopted the NAIC's recommendation to exclude the conversion of code sets from ICD–9 to ICD–10 as a quality improvement activity. In general, the development and maintenance of claims adjudication systems are not designed primarily to improve the quality of care received by an individual. However, since there is general recognition that the conversion to ICD–10 will enhance the provision of quality care through the collection of more refined data, HHS intends to examine the reported conversion costs along with other quality activity costs in the NAIC supplemental form in 2011 to determine whether the policy in the MLR regulation should be revisited.

QUESTIONS SUBMITTED TO TONY WEST

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

Question. In your testimony, you highlight that in fiscal year 2010 the Justice Department secured $2.5 billion in civil healthcare fraud recoveries and $1.8 billion in criminal fines and forfeitures, which were the largest amounts in the Department's history. Can you elaborate further in your view, what led to these record amounts for fiscal year 2010?

Answer. The HEAT initiative instituted by the Attorney General and the Secretary of Health and Human Services in May 2009 has brought an unprecedented degree of coordination to healthcare fraud enforcement matters at very high levels within the Departments of Justice and Health and Human Services. This coordination has improved information sharing between our Departments and has enhanced our collective ability to allocate resources to pending matters. This cooperation greatly contributed to the record recoveries obtained in fiscal year 2010. The resolution of some of these matters also was hastened by the additional resources given to the Department of Justice by recent appropriations which enabled the Department to hire additional attorneys, agents, and support personnel dedicated to healthcare fraud matters.

Nearly every healthcare fraud investigation requires extensive document review, interviews of many witnesses, and a myriad of other analyses. In the more complex matters involving large corporate entities, such as pharmaceutical and device manufacturers, the investigative resources required by the Government to successfully investigate allegations are magnified considerably. These complex, nationwide investigations commonly require reviewing millions of documents and interviewing hundreds of witnesses, while also consuming months (and sometimes years) of attorney,

investigative, and litigation support resources. The President's budget has sought additional funding to further enhance these efforts.

Question. Given your experience litigating fraud, what recommendations would you make to prevent fraud before it happens as part of a national healthcare integrity strategy? Are there actions that Congress could take to ensure that the tools are available to engage in proactive fraud prevention?

Answer. Preventing healthcare fraud requires a multipronged strategy and close coordination between the Departments of Justice and Health and Human Services (HHS). Earlier this year, HHS published a final rule implementing several significant anti-fraud provisions that will materially enhance its ability to screen potential providers and prevent payment to those committing fraud. See Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5862 (Feb. 2, 2011) (to be codified at 42 C.F.R. 405.370). As noted by Dr. Peter Budetti, Deputy Administrator and Director of the Center for Program Integrity, Centers for Medicare & Medicaid Services, in his March 2, 2011 testimony before United States Senate Committee on Finance, the final rule implements many anti-fraud provisions that Congress passed under the Affordable Care Act. While the Department of Justice does not play a direct role in screening those seeking to enroll in government healthcare programs, the enforcement actions brought by the Department provide an effective deterrent to those who would seek to commit fraud against government healthcare programs.

Question. The fiscal year 2012 budget requests $283.4 million for the Department of Justice for reimbursable funding to combat healthcare fraud. This amount represents an increase of $63.4 million, or nearly 30 percent, over the fiscal year 2011 Continuing Resolution level. Recognizing the need for Congress to balance the importance of fighting fraud and waste against the backdrop of the current fiscal climate, can you provide additional detail with regard to the request?

Answer. In fiscal year 2012, the Department of Justice (DOJ) is requesting an increase of $63.4 million in reimbursable Health Care Fraud Abuse and Control (HCFAC) funding to support the expansion of the Medicare Fraud Strike Forces (MFSF), increase our efforts to support civil healthcare fraud enforcement, and provide additional resources to ensure that home health facilities and nursing homes are providing proper care to their patients. In fiscal year 2010, DOJ received $29.8 million in reimbursable funding for the discretionary HCFAC account. These funds provided additional investigators and prosecutors at existing MFSF locations, as well as supported the expansion to two additional locations. The additional funds requested in the fiscal year 2012 budget will allow the Department to expand to additional locations, as well as support the annualization of the personnel added in fiscal year 2010 and fiscal year 2011.

In addition to providing additional resources for MFSF locations, the resources requested in the fiscal year 2012 President's budget will also allow DOJ to expand our efforts in civil fraud enforcement, in areas such as pharmaceutical fraud. DOJ's civil fraud enforcement efforts are responsible for generating the largest share of returns to the Medicare Trust Fund. The increase in funding will support additional investigatory personnel and attorneys to address the increase in qui tam filings which has occurred in recent years.

Finally, the requested funds will also support additional personnel to investigate home health facilities and nursing homes to ensure that patients of these facilities receive the care they need within Federal guidelines and to prevent any abuse that may be occurring.

PREPARED STATEMENT OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION (NCPA)

NCPA recommends that Congress:

—Pass legislation to rein in the waste being generated by PBMs within Medicare and Medicaid.

—Pass legislation to increase the transparency of PBM audit practices within Medicare and Medicaid and to prohibit certain abusive auditing practices by PBM auditors.

—Address through oversight or legislation CMS's failure, in certain circumstances, to assert its authority to fight fraud, waste and abuse.

Chairman Harkin, Ranking Member Shelby, and Members of the Subcommittee: The National Community Pharmacists Association ("NCPA") welcomes and appreciates this opportunity to provide input and suggestions regarding efforts to combat fraud, waste and abuse in Medicare and Medicaid as they relate to pharmacy care

providers and the healthcare arena in general. NCPA represents the pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. The Nation's independent pharmacies, independent pharmacy franchises and independent chains dispense nearly half of the Nation's retail prescription medicines.

NCPA strongly believes in the mission to cut fraud, waste and abuse in Medicare and Medicaid in order to bolster the integrity of the two programs and maximize the benefits provided to beneficiaries. NCPA and our members strive hard to do their part to help ensure the integrity of Medicare and Medicaid and to cooperate with Medicare and Medicaid auditors. In fact, statistics demonstrate that independent community pharmacists are not a significant part of the fraud, waste and abuse problem.

NCPA thanks Congress for recognizing the integrity demonstrated by independent community pharmacists in their participation in Medicare and Medicaid. While no industry can claim to be completely void of bad actors, Congress has recognized that independent community pharmacists, as a whole, represent a very low risk in terms of fraud, waste and abuse of the Medicare and Medicaid programs.

For example, in 2008, Congress enacted the Medicare Improvements for Patients and Providers Act (MIPPA), which, in part, required Part D sponsors to pay all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise. Similarly, just this past year, through the Patient Protection and Affordable Care Act (PPACA), Congress enacted legislative provisions to allow most independent community pharmacists to be exempt from Medicare DME accreditation requirements. Recent legislative history demonstrates the trust that Congress has in the integrity of independent community pharmacies. We appreciate that trust and try to live up to high standards every day.

Contrary to the trust that Congress holds for independent community pharmacies, the same cannot generally be said of policymakers' view of Pharmaceutical Benefit Managers (PBMs). Through recent legislative action, Congress has seemingly demonstrated that it continues to be concerned regarding how PBMs run their businesses. While Congress provided additional flexibility for independent community pharmacies through accreditation exemptions under the PPACA, in the same legislation Congress imposed new transparency requirements on the PBMs operating within the Medicare Part D program and for PBMs operating in the new State-based health insurance exchanges, which come on line in 2010.

Congress apparently has strong reservations regarding the integrity of the PBMs and, we believe, rightfully so. From 2004–2008, the three major PBMs (Medco, CVS Caremark, and Express Scripts) faced six major Federal or multidistrict cases over allegations of fraud; misrepresentation to plans, patients, and providers; improper therapeutic substitution; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases have resulted in over $370 million in payments for fines and damages to States, plans, and patients so far. The most prominent cases were brought by a coalition of over 30 States and the Department of Justice.

Because NCPA and independent community pharmacists are committed to fighting fraud, waste and abuse within Medicare and Medicaid, we have a number of concerns regarding existing fraud, waste and abuse within Medicare and Medicaid and how those problems are presently being addressed. First, NCPA is concerned that some PBMs are apparently contributing to waste within the Medicare and Medicaid system. Second, NCPA believes that PBMs, in their auditing capacity, are abusing their oversight authority to the detriment of independent community pharmacists and the beneficiaries that they serve. Finally, NCPA believes that CMS, in some instances, is not effectively performing its oversight role for fraud, waste and abuse.

PBM Waste within Medicare and Medicaid

PBMs administer the pharmacy benefit within some Medicaid managed care programs and many in Medicare Part D. These complex business entities have multiple, extremely profitable, revenue streams. The "Big 3 PBMs" (Medco, Express Scripts, and CVS/Caremark) manage drug benefits for approximately 95 percent of Americans with prescription drug coverage, and each of these companies have annual revenues exceeding $15 billion. In spite of these facts, PBMs are virtually unregulated at the State or Federal level—even though they manage numerous prescription plans funded by billons of taxpayer dollars.

PBMs negotiate contracts with many participants in the pharmaceutical supply chain; two of the most important contracts are with pharmacies ("the pharmacy network") and plan sponsors. PBMs primary profit streams include rebates provided by

drug manufacturers for driving brand drug market share; administrative fees charged directly to the health plans; revenues from PBM-owned mail service pharmacies and the clinical programs sold to health plans. From each of these revenue streams the PBMs are earning sizeable profits, which are enhanced by potential conflicts of interest built into the payment system. Such profits are a waste of taxpayer money used to fund Medicaid managed care and Medicare Part D. Outlined below is a description of how these large profits arise under each revenue stream and the conflicts of interest within each revenue stream.

PBMs Pocket Manufacturer Rebates

Pharmaceutical manufacturers provide "rebates" to PBMs on brand name drugs purchased on behalf of PBM clients. The manufacturers pay billions of dollars to the PBMs to drive/increase certain brand drug usage by Medicare and Medicaid beneficiaries. These manufacturer incentives and the resulting PBM behavior conflict with the interests of patients and Medicare/Medicaid, which seek to maximize the use of generic drugs that are equally as effective as brand name drugs, but are less costly and save money. In 2009, retail pharmacies drove a 69 percent generic dispensing rate (GDR) while the mail order PBMs Medco Health Solutions, Inc., Express Scripts, Inc. and CVS/Caremark had GDRs under 58 percent generic dispensing rate. In the end, the PBMs do not share all of the rebate savings with the patients, the plans or the government.

PBMs "Play the Spread" in Retail Pharmacy Networks

The PBMs also generate substantial profits by charging Part D plans and Medicaid one price for a given drug and then reimbursing retail pharmacies a lower dollar amount. This practice needlessly adds costs for the government and squeezes retail providers.

PBM-Owned Mail Order Pharmacies

Along with supplying drugs to retail pharmacies, the PBMs also own and operate their own mail order pharmacies. These mail order pharmacies are automated dispensing facilities that fill and ship prescriptions requiring 90-day supplies. They operate in a "Black Box" environment without transparency. Accordingly, these mail order pharmacies are able to engage in practices that can provide the PBMs with large profits, with little or no scrutiny.

Not only do the PBM mail order pharmacies pad the PBM's profits, but they do so without delivering to the patient the benefits of a traditional community pharmacy. Face-to-face consultation between a pharmacist and patient, the most effective type of intervention to ensure that patients adhere to their prescribed medication regime and are counseled about possible negative side effects, is replaced with patient e-mail and calls to 1–800 numbers to seek assistance from rotating out-of-State corporate pharmacists. Outlined below are a couple of examples of problems faced by mail order patients.

First, no patient can "fire" their PBM-owned mail service, no matter how poorly it performs. Patients have reported numerous delivery (or non-delivery) issues that have caused patients to be unable to take medications that are vital to their health and well-being, yet they are forced to continue using the PBM-owned mail service.

Second, when given a choice, 83 percent of customers prefer to fill their prescription at a community pharmacy rather than at a so called mail order pharmacy. Nonetheless, PBMs support policies that penalize patients for using community pharmacies.

PBMs Make Money on Provider Reimbursement Float

PBMs also pocket the monetary interest generated from the lag time between the pharmacy dispensing a drug to plan members and the time when reimbursements are paid to the pharmacy. While this practice was all but eliminated in Medicare Part D, it continues to exist in other Federal programs and the commercial market. On a macro-scale the amount of interest generated during this time lag period is significant and it is inequitable that community pharmacies do not share in the value of the interest generated during this lag time.

Legislative Solutions

In light of the PBM generated Medicare/Medicaid waste and abuse outlined above, NCPA urges Congress to pass legislation that includes the following provisions:

—Requiring PBMs to fully disclose to Part D plans and Medicaid potential conflicts of interest in PBM service contracts.

—Establishing an "any willing provider provision" in all PBM mail service contracts.

—Requiring PBMs to fully disclose "spread" pricing to all impacted parties, including pharmacies, patients and Part D plans/Medicaid.
—Require PBMs to pass through to pharmacies at least a portion of the interest earned by the PBM on the pharmacy reimbursement "float."

PBM Audit Abuses

Not only do PBMs generate their own waste within Medicare and Medicaid, but they also seem to abuse their role as auditors of pharmacies within both programs, as well. PBMs typically audit pharmacies in order to detect any improper payment by the PBM on behalf of Medicare or Medicaid and to verify that the patient received the correct medication in the appropriate dose. NCPA believes that auditing is a necessary activity in order to detect and prevent fraud, waste and abuse in Federal healthcare programs.

However, many times PBM auditors, some of whom are paid based on the number of "discrepancies" found, go beyond the basic intent of the audit (to detect fraud, waste and abuse) and instead focus on typographical or administrative errors for which they use as the basis to recoup money from the pharmacy.

In most cases, if a PBM auditor does identify an administrative error, he or she will "take back" 100 percent of the value of the prescription—an extreme financial penalty that is out of proportion to the gravity of the offense.

In most cases, money recouped from a pharmacy as the result of an audit is not returned to the plan sponsor—but is simply pocketed by the PBM. Many times, PBM audits of pharmacies—operating under the guise of combating fraud, waste and abuse—are simply an additional revenue stream for the PBM.

One way many PBMs "ensure" that discrepancies will be found is to establish elaborate record keeping requirements well in excess of what is required under State or Federal law. Pharmacies typically maintain contracts with multiple PBMs. The result is a myriad of conflicting documentation requirements that can make operating a busy pharmacy and responding to patient concerns an even greater challenge.

Another abusive audit practice involves PBM auditors who, in order to maximize revenue generation, zero in on auditing high dollar specialty prescriptions. One pharmacist reported that he gets audited very frequently based on the fact that he serves a large number of HIV patients—typically prescribed very expensive medications. Pharmacists also report that auditors frequently question the directions for use that the pharmacist typically types onto the medication. Many physicians will include "take as directed" on the prescription that they issue to a patient and the pharmacist is therefore charged with providing the appropriate instructions. Auditors frequently question whether or not the directions are specific enough. One particularly egregious example of this occurs when auditors question the adequacy of instructions included on a "Z-Pak". A Z-Pak is a pre-packaged dosage form that simply requires the patient to "punch out" a specified number of pills per day at designated intervals from the blister packaging.

To increase the chances of a "successful" audit and more revenue, PBMs also focus on claims in which they can easily question the professional judgment of the pharmacist. Many times a physician will issue a prescription that directs the pharmacist to dispense a certain number of days supply of a medication. There are times when this is open to interpretation—particularly with respect to lotions, creams or particularly eye drops. Another area of concern is dispensing a certain number of days supply of insulin; depending on blood sugar levels, the amount of insulin that a patient needs on any particular day can vary.

Pharmacists frequently report that many times elderly patients need an additional quantity of eye drops that somewhat exceeds that which may be necessary for other patients. Many elderly patients have difficulty instilling just one or two drops or due to hand tremors, and typically end up spilling a fair quantity of the product. Auditors typically do not accept these types of explanations, which boil down to questioning the professional judgment of the pharmacist. In response, many pharmacists have had to stop dispensing larger sized ophthalmic solutions.

PBM's audit revenue is also enhanced inappropriately through the questionable statistical methods that some of them use to assess fines. Sometimes PBM auditors will use extrapolation or other statistical expansion techniques to calculate the amount of any audit recoupment.

With extrapolation, a few prescriptions are extracted from the total number of prescriptions filled for the particular PBM—and those are examined for any errors. The number of errors detected in the small sample is then extrapolated across a pool of prescriptions to arrive at a questionably inflated number of discrepancies and corresponding penalties.

One pharmacist recounted an example of the use of this technique in connection with a recent Medicaid audit by a PBM. After the auditor complimented the pharmacist on his "clean documentation" for the audit sample, she presented him with an audit findings report that detailed over $137,000 in alleged extrapolated clerical errors based on findings from two prescription claims. Ultimately, the pharmacist was able to prove that the auditor made a mistake on one of the two claims, and the recoupment amount was then reduced to $3,000. Extrapolation has been widely criticized as an auditing technique and a number of States have passed legislation to prohibit or limit its use.

Finally, pharmacists have little recourse to fight back against PBM abusive auditing practices. Pharmacists faced with significant recoupments that they believe are in error are frequently without recourse. Even if the PBM does have an appeals process, the PBM still may withhold funds while waiting for the appeals process to be completed. In addition, PBMs are not required to resolve appeals in a timely manner and many pharmacists fear that if they complain too much, the PBM may simply drop their contract. Many pharmacists, when faced with unfair audit recoupments, are forced to weigh the amount of the threatened recoupment with the likely cost of hiring legal counsel. Some pharmacists are reporting a recent trend in which PBMs are keeping recoupments to just under a certain dollar amount in recognition of the fact that the threatened dollar loss to the pharmacist will not outweigh the cost of hiring an attorney.

Legislative Solutions

In light of the PBM audit abuses outlined above, NCPA urges Congress to enact H.R. 5234, the PBM Audit Reform and Transparency Act of 2010, sponsored by Congressman Anthony Weiner (D-NY). Generally, H.R. 5234 provides for the following: (1) Requiring PBM's to make certain disclosures in an annual report to drug plan sponsors; (2) increased regulation of PBM contracts with pharmacies; (3) prohibitions against certain conflicts of interest involving PBMs and the entities that they own; (4) restrictions on PBM auditing practices of pharmacies; and (5) restrictions on PBM use of HIPAA information.

Turning more specifically to auditing practices, NCPA endorses the following protections against abusive PBM audit practices:

—Requiring, where an audit results in the identification of solely clerical or record keeping errors, that the pharmacy not be subject to recoupment of funds by the PBM unless: (i) the PBM can provide objective proof of intent to commit fraud; or (ii) such error results in actual financial harm to the PBM, a health insurance plan managed by the PBM, or a consumer.

—Prohibiting PBMs from requiring more stringent record keeping by a pharmacy than is required by State or Federal law and regulation.

—Requiring that PBMs accept records of a hospital, physician or other authorized practitioner to validate pharmacy records and prescriptions with respect to confirming the validity or claims in connection with prescriptions, refills, or changes in prescriptions.

—Requiring that PBM audits be conducted by or in consultation with a pharmacist who is licensed in the State in which the audit is being conducted, where the audit requires the application of clinical or professional judgment.

—Prohibiting PBMs from using extrapolation or other statistical expansion techniques in calculating the amount of any recoupment or penalty resulting from an audit.

—Requiring PBMs to establish a written appeals process that shall include procedures to allow pharmacies to appeal to the PBM the preliminary reports and final reports resulting from the audit and any resulting recoupment or penalty.

—Prohibiting the period covered by an audit from exceeding 2 years from the date that the claim was submitted to or adjudicated by the PBM.

—Providing that any legal prescription may be used to validate claims in connection with prescriptions, refills or changes in prescriptions.

—Requiring that each pharmacy be audited under the same standards and parameters as other similarly situated pharmacies.

Conclusion

NCPA and its members remain committed to combating fraud, waste and abuse within Medicaid and Medicare, and eagerly wish to be a part of the solution. However, NCPA has concerns about certain aspects of existing efforts to combat Medicare/Medicaid fraud, waste and abuse. To summarize, as to the PBMs, NCPA is concerned that more needs to be done to address the waste generated by some PBMs within Medicaid and Part D. NCPA is also concerned that there needs to be more

transparency and oversight over PBM auditing practices under Medicaid and Medicare.

CONCLUSION OF HEARING

Senator HARKIN. And with that, the subcommittee will stand recessed.

Thank you.

[Whereupon, at 11:28 a.m., Tuesday, February 15, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to reconvene at the call of the Chair.]

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